No. 19-1062

In the Supreme Court of the United States

CJ CHEILJEDANG CORP., ET AL., PETITIONERS

v.

INTERNATIONAL TRADE COMMISSION, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

The doctrine of equivalents typically allows a patentee to assert patent infringement against a person who has made "insubstantial alterations" to a claimed invention that are "not captured in drafting the original patent claim but which could be created through trivial changes." *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 733 (2002). When a patent claim has been narrowed during prosecution to overcome a rejection by the U.S. Patent and Trademark Office, the patentee in a subsequent infringement suit is presumptively estopped from invoking the doctrine of equivalents to recapture the surrendered territory between the original and amended claims. A patentee may rebut that presumption, however, by demonstrating that "the rationale underlying the amendment * * * bear[s] no more than a tangential relation" to the equivalent at issue. *Id.* at 740. The question presented is as follows:

Whether the court of appeals correctly held that the patentee had demonstrated in this case that the rationale underlying an amendment made during the prosecution of its patent bore no more than a tangential relationship to the equivalent at issue.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-43a) is reported at 932 F.3d 1342. The opinion of the United States International Trade Commission (Pet. App. 44a-109a) is unreported.

JURISDICTION

The judgment of the court of appeals (Pet. App. 112a-113a) was entered on August 6, 2019. A petition for rehearing was denied on November 25, 2019 (Pet. App. 110a-111a). The petition for a writ of certiorari was filed on February 24, 2020 (a Monday). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

This case concerns orders issued by federal respondent the International Trade Commission (ITC or Com-

mission) to prevent petitioners from importing and selling articles that infringe a patent held by private respondents Ajinomoto Co. and Ajinomoto Animal Nutrition North America, Inc. (Ajinomoto).

A. Legal Background

1. The Patent Act of 1952 (Patent Act), 35 U.S.C. 1 *et seq.*, governs the issuance of patents for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. 101. Sections 101-103 establish the basic criteria for determining whether "[a] person shall be entitled to a patent." 35 U.S.C. 102(a). Those criteria include that the patent must claim patentable subject matter, 35 U.S.C. 101; that the invention must be novel, 35 U.S.C. 102; that the applicant must be the first inventor to seek a patent for the invention, *ibid.*; and that the invention must be non-obvious, 35 U.S.C. 103.

When an inventor applies for a patent, the U.S. Patent and Trademark Office (USPTO) conducts an examination to determine whether a patent should issue. 35 U.S.C. 131; see *Cuozzo Speed Techs., LLC* v. *Lee*, 136 S. Ct. 2131, 2136-2137 (2016). During this examination (or "prosecution"), the patent examiner analyzes the application and the invention it describes, as well as the prior art in the field, to determine whether the application satisfies the statutory requirements for patentability. 35 U.S.C. 131; 37 C.F.R. 1.104(a)(1). If the examiner determines that a proposed claim is not patentable—for example, because it is anticipated by prior art, 35 U.S.C. 102—the examiner rejects the claim

and informs the applicant of "the reasons for such rejection * * * together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application." 35 U.S.C. 132(a).

An applicant who is notified of a rejection may respond with amendments to the claims, evidence of patentability, arguments in favor of patentability, or some combination of those. See 35 U.S.C. 132(a); 37 C.F.R. 1.111(a)-(b). If the applicant offers any such response, the patent examiner will further examine the application in light of the new submissions and will notify the applicant of the results "in the same manner as after the first examination." 37 C.F.R. 1.112; see 35 U.S.C. 132(a). Unless the examiner indicates that his response is final, the patent applicant generally may reply again "in the same manner" as after the first examination. 37 C.F.R. 1.112. This iterative process generally continues until the examiner issues either a notice of allowance or a final rejection. 37 C.F.R. 1.113(a), 1.311(a). An applicant can appeal a final rejection to the Patent Trial and Appeal Board, 35 U.S.C. 134(a), and can seek judicial review of the Board's decision, 35 U.S.C. 141, 145.

2. An allowed patent claim does not merely protect the inventor against infringement by products or processes that fall within the claim's literal terms. Under the doctrine of equivalents, "a product or process that does not literally infringe upon the express terms of a patent claim 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 Co.* v. *Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997) (quoting *Graver Tank & Mfg. Co.* v. *Linde Air Prods. Co.*, 339 U.S. 605, 609 (1950)). This doctrine protects a patentee from "insubstantial alterations" to an invention that are "not captured in drafting the original patent claim but which could be created through trivial changes." *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 733 (2002). Determining whether one invention is equivalent to another requires a context-specific and fact-dependent inquiry that turns on "the particular circumstances of the case." *Graver Tank*, 339 U.S. at 609.

To reduce any "uncertainty about where the patent monopoly ends," this Court has limited a patentee's ability to invoke the doctrine of equivalents in light of the patent's prosecution history—the "public record of the patent proceedings." *Festo Corp.*, 535 U.S. at 727. As noted, the USPTO sometimes "reject[s] an earlier version of [a] patent application on the ground that a claim does not meet a statutory requirement for patentability." *Ibid.* "When the patentee responds to the rejection by narrowing his claims, this prosecution history [presumptively] estops him from later arguing that the subject matter covered by the original, broader claim was nothing more than an equivalent" of the surrendered territory. *Ibid.* Competitors of the patentee may rely on the doctrine of prosecution history estoppel to "ensure that their own devices will not be found to infringe by equivalence." *Ibid.*

Because prosecution history estoppel is an equitable doctrine, this Court has "consistently applied" it "in a

flexible way, not a rigid one." *Festo Corp.*, 535 U.S. at 738-739. In particular, the Court has identified various circumstances in which, notwithstanding the general rule, an amendment "cannot reasonably be viewed as surrendering a particular equivalent"—for example, if "the rationale underlying the amendment * * * bear[s] no more than a tangential relation to the equivalent in question." *Id.* at 740-741. By demonstrating that such circumstances apply, the patentee "can overcome the presumption that prosecution history estoppel bars a finding of equivalence." *Id.* at 741.

B. The '655 Patent

1. Ajinomoto owns U.S. Patent No. 7,666,655 (the '655 patent), which claims *E. coli* bacteria genetically engineered to produce more tryptophan than the bacteria would naturally make. Pet. App. 2a-3a. Tryptophan is an amino acid—one of 20 different molecules used to build proteins—used in animal feed. *Id.* at 6a; see National Human Genome Research Institute, *Talking Glossary of Genetic Terms—Amino Acids*, https://www.genome.gov/genetics-glossary/Amino-Acids.

Claim 20 of the '655 patent covers a process for producing certain amino acids "which comprises cultivating the [*E. coli*] bacterium according to any one of" a number of other claims, including as relevant here Claims 9 and 15. Pet. App. 4a. Claims 9 and 15 both describe *E. coli* bacteria genetically modified by increasing the activity of one particular gene in the *E. coli* genome—the *yddG* gene. *Id.* at 3a. A gene "form[s] the basis for hereditary traits in living organisms." *Association for*

Molecular Pathology v. *Myriad Genetics, Inc.*, 569 U.S. 576, 580 (2013). All genes are encoded as DNA, a molecule that takes the form of a double helix made up of pairs of chemically joined nucleotide bases. *Id.* at 580-581. The four bases are adenine (A), thymine (T), cytosine (C), and guanine (G), each of which pairs (or "hybridizes") with only one other type of base: A only pairs with T (and vice versa), and C only pairs with G (and vice versa). *Id.* at 581.

A gene's nucleotide sequence "contain[s] the information necessary to create strings of amino acids, which in turn are used * * * to build proteins." *Myriad*, 569 U.S. at 581; see National Human Genome Research Institute, *Talking Glossary of Genetic Terms—Protein*, https://www.genome.gov/genetics-glossary/Protein. The *yddG* gene, for example, has a nucleotide sequence that encodes for and produces the YddG protein. Pet. App. 3a. The YddG protein acts by transporting tryptophan out of the *E. coli* bacterium into the surrounding medium, where the tryptophan can be collected. *Ibid.* Accordingly, the more YddG protein that an *E. coli* bacterium produces, the more tryptophan that bacterium tends to produce as well. *Ibid.*

Claim 9 claims a genetically engineered *E. coli* bacterium with three features. First, the bacterium's ability to produce tryptophan must be enhanced by increasing the activity of the YddG protein, which the claim describes as the protein "consist[ing] of the amino acid sequence" labeled SEQ ID NO: 2. Pet. App. 5a. The SEQ ID NO: 2 sequence sets forth the particular sequence of amino acids that makes up the YddG protein. *Id.* at 93a

n.39. Second, the specified protein must increase the *E. coli* bacterium's resistance to tryptophan—that is, the bacterium's ability to grow notwithstanding the presence of tryptophan. *Id.* at 5a; see *id.* at 3a n.1. Third, the specified protein's activity must be enhanced in one of several ways, such as by altering the *E. coli* genome to contain multiple copies of the *yddG* gene. *Id.* at 5a.

Claim 15 is identical to Claim 9 in all respects except one—its description of the YddG protein. Unlike Claim 9, Claim 15 does not describe the YddG protein using its amino-acid sequence (that is, using SEQ ID NO: 2). Pet. App. 5a. Instead, Claim 15 describes the YddG protein by reference to the gene that produces it. Specifically, the claim covers any protein that is produced "by the nucleotide sequence [gene] which hybridizes with the complement of" a nucleotide sequence labeled SEQ ID NO: 1. *Id.* at 6a. The SEQ ID NO: 1 sequence is the nucleotide sequence of the *yddG* gene in the *E. coli* bacterium. *Id.* at 93a n.39. The complement of that sequence is a sequence of nucleotide bases that pairs with SEQ ID NO: 1.

2. The scope of the '655 patent's claims changed during the prosecution process. Claim 1 of the original patent application claimed bacteria in which the activity of the *yddG* gene had been enhanced, and it described the protein produced by that gene in two different ways. The first description—"a protein which comprises the amino acid sequence shown in SEQ ID NO: 2"—is identical to the description in the issued Claim 9. Pet. App. 18a. The second, which broadly recited "a protein which comprises an amino acid sequence including deletion,

substitution, insertion[,] or addition of one or several amino acids in the amino acid sequence shown in SEQ ID NO: 2," does not appear in the '655 patent claims as issued. *Id.* at 18a-19a.

During prosecution, the patent examiner rejected Claim 1 of the original patent application on the ground that the second description of the protein was anticipated by prior art. Pet. App. 19a. The examiner identified a publication by Livshits describing a different gene (the *yfiK* gene) that makes a different protein (the YfiK protein). *Ibid.* The amino-acid sequence of the YfiK protein is a sequence characterized by "deletion, substitution, insertion[,] or addition of one or several amino acids" in SEQ ID NO: 2. C.A. App. 5377-5379 (emphasis omitted); see *id.* at 5136-5162.

Ajinomoto responded to this rejection by amending its application to replace the anticipated second description with the claim limitation that is now in Claim 15. As noted, unlike the prior description, which defined the protein in terms of a particular amino-acid sequence, Claim 15 defines the protein in terms of a particular nucleotide sequence involved in its creation—namely, as the protein produced by any gene that hybridizes with the complement of the nucleotide sequence contained in SEQ ID NO: 1. Pet. App. 19a. Ajinomoto explained that, in light of this amendment, the prior art "no longer anticipates" the claim. C.A. App. 5617. After these representations and amendments, the USPTO issued the patent.

C. The Present Dispute

1. Section 337 of the Tariff Act of 1930, 19 U.S.C. 1202 *et seq.*, prohibits the importation and sale of articles that "infringe a valid and enforceable United States patent," 19 U.S.C. 1337(a)(1)(B)(i), or that are "produced * * * under, or by means of, a process covered by the claims of a valid and enforceable United States patent," 19 U.S.C. 1337(a)(1)(B)(ii). The ITC is charged with investigating violations of Section 337, and it may direct that infringing articles "be excluded from entry into the United States." 19 U.S.C. 1337(d)(1).

In 2016, Ajinomoto filed a complaint in the ITC alleging that petitioners were importing articles that infringed the '655 patent. Pet. App. 2a. Specifically, Ajinomoto alleged that petitioners were importing tryptophan products produced by various strains of *E. coli* bacteria covered by the '655 patent. *Id.* at 6a. An administrative law judge found no infringement and no violation of Section 337. See *id.* at 7a. The full Commission reversed with respect to two bacterial strains. *Id.* at 44a-109a.

a. The first allegedly infringing product contained tryptophan made by a strain of *E. coli* bacteria that is genetically modified to contain a version of the *yddG* gene derived from the genome of a different bacterium. Pet. App. 6a-7a. This non-*E. coli yddG* gene produces a version of the YddG protein with an amino-acid sequence that is different from, but structurally similar to, that of the YddG protein produced by the *E. coli yddG* gene. See *id.* at 25a (explaining that the two proteins are "85% to 95% identical in structure").

The Commission found that this bacteria strain infringed Claim 9 of the '655 patent (as incorporated by Claim 20) because the strain had been edited to contain multiple copies of a *yddG* gene, Pet. App. 86a; the protein produced by the non-*E. coli yddG* gene increased the strain's resistance to tryptophan, *id.* at 81a-85a; and the non-*E. coli* YddG protein was equivalent to the *E. coli* YddG protein as defined by SEQ ID NO: 2, *id.* at 88a-91a. With respect to the last finding, the Commission explained that, although the non-*E. coli* YddG protein did not have the exact amino-acid sequence set forth in SEQ ID NO: 2, the non-*E. coli* YddG protein is "'functionally equivalent'" to the YddG protein because it "performs substantially the same function, in the same way, to obtain the same result"—namely, increasing the ability of the bacteria strain containing it to produce tryptophan. *Id.* at 88a (citation omitted); see C.A. App. 37-38. Accordingly, the Commission concluded that petitioners' use of the non-*E. coli* YddG protein infringed Claim 9 under the doctrine of equivalents. Pet. App. 91a; see C.A. App. 39-40.

The Commission separately found that this strain literally infringed Claim 15 (as incorporated by Claim 20). As noted, the only difference between Claim 9 and Claim 15 is in the claims' descriptions of the YddG protein. See p. 7, *supra*. While Claim 9 defines the YddG protein in terms of its amino-acid sequence, Claim 15 defines the YddG protein in terms of the *yddG* gene that encodes for it—that is, as any gene that hybridizes with the complement of SEQ ID NO: 1, the nucleotide sequence of the *yddG* gene in the *E. coli* genome. The

Commission determined that the non-*E. coli yddG* gene hybridizes with the complement of SEQ ID NO: 1. Pet. App. 86a n.37; see *id.* at 27a n.9.

b. The second allegedly infringing product contained tryptophan made by a strain of *E. coli* very similar to the first strain. Like the first strain, the second strain was genetically modified to contain a version of the *yddG* gene derived from the genome of a different bacterium. Pet. App. 7a. This version of the non-*E. coli yddG* gene produced the exact same non-*E. coli* YddG protein made by the first strain. The only pertinent difference is that this version of the non-*E. coli yddG* gene was "codon-randomized." *Ibid.*

A codon is a set of three sequential nucleotide bases that corresponds to a particular amino acid. Pet. App. 7a n.5; see National Human Genome Research Institute, *Talking Glossary of Genetic Terms—Codon*, https://www.genome.gov/genetics-glossary/Codon. Each codon that produces an amino acid "always encodes for the same amino acid." Pet. App. 7a n.5. But "many of the 20 amino acids are encoded by more than one of the 64 codons." *Ibid.* For example, the sequences TTA and TTG both produce the amino acid leucine. *Ibid.* The term "'[c]odon randomization'" refers to the creation of a gene that "use[s] different codons (*e.g.*, TTA or TTG) to code for the same amino acid (*e.g.*, leucine) in building the same protein." *Ibid.* Codon randomization thus "takes advantage of redundancy in the genetic code, whereby different [genes] can be synthesized that still encode the exact same protein." C.A. App. 43 n.43.

The Commission determined that the second strain did not literally infringe Claim 15 because, by codon-randomizing the sequence of the non-*E. coli yddG* gene, petitioners had ensured that the second strain's version of that gene would not hybridize with the complement of the nucleotide sequence of SEQ ID NO: 1. Pet. App. 95a-96a. The Commission nevertheless concluded that the second strain infringed Claim 9 for the same reasons that the first strain infringed Claim 9—because the non-*E. coli* YddG protein produced by the codon-randomized non-*E. coli yddG* gene (which is identical to the protein produced by the non-*E. coli yddG* gene in the first strain) was equivalent to the *E. coli* YddG protein described in SEQ ID NO: 2. *Id.* at 91a; see *id.* at 98a; C.A. App. 37-40.

Petitioners argued that prosecution history estoppel barred Ajinomoto from invoking the doctrine of equivalents. See Pet. App. 95a-97a; C.A. App. 42-44. The Commission rejected that argument, concluding that Ajinomoto had "rebut[ted] the presumption of prosecution history estoppel by showing that the narrowing amendment bears no more than a tangential relationship to the accused equivalent." Pet. App. 95a; see *id.* at 96a-97a; C.A. App. 44.

c. Having found that both *E. coli* strains infringed the '655 patent, the Commission entered an exclusion order against tryptophan products produced by those strains. Pet. App. 102a-104a; see *id.* at 8a. The Commission also entered a cease-and-desist order prohibiting the domestic sale of those imported products. *Id.* at 104a-106a; see 19 U.S.C. 1337(f)(1).

2. Petitioners appealed, again arguing that "prosecution history estoppel bars Ajinomoto from relying on the doctrine of equivalents" to establish that petitioners' second strain infringed Claim 9. Pet. App. 17a. The court of appeals rejected that contention and affirmed. *Id.* at 1a-35a.

a. The court of appeals explained that petitioners' assertion of prosecution history estoppel "involves an unusual circumstance." Pet. App. 19a. The court noted that the original patent application had claimed (in what was then Claim 1) two alternative processes for producing tryptophan using genetically engineered *E. coli* bacteria. *Ibid.* The court explained that only the second of those two processes was modified by amendment, using the "SEQ ID NO: 1 language now in claim 15." *Ibid.* And yet, the court observed, only the first of those two processes—the "SEQ ID NO: 2 language now in claim 9"—is "asserted as the basis for infringement." *Ibid.* Ajinomoto argued that those circumstances did not establish "even a presumed (though rebuttable) surrender of the asserted equivalent." *Id.* at 20a.

The court of appeals determined, however, that it "need not reach" that argument, because it agreed with the Commission that Ajinomoto had rebutted any presumption of estoppel that attached to the amendment with regard to the equivalent at issue. Pet. App. 20a. In particular, the court agreed that the "rationale underlying [Ajinomoto's] amendment * * * bear[s] no more than a tangential relation to the equivalent in question." *Id.* at 18a (quoting *Festo*, 535 U.S. at 740); see *id.* at 18a-24a. The court explained that, under its

precedents, "[t]he inquiry into whether a patentee can rebut the *Festo* presumption under the 'tangential' criterion focuses on the patentee's objectively apparent reason for the narrowing amendment." *Id.* at 20a (quoting *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1369 (Fed. Cir. 2003) (en banc) (*Festo II*), cert. denied, 541 U.S. 988 (2004)). It determined that "[t]he objectively evident rationale for the amendment [to Claim 1] was to limit the set of proteins within the claim's scope so that it no longer included the prior-art *E. coli* YfiK protein [disclosed by Livshits] and, more generally, no longer allowed as wide a range of *amino acid* alterations." *Id.* at 23a. And it concluded that this reason "had nothing to do with choosing among several DNA sequences in the redundant genetic code" of the YddG protein that is described in Claim 9 of the '655 patent and used in petitioners' second strain. *Ibid.*

b. Judge Dyk dissented in relevant part. Pet. App. 36a-43a. He agreed that the inquiry for the "tangential relation" exception "'focuses on the patentee's *objectively apparent reason* for the narrowing amendment.'" *Id.* at 39a (quoting *Festo II*, 344 F.3d at 1369). In his view, however, the objectively apparent reason for the Claim 1 amendment was to "exclude those proteins made by an encoding nucleotide sequence that does not hybridize with [the complement of] SEQ ID NO: 1." *Id.* at 43a. Judge Dyk would have held that, because the accused equivalent in this case is "produced based on an encoding nucleotide sequence that does not hybridize with SEQ ID NO: 1," it is "directly related to the reason for the amendment." *Id.* at 40a, 43a.

ARGUMENT

Petitioners contend (Pet. 13-28) that prosecution history estoppel bars Ajinomoto from relying on the doctrine of equivalents to prove patent infringement in this case. The court of appeals correctly rejected that contention. Contrary to petitioners' assertion (Pet. 3), the court's decision breaks no new ground and does not conflict with any decision of this Court. The court's application of settled law to the highly technical facts of this case does not warrant this Court's review. And even if further guidance from this Court on the scope of prosecution history estoppel were warranted, the unusual circumstances of this case would make it an unsuitable vehicle for providing that guidance. The petition for a writ of certiorari should be denied.

1. a. The court of appeals correctly held that prosecution history estoppel does not bar Ajinomoto from invoking the doctrine of equivalents in this case. Prosecution history estoppel prevents a patentee from relying on the doctrine of equivalents to recapture in an infringement suit subject matter that was surrendered during prosecution. "The doctrine of equivalents is premised on language's inability to capture the essence of innovation." *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 734 (2002). "Where the original application once embraced the purported equivalent but the patentee narrowed his claims to obtain the patent or to protect its validity, the patentee cannot assert that he lacked the words to describe the subject matter in question." *Ibid.* Accordingly, it will often be inappropriate to permit the patentee to claim

the benefits of the doctrine of equivalents in those circumstances.

The Court in *Festo* declined, however, to make the doctrine of equivalents categorically inapplicable whenever a claim was narrowed to remove a potential obstacle to patentability. Although an amendment "may be presumed to be a general disclaimer of the territory between the original claim and the amended claim," in some circumstances "the amendment cannot reasonably be viewed as surrendering a particular equivalent." *Festo*, 535 U.S. at 740. Sometimes, for example, "the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question." *Ibid.*

Since this Court's decision in *Festo*, the Federal Circuit has consistently held that the inquiry into whether an amendment can reasonably be viewed as surrendering a particular equivalent "focuses on the patentee's objectively apparent reason for the narrowing amendment." *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1369-1370 (2003) (en banc), cert. denied, 541 U.S. 988 (2004); see *Integrated Tech. Corp.* v. *Rudolph Techs., Inc.*, 734 F.3d 1352, 1358 (2013), cert. denied, 573 U.S. 946 (2014); *Felix* v. *American Honda Motor Co.*, 562 F.3d 1167, 1184 (2009); *Honeywell Int'l, Inc.* v. *Hamilton Sundstrand Corp.*, 523 F.3d 1304, 1315, cert. denied, 555 U.S. 939 (2008); *O_2 Micro Int'l Ltd.* v. *Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1364 (2008). The court has made clear that, "[i]n order to maintain the public notice function of a patent, 'that reason should be discernible from the prosecution history record.'" *O_2 Micro Int'l*, 521 F.3d at

1364 (quoting *Festo II*, 344 F.3d at 1369); see *Eli Lilly & Co.* v. *Hospira, Inc.*, 933 F.3d 1320, 1331 (Fed. Cir. 2019) ("[A] patentee seeking to use the [tangential relation] exception 'must base his arguments solely upon the public record of the patent's prosecution.") (citation omitted), petitions for cert. pending, Nos. 19-1058 and 19-1061 (filed Feb. 24, 2020); *Integrated Tech. Corp.*, 734 F.3d at 1358; *Felix*, 562 F.3d at 1184; *Honeywell Int'l*, 523 F.3d at 1315.

In this case, the court of appeals concluded, based on a highly technical record, that Ajinomoto's objectively apparent reason for narrowing the claim limitation that is now in Claim 15 of the '655 patent was to "limit 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 (hence changes in the protein) as" the original language in Claim 1. Pet. App. 23a. The court further concluded that the equivalent employed by petitioners' second strain was entirely unrelated to the territory that Ajinomoto had surrendered. *Ibid.* The court found nothing in the prosecution history to suggest that, by restricting its claim to proteins produced by genes that hybridize with the complement of the *E. coli yddG* gene, Ajinomoto had meant to give up proteins that are equivalents to the protein of Claim 9 but are produced by genes that hybridize with the complement of the *E. coli yddG* gene in their native form but not after codon-randomization—a process with no "scientifically reasonable use," C.A. App. 44 n.44. See Pet. App. 24a.

Petitioners no longer contest that the protein produced by the second strain's codon-randomized non-*E. coli yddG* gene is an equivalent of the protein described by Claim 9 (SEQ ID NO: 2). They do not argue that the equivalent at issue bears more than a tangential relation to the reason behind the amendment as determined by the court of appeals. And while petitioners suggest at various points (*e.g.*, Pet. 21) that the court's assessment of the "objectively apparent reason" for the amendment was incorrect, they rightly do not contend that this case-specific disagreement warrants the Court's review. See Sup. Ct. R. 10 ("A petition for a writ of certiorari is rarely granted when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law.").

b. Instead, petitioners urge (Pet. 18) this Court to grant certiorari to hold that a patentee can never invoke the doctrine of equivalents unless it can identify a "contemporaneous explanation in the prosecution history" for that amendment. No member of the panel advocated that approach, and such a bright-line rule is inconsistent with this Court's approach to prosecution history estoppel.

This Court has "consistently applied the doctrine [of prosecution history estoppel] in a flexible way, not a rigid one." *Festo*, 535 U.S. at 738. In *Warner-Jenkinson Co.* v. *Hilton Davis Chem. Co.*, 520 U.S. 17 (1997), the Court rejected a bright-line rule that would have barred reliance on the doctrine of equivalents to recapture "any surrender of subject matter during patent prosecution, regardless of the reason for such surrender." *Id.* at 30.

And in *Festo*, the Court rejected a bright-line rule that would have rendered the doctrine of equivalents categorically inapplicable to any claim element narrowed for a substantial reason related to patentability. 535 U.S. at 737.

Like the bright-line rules that this Court rejected in *Warner-Jenkinson* and *Festo*, petitioners' "approach is inconsistent with the purpose of applying the estoppel in the first place." *Festo*, 535 U.S. at 737. By amending a patent application to overcome an objection related to patentability, "the inventor is deemed to concede that the patent does not extend as far as the original claim." *Id.* at 738. Petitioners' rule would make that concession absolute absent an explicit, contemporaneous explanation by the patentee. See Pet. 20. But even when a claim is amended, "language remains an imperfect fit for invention," and an amendment should not be treated as "so perfect in its description that no one could devise an equivalent." *Festo*, 535 U.S. at 738. There is consequently "no reason why a narrowing amendment should be deemed to relinquish equivalents * * * beyond a fair interpretation of what was surrendered" or "for aspects of the invention that have only a peripheral relation to the reason the amendment was submitted." *Ibid.*

That rationale applies equally whether the reason for the amendment is expressly stated by the patentee during prosecution or is evident from other aspects of the public prosecution history. In either case, when the objectively apparent reason for the amendment "bear[s] no more than a tangential relation to the equivalent in question," the amendment cannot "reasonably be viewed

as surrendering [the] particular equivalent." *Festo*, 535 U.S. at 740. Even in the absence of an express statement by the patentee, there is "no more reason for holding the patentee to the literal terms of [the] amended claim than there is for abolishing the doctrine of equivalents altogether and holding every patentee to the literal terms of the patent." *Id.* at 738.

c. Contrary to petitioners' assertion (Pet. 20), the court of appeals' approach does not leave patentees "free to invent, *post hoc*," any plausible reason for an amendment. Consistent with this Court's focus on what an amendment may "reasonably" be understood to surrender, *Festo*, 535 U.S. at 740, the Federal Circuit applies an objective standard that turns solely on what inferences can reasonably be drawn from the public prosecution history. See *Festo II*, 344 F.3d at 1370. If the prosecution history reveals no objectively apparent reason, the patentee will be unable to rebut the presumption of estoppel no matter what *post hoc* reasons it offers. And if the prosecution history discloses a reason different from the patentee's *post hoc* explanation, the objectively apparent reason from the public record controls.

Indeed, petitioners acknowledge (Pet. 11-12) that in this very case the court of appeals concluded that the objectively apparent reason for Ajinomoto's amendment was somewhat different from the reason articulated by Ajinomoto in litigation. That reason was based not on any *post hoc* rationalization, but on the public prosecution history of the '655 patent as it would have been understood by those skilled in the art. Pet. App.

23a-24a; see *id.* at 93a-97a & n.39. The difficulty for petitioners is simply that the objectively apparent reason the court identified permitted Ajinomoto to invoke the doctrine of equivalents with respect to the second strain.

Petitioners contend (Pet. 23-24) that their rule would provide greater certainty than the court of appeals' approach, and thereby foster innovation. But this Court has repeatedly rejected similar arguments for broadening prosecution history estoppel or narrowing the doctrine of equivalents. See, *e.g.*, *Festo*, 535 U.S. at 732; *Warner-Jenkinson*, 520 U.S. at 30. The Court has recognized that "the doctrine of equivalents renders the scope of patents less certain." *Festo*, 535 U.S. at 732. Nevertheless, "[e]ach time the Court has considered the doctrine, it has acknowledged this uncertainty as the price of ensuring the appropriate incentives for innovation." *Ibid.*

Rather than imposing categorical limits on a patentee's ability to invoke the doctrine of equivalents, the Court has balanced concerns about innovation, clarity, and public notice by requiring the patentee to prove that application of that doctrine is appropriate in a given case. In particular, "[m]indful that claims do indeed serve both a definitional and a notice function," the Court has "place[d] the burden on the patent holder to establish the reason for an amendment required during patent prosecution." *Warner-Jenkinson*, 520 U.S. at 33; see *Festo*, 535 U.S. at 740 ("Just as *Warner-Jenkinson* held that the patentee bears the burden of proving that an amendment was not made for a reason that would give

rise to estoppel, we hold here that the patentee should bear the burden of showing that the amendment does not surrender the particular equivalent in question.").

Contrary to petitioners' assertion (Pet. 25), the Federal Circuit has remained faithful to that approach. See Pet. App. 20a ("Our cases require the patentee to show that the way in which the alleged equivalent departs from what the claim limitation literally requires is tangential to the discernible objective reason for the narrowing amendment."); *Festo II*, 344 F.3d at 1368 ("[T]he Supreme Court made clear that the patentee bears the burden of showing that a narrowing amendment did not surrender a particular equivalent."). The court of appeals has simply declined to treat a patentee's own words during prosecution as the only evidence through which the patentee may carry that burden.

2. Petitioners contend (Pet. 24-26) that the decision below represents a "dramatic departure" from the Federal Circuit's own precedent. Pet. 8. That contention lacks merit. Petitioners suggest (Pet. 25) that, in applying the "tangential relation" exception, the court of appeals had previously limited its inquiry "to a patentee's explicit and contemporaneous explanations in the prosecution history as to what the patentee was surrendering and what it was not." But the decisions on which petitioners rely demonstrate only that such explicit statements are highly probative of the reason behind a particular amendment. No decision treats such an explicit, contemporaneous explanation as the *only* means of rebutting the presumption of prosecution history estoppel.

Rather, consistent with the decision below, each of the decisions on which petitioners rely considers the reason that is discernible, by an objective observer, from the prosecution history as a whole. See *Intervet Inc.* v. *Merial Ltd.*, 617 F.3d 1282, 1291 (Fed. Cir. 2010) (instructing district courts to "look to the specifics of the amendment and the rejection that provoked [it] to determine whether estoppel precludes the particular doctrine of equivalents argument being made"); *Regents of Univ. of Cal.* v. *Dakocytomation Cal., Inc.*, 517 F.3d 1364, 1378 (Fed. Cir. 2008) (asking what "[t]he prosecution history * * * reveal[ed]" to be the "'objectively apparent reason for the narrowing amendment'") (citation omitted); *Felix*, 562 F.3d at 1184 (determining the "objectively apparent" reason for an amendment in light of the patentee's express statements during prosecution); *Insituform Techs., Inc.* v. *CAT Contracting, Inc.*, 385 F.3d 1360, 1370 (Fed. Cir. 2004) (finding the "tangential relation" exception applicable based on the patentee's explicit statement *and* the absence of any "indication in the prosecution history of any relationship between the narrowing amendment and * * * the alleged equivalent").

Petitioners highlight (*e.g.*, Pet. 3, 25) the Federal Circuit's statement in *Honeywell Int'l, Inc.* v. *Hamilton Sundstrand Corp.*, *supra*, that "[s]ilence does not overcome the presumption" of estoppel. 523 F.3d at 1316. Read in context, however, that statement clearly refers to circumstances in which the prosecution history as a whole "reveals no reason for the narrowing amendment." *Id.* at 1315. In declining to apply the "tangential

relation" exception, the *Honeywell* court did not rely solely on the absence of any explicit prosecution-stage statement by the patentee concerning the reason for the amendment. Instead, the court determined the objectively apparent reason for the amendment by focusing on "the context in which the amendment was made," including the content of the original claim, the examiner's rejection, and the result of the amendment. *Id.* at 1316. It then compared that reason to the equivalent at issue to determine whether "the amendment bore a direct, not merely tangential, relation to the equivalent." *Ibid.* The court of appeals applied the same approach here.

3. Petitioners also contend (*e.g.*, Pet. 13, 17, 21) that the Federal Circuit's subsequent decision in *Eli Lilly & Co.* v. *Hospira*, *supra*, confirms the importance of the ruling below. But the court in *Hospira* did not treat the decision here as establishing any new rule about the significance of patentee silence during prosecution. To the contrary, the *Hospira* court did not even cite the decision below.

The defendants in *Hospira* have filed two certiorari petitions seeking review of that decision. Those two petitions allege somewhat different intra-circuit splits concerning the "tangential relation" exception. See Pet. at 17-24, *Dr. Reddy's Labs., Ltd.* v. *Eli Lilly & Co.*, No. 19-1061 (Feb. 24, 2020) (describing "two irreconcilable" lines of Federal Circuit precedent that have "crystallized" over the past 18 years); Pet. at 27-30, *Hospira, Inc.* v. *Eli Lilly & Co.*, No. 19-1058 (Feb. 24, 2020) (alleging an intra-circuit conflict that does not include the decision below). And those petitions seek review of a

question—*i.e.*, whether a patentee can invoke the "tangential relation" exception to prosecution history estoppel when the patentee could reasonably have drafted a claim that literally covers the alleged equivalent—that is distinct from the one presented here. See Pet. at i, *Hospira*, *supra* (No. 19-1058); Pet. at i, *Dr. Reddy's*, *supra* (No. 19-1061).

4. Even if the question presented otherwise warranted review, this case would be a poor vehicle for deciding it.

First, petitioners' "argument for prosecution history estoppel in this case involves an unusual circumstance." Pet. App. 19a. In a typical prosecution history estoppel case, the patentee argues that the defendant's product infringes a patent's claim through the use of an equivalent to an element of the claim, and the defendant contends that the patentee surrendered the equivalent in question when it narrowed the pertinent claim element during prosecution. In this case, Ajinomoto alleged, and the Commission found, that petitioners' second strain infringed Claim 9 of the '655 patent (as incorporated by Claim 20) because the strain included a protein that is an equivalent of the protein described by Claim 9 (defined in terms of SEQ ID NO: 2). See pp. 11-12, *supra*. Although petitioners assert that Ajinomoto surrendered that equivalent during prosecution, Ajinomoto did not amend the SEQ ID NO: 2 limitation during the prosecution of the '655 patent. Rather, Ajinomoto's amendment was directed at a separate claim limitation that does not appear in the patent as issued. See pp. 7-8, *supra*.

Ajinomoto argued below that, "in this circumstance, prosecution history estoppel does not apply at all, *i.e.*, that there is not even a presumed (though rebuttable) surrender of the asserted equivalent." Pet. App. 20a. The court of appeals declined to resolve the issue because it agreed with the Commission that the "tangential relation" exception applied. *Ibid.* (citation omitted). But if this Court granted review, Ajinomoto could "rely upon any matter appearing in the record in support of the judgment." *Union Pac. R.R.* v. *Brotherhood of Locomotive Eng'rs & Trainmen Gen. Comm. of Adjustment*, 558 U.S. 67, 80 (2009) (citation omitted). And any further guidance on the scope of prosecution history estoppel and the "tangential relation" exception should await a case that presents a more typical estoppel claim.

Second, despite petitioners' repeated assertions that the prosecution history is "silent" as to the reason for the narrowing amendment, Pet. 22; see, *e.g.*, Pet. I, 11, 18, 21, Ajinomoto in fact offered an explanation of its amendment, see C.A. App. 5617. Although petitioners view (Pet. 26-27) that explanation as insufficient, it is part of the prosecution history. Considered together with the examiner's rejection and the relevant prior art, Ajinomoto's explanation supports the court of appeals' determination of the objective reason for the claim amendment at issue, and the court's conclusion that the reason bears no more than a tangential relation to the accused equivalent. See Pet. App. 18a-19a, 23a-24a.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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