Nos. 2018-1590, 2018-1629

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

AJINOMOTO CO., INC., AJINOMOTO HEARTLAND INC.,
Appellants

v.

INTERNATIONAL TRADE COMMISSION,
Appellee

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

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

v.

INTERNATIONAL TRADE COMMISSION,
Appellee

AJINOMOTO CO., INC., AJINOMOTO HEARTLAND INC.,
Intervenors

Appeals from the United States International Trade Commission,
Investigation No. 337-TA-1005

OPPOSITION OF APPELLEE INTERNATIONAL TRADE COMMISSION TO PETITION FOR PANEL REHEARING AND REHEARING *EN BANC*

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases **Page(s)**

I. INTRODUCTION

This case presents a fact-specific question in a complex technological field, of whether the rationale for a claim amendment was merely tangential to an alleged equivalent. Petitioners[1] argue: "The appropriate inquiry—the analysis Judge Dyk correctly followed—is whether the rationale for the narrowing amendment is discernible from the prosecution history and whether that rationale is tangential to the equivalent." ECF No. 92 at 13 (hereinafter, "Pet."). But that is precisely the test applied by the Majority[2]; Petitioners merely disagree as to the result. The Majority cogently applied the governing precedent in the context of the complex genetic engineering issues in this appeal. Even if the present case were close, and even if different members of the panel perceived different rationales for the amendment in question, it does not mean that the Majority's legal test is flawed or that rehearing is warranted.

The petition argues that the Majority relied on a "prosecution-remorse" theory in applying the "tangential relation" exception in the present case. The Majority did no such thing. Petitioners conflate the test

[1] "Petitioners" are CJ CheilJedang Corp., CJ America, Inc., and PT CheilJedang Indonesia (collectively, "CJ").

[2] "Majority" means the panel's majority opinion in this case and "Dissent" means the panel's dissenting opinion. *See* ECF No. 90.

for tangentiality with the test for disavowal in claim construction. In claim construction, the tribunal does not try to glean *why* an applicant amended a claim, the rationale for an amendment—even a rationale objectively evident from prosecution history—is simply irrelevant. *See, e.g.*, *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 985-86 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996).

That is simply not so in connection with prosecution history estoppel, which looks to whether there is a "*reason* suggesting that the patentee could not *reasonably be expected* to have described the insubstantial substitute in question." *Festo Corp. v. Shoketsu Kinzoku Kogyu Kabushiki Co.*, 535 U.S. 722, 740-41 (2002) (emphasis added). Prosecution history estoppel turns on "reason[s]" and "reasonabl[e] … expect[ations]" in a way that claim construction does not. *Id.* In another case that the Court is concurrently considering for rehearing, the infringer urged a bright-line rule: "where the reason for the amendment and the equivalent in question both relate to the same claim element, the tangential exception does not apply." *Eli Lilly & Co. v. Hospira, Inc.*, 933 F.3d 1320, 1333 (Fed. Cir. 2019) (quotation omitted). The Court there properly rejected that proposed test as "contrary to the equitable nature of prosecution history estoppel" and the "equitable spirit that animates the doctrine of equivalents." *Id.*

The Majority correctly and unexceptionally applied the "tangential relation" precedent of the Supreme Court and this Court to the facts of the case. Panel rehearing and rehearing *en banc* are therefore not warranted and the petition should be denied.

II. BACKGROUND OF THE PROSECUTION HISTORY ESTOPPEL AT ISSUE IN THIS CASE

Under *Festo*, a patentee relying on the "tangential relation" exception must demonstrate that "the rationale underlying the amendment … bear[s] no more than a tangential relation to the equivalent in question." *Festo*, 535 U.S. at 740. "[T]he inquiry into whether a patentee can rebut the *Festo* presumption [of prosecution history estoppel] under the 'tangential' criterion focuses on the patentee's objectively apparent reason for the narrowing amendment." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 344 F.3d 1359, 1369 (Fed. Cir. 2003), *cert. denied*, 541 U.S. 988 (2004). And this objectively apparent reason is based upon the intrinsic record, "without the introduction of additional evidence, except, when necessary, testimony from those skilled in the art as to the interpretation of that record." *Id.* at 1370.

In the present appeal, the level of skill in the art is very high: "Ph.D degree in biochemistry, biochemical engineering, microbiology, chemical engineering, or an equivalent field along with at least five years of

experience in metabolic engineering of microorganisms." Appx78. The Majority gave due consideration to the prosecution history and the technology at issue from the perspective of the person of ordinary skill in this art.

A. The Asserted Patent and Its Prosecution History

1. The Asserted Patent

The patent at issue, U.S. Patent No. 7,666,655, is owned by Ajinomoto[3] and relates to specific modifications of an *Escherichia coli* bacterium (*e.g.*, *E. coli*) to improve the bacterium's production of L-amino acids (*e.g.*, L-tryptophan). Appx187. More specifically, the patent discloses enhancing L-amino acid production by "enhancing an activity of [the] protein encoded by the *yddG* gene," *i.e.*, the YddG protein. *Id.*

The asserted claim (claim 20, Appx201) recites:

> **20.** A method for producing an aromatic L-amino acid, which comprises cultivating the bacterium according to any one of claims 9-12, 13, 14, 15-18, or 19.

Claim 20 depends from a number of other claims. In particular, Ajinomoto accused CJ of infringing claim 20 through claim 9 or claim 15 which differ only with respect to the "protein" limitation:

[3] "Ajinomoto" means Intervenors Ajinomoto Co., Inc. and Ajinomoto Heartland Inc., collectively.

Claim 9 (Appx200)	**Claim 15 (Appx201)**
said protein consists of the amino acid sequence of SEQ ID NO:2	said protein is encoded by the nucleotide sequence which hybridizes with the complement of the nucleotide sequence of SEQ ID NO:1 under stringent conditions comprising 60° C., 1xSSC, 0.1% SDS

CJ's petition concerns the term "said protein consists of the amino acid sequence of SEQ ID NO:2" of claim 9. Appx200. That term relates to the term "SEQ ID NO:1" of claim 15. Appx201. In particular, SEQ ID NO:1 is the nucleotide sequence of the *E. coli yddG* gene and it encodes for a protein having the amino acid sequence of SEQ ID NO:2 which is the *E. coli* YddG protein. Appx41 n.39 (citing Appx524 (QA576)).

In Commission proceedings, Ajinomoto accused CJ of infringement based on two categories of bacterial strains ("Earlier Strains" and "Later Strains"). The Commission found that the "Earlier Strains" did not infringe the patent (Appx31), and the panel affirmed that decision unanimously (Majority at 8-15; Dissent at 2); those strains are not at issue here. There are two Later Strains: a "first later strain" or "Strain A" and a "second later strain" or "Strain B."

Both CJ's Later Strains (Strains A and B) include non-*E. coli yddG* genes[4] which encode for the same non-*E. coli* YddG protein. Appx43 n.41 (citing Appx551 (QA686)). The non-*E. coli yddG* gene of Strain A is not codon randomized, hybridizes with the complement of SEQ ID NO:1, and produces a non-*E. coli* YddG protein that is homologous and equivalent to the *E. coli* YddG protein, *i.e.*, SEQ ID NO:2.[5] *Id.*; Appx38 (citing Appx546 (QA671)). Strain B differs from Strain A through codon randomization, such that the non-*E. coli yddG* gene of Strain B does not hybridize with the complement of SEQ ID NO:1, unlike Strain A, but encodes for the same protein as Strain A. Majority at 21-22, 25 n.9; Appx43 (citing Appx838 (QA97)); Appx820 (QA25). Codon randomization is a process that can modify DNA without modifying the protein that is generated by that DNA. Majority at 7 n.5 ("'Codon randomization' refers to creation of DNA molecules that use different codons (*e.g.*, TTA or TTG) to code for the same

[4] The specific bacterium from which the *non-E. coli yddG* gene is obtained is discussed in the parties' confidential briefs. *See*, *e.g.*, ECF No. 52 at 16-17 (hereinafter, "ITCBr.").

[5] CJ did not petition for rehearing with respect to the Majority's finding that the non-*E. coli* YddG protein is equivalent to the *E. coli* YddG protein, *i.e.*, SEQ ID NO:2. Majority at 22-24; Appx37-40. In particular, the Majority determined that "the two proteins are 85% to 95% identical in structure." Majority at 23; Appx37.

amino acid (*e.g.*, leucine) in building the same protein.") (quotation omitted); Appx43 n.43 ("'[C]odon randomization' takes advantage of redundancy in the genetic code, whereby different DNA sequences can be synthesized that still encode the exact same protein."). As noted by the Commission, "[t]here is no scientifically reasonable use [for codon randomization]." Appx44 n.44.

2. The Prosecution History

CJ argues that the Majority erred in finding that Ajinomoto rebutted the presumption of prosecution history estoppel such that CJ's Strain B can satisfy the "protein" limitation of claim 9 under the doctrine of equivalents.

The relevant prosecution history leading to the alleged estoppel traces back to the first office action issued by examiner.

Claim 1 originally recited:

> [A] … bacterium … enhanced by enhancing activity of a protein as defined in the following (A) or (B) …:
>
> (A) a protein which comprises the amino acid sequence shown in SEQ ID NO:2 in Sequence listing;
>
> (B) 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 ….

Appx5047. The examiner rejected claim 1 over Livshits which discloses a specific gene (*yfiK*) that satisfies original limitation (B). Appx5377-5379; Appx5136-5162 (Livshits).

After the examiner's rejection, the patentee amended limitation (B) of claim 1 as follows:

> (B) 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 in Sequence listing~~ … that is encoded by a nucleotide sequence that hybridizes with the nucleotide sequence of SEQ ID NO:1 ….

Appx5609; Appx5691 (further amending the limitation to require hybridization with the "complement" of SEQ ID NO:1). The patentee stated that "[i]n view of this amendment, Livshits … no longer anticipates the claimed invention." Appx5617. In other words, the patentee represented that the *yfiK* gene of Livshits does not hybridize with the complement of SEQ ID NO:1.

While limitation (A) ("SEQ ID NO:2") of original claim 1 (*i.e.*, the protein limitation of claim 9 as issued) was not amended, it is indirectly impacted by the claim amendment of limitation (B). In effect, the range of equivalents of "SEQ ID NO:2" in claim 9 coincides with the literal scope of the protein limitation of claim 15, *i.e.*, the protein encoded by a nucleotide

sequence that hybridizes with the complement of SEQ ID NO:1. Appx41-42 ("[A]ny range of equivalents afforded to limitation (A) cannot recapture subject matter surrendered through the amendment of limitation (B)."); ECF No. 42 at 11 ("Ajinomoto's amendment excluded … every protein … except that of SEQ ID NO:2 and those variants encoded by DNAs hybridizing with the complement of SEQ ID NO:1 ….").

The intrinsic record and undisputed expert testimony demonstrate that, by amending the claim to recite "a protein … encoded by a nucleotide sequence that hybridizes with the complement of the nucleotide sequence of SEQ ID NO:1" (Appx5609, Appx5691), the patentee sought to cover genes that are homologous to SEQ ID NO:1 (and therefore proteins that are homologous to SEQ ID NO:2). Indeed, as noted by the Commission, "[h]ybridization allows some flexibility in the nucleotide sequence such that the exact SEQ ID NO:1 sequence is not required, but a highly homologous nucleotide sequence could still be within the scope of the claim." Appx41 n.39 (citing Appx192 (5:40-43) ("For example, the stringent conditions includes a condition under which DNAs having high homology, for instance DNAs having homology no less than 70% to each other, are hybridized."); Appx822-823 (QAs 33-34) (expert testimony providing that DNA strands need not match up perfectly to hybridize)). In other words, hybridization

and homology ensure sufficient structural similarity with SEQ ID No:2 to achieve the patent's stated purpose of enhancing the bacterium's production of L-amino acids while providing a broader scope for the protein limitation (than the exact SEQ ID No:2).

B. The Panel's Decision

1. The Majority

In a 2-1 decision, a panel of this Court affirmed the Commission's determination that CJ's Strain B infringes the asserted claim under the doctrine of equivalents and that Ajinomoto rebutted the presumption of prosecution history estoppel as to that Strain.

The Majority discussed the applicable legal precedent and found that, consistent with that precedent, "Ajinomoto … rebutted the *Festo* presumption because the amendment was tangential to the equivalent in question." Majority at 21.

The Majority found that "[t]he objectively evident rationale for the amendment 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 original alternative (B), which had allowed 'deletion, substitution, insertion or addition of one or several amino acids in the amino

acid sequence shown in SEQ ID NO:2.'" *Id.* The Majority further found 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." *Id.* Indeed, the Majority continued, "it is undisputed that the non-*E. coli* YddG protein produced without codon randomization remains within the literal claim scope even after the amendment and that the non-*E. coli* YddG protein is identical whether produced from the codon randomized or the non-codon randomized version of the non-*E. coli yddG* gene." *Id.* at 21-22.

Thus, the Majority concluded, "the reason for the narrowing amendment—limiting the amino-acid makeup of the proteins included in one of the alternatives covered by the claim—is unrelated to differences among the several DNA sequences that encode a given protein." *Id.* at 22.

2. The Dissent

The Dissent argues that "the 'reason for the narrowing amendment' in this case" is not tangentially but "directly related to the equivalent." Dissent at 4 (quoting *Festo*, 344 F.3d at 1369). The Dissent reasons that "the patentee deliberately chose to redefine the claimed proteins in terms of the ability of their encoding nucleotide sequences to hybridize with [the complement of] SEQ ID NO:1 under the claimed conditions." *Id.* Like the

prior art protein, the Dissent continues, "[t]he accused equivalent is similarly not covered by the amended claims because it is produced based on an encoding nucleotide sequence that does not hybridize with SEQ ID NO:1 under the claimed conditions." *Id.* Thus, the Dissent fails to "see how the reason for the narrowing amendment is tangential to the accused equivalent." *Id.* at 4-5.

While the Dissent correctly notes that the patentee "was relying on [hybridization] to overcome the prior art," *id.* at 5, the Dissent does not address the rationale for the "hybridization" amendment which is to cover homologous genes that produce homologous proteins. And the Dissent does not acknowledge that the genes contemplated in the prosecution history are non-codon randomized genes. Indeed, codon randomization destroys the ability of the native genes to hybridize with the complement of SEQ ID NO:1 and defeats the purpose of using hybridization as a means to cover homologous genes (and therefore homologous proteins). Thus, the Dissent does not address that the alleged equivalent ***does*** hybridize in its native form and produces a protein that is homologous to SEQ ID NO:2 and undisputedly within its range of equivalents.

III. ARGUMENT

A. The Majority's Decision Is Well Supported by the Record.

Petitioners repeatedly assert that the prosecution history is "silent" and that the patentee identified no rationale for the narrowing amendment. *See* Pet. at 9-11. This is not so. The claim amendment, the specification, the prosecution history, and undisputed expert testimony demonstrate that the purpose of the "hybridization" amendment was to "allow[] some flexibility in the nucleotide sequence such that the exact SEQ ID NO:1 sequence is not required, but a highly homologous nucleotide sequence could still be within the scope of the claim." Appx41 n.39; Appx192, 5:40-43 ("For example, the stringent conditions include[] a condition under which DNAs having high homology, for instance DNAs having homology no less than 70% to each other, are hybridized."); Appx822-823 (QAs 33-34) (expert testimony providing that DNA strands need not match up perfectly to hybridize); Appx546 (QA671) (expert testimony providing that the protein produced by the alleged equivalent is homologous to SEQ ID NO:2). Thus, to a person of ordinary skill in the art, the objectively apparent reason for the amendment is to cover homologous genes through hybridization (and therefore homologous proteins).

Codon randomization is an entirely different process. The Commission found that "[t]here is no scientifically reasonable use [for codon randomization]." Appx44 n.44. Rather, it is a process that can modify DNA without modifying the protein that is produced by that DNA. The prosecution history says nothing about (and the claim amendment is unrelated to) codon randomization of genes that otherwise (*i.e.*, in their native or non-codon randomized form) hybridize with the complement of SEQ ID NO:1 (*e.g.*, CJ's alleged equivalent) and produce a protein that is undisputedly within the range of equivalents of SEQ ID NO:2. Indeed, there can be no question that the genes contemplated in the prosecution history are native genes because codon randomization destroys the ability of the native genes to hybridize with the complement of SEQ ID NO:1 and defeats the purpose of using hybridization as a means to achieve homologous genes (and therefore homologous proteins).

Petitioners and the Dissent gloss over the prosecution history and apply a rigid rule that the tangential relation exception does not apply because the alleged equivalent does not literally hybridize. However, Petitioners (and the Dissent) omit a central fact in this case: the gene in CJ's accused strain ***does*** hybridize with the complement of SEQ ID NO:1 in its non-codon randomized or native form. As the Commission correctly found

(and the Majority affirmed), "the narrowing amendment limits the range of equivalents to certain types of genes" (*i.e.*, genes that hybridize with the complement of SEQ ID NO:1 in their native form, unlike *yfiK*) but is "unrelated to codon randomization of genes that would otherwise be within the scope of the asserted claim or range of equivalents" (*e.g.*, CJ's alleged equivalent). Appx44. As such, the Majority and the Commission correctly determined that the tangential relation exception applies, that the presumption of prosecution history estoppel is rebutted, and that the range of equivalents includes CJ's alleged equivalent.[6]

B. The Majority's Decision Is Consistent with Legal Precedent.

Petitioners do not identify any specific flaw in the Majority's discussion of the legal precedent but they argue that "[the cases] are distinguishable and demonstrate the deficiency in the majority's analysis" because "[i]n those cases—unlike here—patentee explicitly explained *how* its amendment overcame the rejection and informed the Court and the public

[6] CJ incorrectly argues that the Majority compared the alleged equivalent (Strain B) to another strain (Strain A) instead of comparing it to the claim amendment. Pet. at 13. As explained in the Commission's brief, ITCBr. at 67-68, the discussion of CJ's Strain A is relevant to establish the undisputed fact that, in its native or non-codon randomized form, the non-*E. coli yddG* gene in Strain B hybridizes with the complement of SEQ ID NO:1. Majority at 21-22; Appx43.

what was being surrendered." *See* Pet. at 11. As discussed herein, however, the claim language, the patent specification, the prosecution history, and undisputed expert testimony also demonstrate how the amendment overcomes the rejection. Specifically, the purpose of the "hybridization" amendment was to cover genes that are homologous to the *E. coli ydd*G gene (*i.e.*, SEQ ID NO:1) in their native form and to exclude genes that are not (*e.g.*, *yfiK*). And as discussed, herein, the claim amendment is unrelated to the codon randomization of genes that hybridize with the complement of SEQ ID NO:1 in their native form (*e.g.*, CJ's alleged equivalent).

Petitioners argue that "[this Court] ha[s] held the patentees to the *scope of what they ultimately claim*, and [has] not allowed them to assert that claims should be interpreted as if they had surrendered only what they had to." Pet. at 8 (citing *Norian Corp. v. Stryker Corp.*, 432 F.3d 1356, 1361-62 (Fed. Cir. 2005)) (emphasis in original). Petitioners conflate the law for claim construction and literal infringement with the law for infringement under the doctrine of equivalents and apply a rigid rule that would effectively extinguish a patentee's ability to overcome a presumption of surrender of claim scope. Indeed, the above-quoted statement is from a portion of *Norian* that relates to the patentee's arguments with respect to claim construction and literal infringement. That statement has nothing to

do with the scope of a claim term under the doctrine of equivalents and whether an alleged equivalent is "beyond a *fair* interpretation of what was surrendered." *Festo*, 535 U.S. at 738 (emphasis added).

The Majority did not "ignor[e] how the patentee deliberately elected to narrow the claims" and did not "limit[] the rationale to simply avoiding the prior art," as Petitioners contend. Pet. 16. Neither the Majority nor the Commission determined that the range of equivalents for "SEQ ID NO:2" was broad enough to include any protein other than the prior art YfiK (or any gene other than *yfiK*). Rather, the Majority recognized that the range of equivalents "no longer allowed as wide a range of *amino acid* alterations … as original [limitation] (B)" (Majority at 21), and the Commission excluded any gene that does not hybridize with the complement of SEQ ID NO:1 in its non-codon randomized or native form (*e.g.*, *yfiK*) (Appx44). Instead, the Majority and the Commission made the narrow finding that Strain B was properly within the range of equivalents, *i.e.*, "beyond a fair interpretation of what was surrendered." *Festo*, 535 U.S. at 738; Majority at 21 ("The 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."); *id.* at 22 ("[The Majority] does not ignore[] how the patentee deliberately elected to narrow the claims; rather, it identifies what was not

within the scope disclaimed.") (citations omitted); Appx44 ("[T]he narrowing amendment … is unrelated to codon randomization of genes that would otherwise [(*i.e.*, in their non-codon randomized or native form)] be within the scope of the asserted claim or range of equivalents (*e.g.*, the [non-*E. coli*] *yddG* gene)."); *id.* ("[T]he presumption of estoppel is rebutted such that the range of equivalents may extend to cover the codon randomized version of the [non-*E. coli*] *yddG* gene [(*i.e.*, the alleged equivalent)] which encodes the same protein [as the non-codon randomized or native version of that gene].").

This Court recognized that "[a]ny analysis of infringement under the doctrine of equivalents *necessarily* deals with subject matter that is 'beyond,' 'ignored' by, and not included in the literal scope of a claim." *See DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1018 (Fed. Cir. 2006) (citation omitted) (emphasis in original). In the context of the doctrine of equivalents, the rule on surrender is not a complete bar but a presumption; and that presumption may be rebutted if the patentee demonstrates that "the rationale underlying the amendment … bear[s] no more than a tangential relation to the equivalent in question." *Festo*, 535 U.S. at 740. For the reasons set forth above, the narrowing amendment here

was no more than tangentially related to the alleged equivalent, and the "very narrow" tangential relation exception properly applies in this case.

IV. CONCLUSION

Contrary to Petitioners' assertions, the Majority followed Supreme Court and Federal Circuit precedent. The Majority thoroughly considered the intrinsic record and the technological field, and compared the claim amendment to the alleged equivalent, making the dispute case-specific and undeserving of *en banc* review. The petition should be denied.

Respectfully submitted,

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Date: November 6, 2019

CERTIFICATE OF SERVICE

I, Houda Morad, hereby certify that, on this 6th day of November 2019, I caused a copy of the foregoing **OPPOSITION OF APPELLEE INTERNATIONAL TRADE COMMISSION TO PETITION FOR PANEL REHEARING AND REHEARING *EN BANC***, to be served on counsel of record via the Court's CM/ECF system.

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CERTIFICATE OF COMPLIANCE
PURSUANT TO FED. R. APP. P. 32(g)

I hereby certify that the attached opposition complies with the type-volume limitation and typeface requirements of Federal Circuit Rules 35(e)(4) and 40(d). The opposition has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in Times New Roman 14-point font, and the opposition contains 3,882 words according to the word-count function of the word-processing system.

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