APPENDIX

APPENDIX A

IN THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Nos. 2018-1590, 2018-1629

AJINOMOTO CO., INC., AJINOMOTO HEARTLAND INC., APPELLANTS

v.

INTERNATIONAL TRADE COMMISSION, APPELLEE

CJ CHEILJEDANG CORP., CJ AMERICA, INC., PT CHEIJEDANG INDONESIA, INTERVENORS

CJ CHEILJEDANG CORP., CJ AMERICA, INC., PT CHEIJEDANG INDONESIA, APPELLANTS

v.

INTERNATIONAL TRADE COMMISSION, APPELLEE,

AJINOMOTO CO., INC., AJINOMOTO HEARTLAND INC., INTERVENORS

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

Decided: August 6, 2019

JOHN D. LIVINGSTONE, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Atlanta, GA, argued for Ajinomoto Co., Inc., Ajinomoto Heartland Inc. Also represented by MARTIN DAVID WEINGARTEN; CHARLES E. LIPSEY, Reston, VA; MAREESA ARNITA FREDERICK, CORA RENAE HOLT, BARBARA RUDOLPH, Washington, DC.

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Before DYK, MOORE, and TARANTO, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* TARANTO.

Opinion concurring in part and dissenting in part filed by *Circuit Judge* DYK.

TARANTO, *Circuit Judge*.

Ajinomoto Co., Inc. and Ajinomoto Heartland Inc. (collectively, Ajinomoto) filed a complaint against CJ CheilJedang Corp., CJ America, Inc., and PT CheilJedang Indonesia (collectively, CJ) with the International Trade Commission, alleging that CJ was importing certain products that infringed Ajinomoto's U.S. Patent No. 7,666,655. CJ used several strains of *Escherichia coli* bacteria to produce L-tryptophan products, which it then imported into the United States. The Commission determined that CJ's earlier strains did not infringe but that CJ's two later strains did. The Commission also found that the relevant claim of the '655 patent is not invalid for lack of an adequate written description.

Ajinomoto appeals the Commission's claim construction underlying the determination of no infringement by the earlier strains. CJ cross-appeals aspects of the determination of infringement by the later strains and the rejection of the invalidity challenge. We affirm.

I

A

The '655 patent claims *E. coli* bacteria that have been genetically engineered to increase their production of aromatic L-amino acids, such as L-tryptophan, during fermentation, as well as methods of producing aromatic L-amino acids using such bacteria. *See* '655 patent, col. 2, lines 4045. In particular, the '655 patent identifies a specific gene in the *E. coli* genome, the *yddG* gene, that encodes a membrane protein, the YddG protein. *Id.*, col. 2, lines 46-48. That protein transports aromatic L-amino acids out of the bacterial cell and into the surrounding culture medium, where they can be collected. *See id.*, col. 7, lines 11-16. When *yddG* gene activity in bacteria is enhanced so that more YddG protein is produced, the bacteria show increased production of, and increased resistance to, aromatic L-amino acids. *Id.*, col. 2, lines 49-57.[1]

The '655 patent describes three ways to enhance the activity of the *yddG* gene. First, plasmids containing additional copies of the *yddG* gene can be introduced into

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[1] The specification defines a bacterium's "resistance" to an amino acid as its ability "to grow on a minimal medium containing" the amino acid on "which unmodified or the wild type, or the parental strain of the bacterium cannot grow," or its ability "to grow faster" on such a medium "than unmodified or the wild type, or the parental strain of the bacterium." '655 patent, col. 4, lines 49-56.

the bacterium. *Id.*, col. 2, lines 50-52; *id.*, col. 5, line 62, through col. 6, line 2. Second, additional copies of the *yddG* gene can be inserted into the bacterial chromosome. *Id.*, col. 2, lines 52-54; *id.*, col. 6, lines 3-6. Third, a stronger "promoter" than the one native to the *E. coli* *yddG* gene can be used. *Id.*, col. 2, lines 54-57; *id.*, col. 6, lines 12-15.[2]

Claim 20, the only claim of the '655 patent still asserted when the Commission issued its decision, claims "[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." *Id.*, col. 24, lines 4-6 (emphasis added). Of the claims in that list, claims 9 and 15 are the independent claims, and they are the two alternatives, under claim 20, of importance in this case.

Claim 9 recites:

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[2] A promoter is a nucleotide sequence within a DNA molecule, located adjacent to the nucleotide sequence that constitutes the gene to be expressed. The Lewin textbook cited by Ajinomoto shows a "typical promoter" around 41 nucleotides long. J.A. 6043; *see also* J.A. 6177 (article by Deuschle et al., cited at '655 patent, col. 6, lines 18-21, showing longer promoters). The promoter is the binding site for RNA polymerase, which initiates transcription (the first step in gene expression) by separating the two strands of DNA. The '655 patent's specification defines "[s]trength of promoter" with reference to the "frequency of acts of the RNA synthesis initiation." '655 patent, col. 6, lines 15-16.

The promoter is only one part of a gene's "expression regulation sequence," which controls expression of the gene. *See id.*, col. 3, line 14; *id.*, col. 5, line 2. Besides promoters, the "expression regulation sequence" can include, *e.g.*, operators, enhancers, terminators, and silencers.

> 9. A recombinant *Escherichia coli* bacterium, which has the ability to accumulate aromatic L-amino acid in a medium, wherein the aromatic Lamino acid production by said bacterium is enhanced by enhancing activity of a protein in a cell of said bacterium beyond the levels observed in a wild-type of said bacterium,
>
> **[1]** and in which said protein consists of the amino acid sequence of SEQ ID NO: 2
>
> **[2]** and said protein has the activity to make the bacterium resistant to L-phenylalanine, fluoro-phenylalanine or 5[-]fluoro-DL-tryptophan,
>
> **[3]** wherein the activity of the protein is enhanced by **[3a]** transformation of the bacterium with a DNA encoding the protein to express the protein in the bacterium, **[3b]** by replacing the native promoter which precedes the DNA on the chromosome of the bacterium with a more potent promoter, **[3c]** or by introduction of multiple copies of the DNA encoding said protein into the chromosome of said bacterium to express the protein in said bacterium.

Id., col. 22, lines 51-67 (paragraph breaks and bold numbering added). The Commission referred to limitation [1] as the "protein limitation," limitation [2] as the "resistance limitation," and limitation [3] as the "enhancement limitation." Claim 15 is materially identical to claim 9, except for the protein limitation. Whereas claim

9 identifies the claimed protein by a specific amino-acid sequence, claim 15 identifies it by reference to a corresponding DNA sequence—a protein "encoded by the nucleotide sequence which hybridizes with the complement of the nucleotide sequence of SEQ ID NO: 1 under" certain conditions. *See id.*, col. 23, lines 14-32.

B

In May 2016, Ajinomoto filed a complaint against CJ with the Commission under 19 U.S.C. § 1337. Ajinomoto alleged that CJ violated § 1337(a)(1)(B)(ii) by importing animal-feed-grade L-tryptophan products produced by a process covered by the '655 patent.[3] The Commission instituted an investigation based on Ajinomoto's complaint.

The parties before us, including the Commission, agree that whether the accused products were produced by a process covered by the patent is a question of infringement. The proceeding focused on three groups of *E. coli* strains that CJ has used to produce tryptophan. First, CJ's "earlier strains" contained both the native *E. coli yddG* gene and the native *E. coli yddG* promoter, except that the first nucleotide of the promoter was changed through chemical mutagenesis, resulting in a stronger promoter. Second, in November 2016, several months after Ajinomoto filed its complaint, CJ began using its first "later strain," which contained two copies of a *yddG* gene: (1) the native *E. coli yddG* gene with the native *E. coli yddG* promoter; and (2) a non-E. coli *yddG*

[3] Ajinomoto also alleged that CJ infringed U.S. Patent No. 6,180,373, which similarly claims methods of producing tryptophan using genetically engineered bacteria. The '373 patent expired on January 30, 2018, and is not at issue in this court.

gene with two promoters—(2a) a native non-*E. coli* *yddG* promoter and (2b) an *rmf* promoter.[4] Third, in December 2016, CJ started using its second "later strain," which also contained two copies of a *yddG* gene: (1) the native *E. coli yddG* gene with the native *E. coli yddG* promoter; and (2) a codon-randomized non-*E. coli yddG* gene with two promoters—(2a) an *rmf* promoter and (2b) an *rhtB* promoter.[5]

In August 2017, the administrative law judge (ALJ) issued a final initial determination. The ALJ construed "replacing the native promoter . . . with a more potent promoter" in the enhancement limitation to mean "removing the native upstream region of the *yddG* gene and inserting one of a class of promoters that controls expression of a different gene." J.A. 90-91. Using that construction, the ALJ found that CJ's earlier strains did not infringe; he found that they failed to meet the enhancement limitation because CJ created the more potent promoter in those strains by mutagenesis of a single nucleotide rather than removal of the entire native promoter

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[4] The *rmf* and *rhtB* promoters are promoters associated with other genes in the *E. coli* genome.

[5] Each particular codon (three nucleotides in a row on a DNA molecule) that encodes for an amino acid always encodes for the same amino acid, but many of the 20 amino acids are encoded by more than one of the 64 codons. *See Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1208 n.4 (Fed. Cir. 1991) (discussing "redundancy" of genetic code). For instance, the DNA sequences TTA and TTG both code for the amino acid leucine. "Codon randomization" refers to creation of DNA molecules that use different codons *(e.g.*, TTA or TTG) to code for the same amino acid *(e.g.*, leucine) in building the same protein. *See Mycogen Plant Sci. v. Monsanto Co.*, 243 F.3d 1316, 1323 (Fed. Cir. 2001) ("[O]ne codon can be substituted for another in the gene without changing the amino acid and resulting protein.").

and insertion of a new promoter. As to CJ's later strains, the ALJ found that (a) the first later strain did not infringe because Ajinomoto had failed to prove that it met the resistance limitation, and (b) the second later strain also did not infringe because its non-*E. coli* YddG protein was not equivalent to the claimed *E. coli* YddG protein under the doctrine of equivalents. Finally, the ALJ found that claim 20 of the '655 patent is invalid for lack of an adequate written description of the "more potent promoter" limitation incorporated into that claim.

In October 2017, the full Commission decided to review the ALJ's final initial determination in its entirety, and in December 2017, the Commission issued its decision. It affirmed the ALJ's construction of "replacing the native promoter . . . with a more potent promoter" and accordingly affirmed the ALJ's finding that CJ's earlier strains did not infringe. But the Commission reversed several of the ALJ's other findings. Specifically, it determined that both of CJ's later strains met all disputed claim limitations and thus infringed claim 20 and that claim 20 was not proved to lack an adequate written description. The Commission accordingly entered a limited exclusion order against CJ's infringing products, *i.e.*, those made by both of CJ's later strains but not its earlier strains. The Commission also issued a cease-and-desist order against CJ America, which held inventory of the infringing products.

Ajinomoto and CJ both timely appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(6).

II

We begin with Ajinomoto's appeal of the Commission's finding of no infringement by the earlier strains. Ajinomoto challenges that finding solely by arguing that

the Commission erred in its claim construction of "replacing the native promoter . . . with a more potent promoter." Ajinomoto argues that, properly construed, the phrase is not limited to removing the entire native promoter and inserting a new promoter, as the Commission concluded, but encompasses mutagenesis of individual nucleotides within the native promoter. We review the Commission's claim construction de novo, as the Commission relied on only intrinsic evidence and made no factual findings based on extrinsic evidence. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015); *see Cont'l Circuits LLC v. Intel Corp.*, 915 F.3d 788, 795 (Fed. Cir. 2019). We agree with the Commission's claim construction and therefore affirm the non-infringement finding.

The ordinary and customary meaning of the claim language provides support for the Commission's claim construction. The language of "replacing the native promoter . . . with a more potent promoter" suggests, in ordinary parlance, an operation at the level of the entire promoter as a unit, not at the level of a single nucleotide that is just one small component of the promoter. To say that one is "replacing" an object *(e.g.*, a laptop computer, a bicycle, a sailboat, a blender) suggests that one is doing more than altering one small part of it. That suggestion is bolstered when one also uses language (here, a "more potent promoter") referring to the replacement at the level of the overall object. The suggestion is further reinforced by the most apt of the dictionary definitions of "replace" introduced before the Commission—"to provide a substitute for." J.A. 10361; *see also* J.A. 5622 (patent applicants explaining "replacing" as "substitut[ing]"). In many contexts, one would not refer to swapping out one small component of a larger unit as

"replacing" the unit or as providing a "substitute" for the unit, even though the net result is a differently constituted larger unit. Context matters, of course, but here, Ajinomoto has not shown a contrary common understanding (or even one of several common understandings) among relevant artisans in the specific context of replacing a promoter with a more potent promoter. Accordingly, the claim language, though hardly establishing a plain meaning, supports the Commission's construction.

The specification offers additional support, though it too is hardly plain insofar as it bears on the particular construction issue. The specification states that "the enhancement of gene expression can be achieved by locating the DNA of the present invention under control of more potent promoter instead of the native promoter." '655 patent, col. 6, lines 12-15. That statement speaks of a promoter as a unit, but it does not use the language of "replacing." Indeed, the specification nowhere uses that language. But it does discuss "substituting" promoters, using a term that, as indicated above, is an apt definition of "replacing" here. The specification describes "[t]he present inventions" as including "[t]he bacterium according to the above bacterium, wherein native promoter of said DNA is substituted with more potent promoter." *Id.*, col. 3, lines 19-21. The term is then used in Example 4, which is titled "Substitution of the Native Upstream Region of yddG Gene by the Hybrid Regulatory Element Carrying the P_L Promoter and SD_{lacZ} in *E. coli* Chromosome," and which involves removing the entire native promoter and inserting a new promoter. *See id.*, col. 11, line 5, through col. 12, line 46. The sole specification example of "substitution" thus fits the

Commission's claim construction. And while the specification discusses mutagenesis, it does so only in the context of the protein-coding region of the *yddG* gene, not the promoter. *See id.*, col. 5, lines 18-30.

We turn finally to the prosecution history—on which the parties to this case have focused most of their competing analyses. We conclude that the best understanding of what transpired before the examiner further supports the Commission's construction. Because the prosecution history reinforces what is already suggested by the claim language and specification, this case provides no occasion, contrary to Ajinomoto's contention (Ajinomoto Br. 34), for requiring clear and unmistakable disavowal or disclaimer to justify a claim construction contrary to a meaning evident from the claim language and specification.

What was claim 2 of the original application recited "[t]he bacterium according to claim 1, wherein said activities of proteins . . . is enhanced by transformation of said bacterium with DNA coding for the protein . . . *or by alteration of expression regulation sequence* of said DNA on the chromosome of the bacterium." J.A. 5047 (emphasis added).[6] The examiner rejected the claim for lack of an adequate written description and lack of enablement. As to written description, the examiner explained that "[w]hile generic expression regulation sequences are known in the art, a particular, endogenous

[6] Although claims 9 and 15 issued from what were numbered as claims 12 and 24 when added during prosecution, the parties do not dispute that the amendments to original claim 2 (which eventually was cancelled) are relevant to construing issued claims 9 and 15. The same "replacing the native promoter . . . with a more potent promoter" language added to original claim 2 was eventually added to claims 9 and 15.

expression regulation sequence for the DNA that encodes [amino-acid] SEQ ID NO: 2, or related sequences, is not described." J.A. 5371. "Without description of the endogenous regulation sequence," the examiner continued, "an endogenous regulation sequence that has been altered to increase expression of said protein also lacks adequate written description." *Id.* Turning to enablement, the examiner stated:

> The specification, while being enabling for *Escherichia* strains wherein the native promoter for the DNA encoding SEQ ID NO: 2 has been changed by substitution with a more potent promoter, does not reasonably provide enablement for the genus of an L-amino acid producing bacterium wherein the activity of proteins described by SEQ ID NO: 2 and related sequences is increased due to specific alterations within the chromosomal expression regulation sequence for DNA encoding said proteins.
>
> . . . .
>
> The instant specification teaches how to select *Escherichia* bacteria that have an increased production of L-amino acids, and the art teaches how to mutagenize chromosomal DNA and how to characterize the mutations in the DNA. However, neither the specification nor the art contain any examples of how to specifically change endogenous *Escherichia* chromosomal expression

> regulation sequences for the DNA encoding proteins described by SEQ ID NO: 2, or related sequences, such that the activity of said proteins in the bacteria is increased. The art and the specification provide enablement for inserting a known promoter in the chromosomal DNA to upregulate the expression of the DNA encoding SEQ ID NO: 2; however, neither the specification nor the art enable making specific changes to expression regulation sequences for DNA encoding SEQ ID NO: 2 and related sequences on the chromosome of *Escherichia* bacteria. The art and specification lack a detailed description of the structure of the instant endogenous expression regulation sequences, and they lack any guidance on how to alter such sequences such that DNA expression is increased; therefore, to make the instant bacteria with altered expression regulation sequences would be unpredictable.

J.A. 5374-75.

In response to the rejections, the applicants amended the claim to recite "replacing the native promoter that precedes a DNA encoding said protein . . . with a more potent promoter" instead of "by alteration of expression regulation sequence of said DNA." J.A. 5610. The applicants explained the amendment as follows: "Applicants have amended Claim 2 consistent with the Examiner's recognition that the specification enables Escherichia strains wherein the native promoter for

the DNA encoding SEQ ID NO: 2 has been changed by substitution with a more potent promoter." J.A. 5622.

Reading the written-description and enablement rejections together, we think that the most reasonable understanding of the examiner's comments is that the examiner was drawing a distinction between alterations to the promoter, which were sufficiently described and enabled because *E. coli* promoters were well understood in the art, and alterations to the expression-regulation sequence more broadly, which were not adequately described or enabled. To be sure, the examiner's statement that the art and the specification "lack any guidance on how to alter such sequences such that DNA expression is increased" might at first suggest that the applicants had not described and enabled the full scope of "alteration." But in context, this statement is best read as meaning that the applicants had not described and enabled the full scope of "expression regulation sequence," so that "alteration" of that sequence also was not adequately described or enabled, even though general techniques for altering DNA sequences were well known in the relevant art.

We need not determine the precise basis for the examiner's rejections, however, as "there is no principle of patent law that the scope of a surrender of subject matter during prosecution is limited to what is absolutely necessary to avoid a prior art reference that was the basis for an examiner's rejection." *Norian Corp. v. Stryker Corp.*, 432 F.3d 1356, 1361 (Fed. Cir. 2005). Rather, patentees frequently "surrender more through amendment than may have been absolutely necessary to avoid particular prior art." *Id.* That principle logically extends to amendments made to overcome rejections under § 112. *Cf. Biogen Idec, Inc. v. GlaxoSmithKline LLC*,

713 F.3d 1090, 1095-96 (Fed. Cir. 2013). Indeed, we have stated more generally that "[t]he question is what a person of ordinary skill would understand the patentee to have disclaimed during prosecution, not what a person of ordinary skill would think the patentee needed to disclaim during prosecution." *Tech. Props. Ltd. LLC v. Huawei Techs. Co.*, 849 F.3d 1349, 1359 (Fed. Cir. 2017). A patentee must "be held to what he declares during the prosecution of his patent," because a contrary rule would undermine "[t]he public notice function of a patent." *Springs Window Fashions LP v. Novo Indus., L.P.*, 323 F.3d 989, 995 (Fed. Cir. 2003).

We conclude that this is a case where the applicants surrendered more than may have been necessary. As discussed above, the best reading of the prosecution history is that, to overcome the written-description and enablement rejections, it might well have sufficed if the applicants had narrowed their claims from alterations to the overall expression-regulation sequence to alterations to the promoter. But the applicants did not merely change "expression regulation sequence" to "native promoter"; they also changed "alteration" to "replacing." Just as "when different words are used in separate claims, they are presumed to have different meanings," *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1349 (Fed. Cir. 2012), when a word is changed during prosecution, the change tends to suggest that the new word differs in meaning in some way from the original word.

That inference is bolstered by the applicants' remarks accompanying the amendment. Those remarks effectively equate "replacing the native promoter . . . with a more potent promoter" in the amended claim with "chang[ing]" the native promoter "by substitution with

a more potent promoter." J.A. 5622. As we have already noted, Example 4, described as involving "substitution" of a promoter, involves removal of the entire native promoter and insertion of a new promoter. '665 patent, col. 11, line 5, through col. 12, line 46. The applicants' remarks, understood in light of the word choices and the specification, thus reinforce the Commission's conclusion that the new claim language does not include mutagenesis of individual nucleotides.

For those reasons, we affirm the Commission's claim construction and its finding that CJ's earlier strains do not infringe based on that claim construction.

III

CJ, in its cross-appeal, challenges the Commission's determinations that CJ's second later strain met the protein limitation, that both of CJ's later strains met the resistance limitation, and that claim 20 is not invalid for lack of an adequate written description. We affirm the Commission as to all three issues.

A determination of infringement or non-infringement, whether literal or under the doctrine of equivalents, is a finding of fact, reviewed here for substantial evidence. *Kinik Co. v. Int'l Trade Comm'n*, 362 F.3d 1359, 1361 (Fed. Cir. 2004). But a determination of the applicability or inapplicability of prosecution history estoppel, which limits the availability of the doctrine of equivalents, is a matter of law, reviewed de novo. *Spectrum Pharm., Inc. v. Sandoz Inc.*, 802 F.3d 1326, 1337 (Fed. Cir. 2015). The determination that a patent claim did not lack adequate support in the written description is a factual finding, reviewed for substantial evidence. *Rivera v. Int'l Trade Comm'n*, 857 F.3d 1315, 1319 (Fed. Cir. 2017). Ajinomoto had to prove infringement by a

preponderance of the evidence, while CJ had to prove invalidity by clear and convincing evidence. *See Motorola Mobility, LLC v. Int'l Trade Comm'n*, 737 F.3d 1345, 1348 (Fed. Cir. 2013); *Enercon GmbH v. Int'l Trade Comm'n*, 151 F.3d 1376, 1384 (Fed. Cir. 1998).

A

The Commission found that CJ's second later strain infringed claim 20, which covers two alternatives of relevance in this case—the claim 9 alternative and the claim 15 alternative. The infringement finding for CJ's second later strain does not rest on the claim 15 alternative, which, in its protein limitation, requires a protein encoded by a nucleotide sequence that hybridizes with the complement of SEQ ID NO: 1 (the nucleotide sequence of the *E. coli yddG* gene). The Commission did not find, and Ajinomoto does not argue for, either literal or equivalents infringement based on claim 15. The Commission found infringement under the claim 9 alternative—specifically, it found that the YddG protein encoded by the codon-randomized non-E. coli *yddG* gene of this strain is an equivalent of SEQ ID NO: 2 (the amino-acid sequence of the *E. coli* YddG protein), as required by the protein limitation of claim 9.

CJ challenges that finding on two grounds. Based on an amendment to original claims made during prosecution, CJ asserts that prosecution history estoppel bars Ajinomoto from relying on the doctrine of equivalents to meet the protein limitation. Separately, CJ asserts that the non-E. coli YddG protein of CJ's second later strain cannot reasonably be found to be an equivalent of the claimed *E. coli* YddG protein under the function-way-result test for equivalence. We address those arguments in turn.

1

Under the doctrine of prosecution history estoppel, "[a] patentee's decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 740 (2002). The Supreme Court has specified three ways the patentee can rebut that presumption, each of which, if established, means that "the amendment cannot reasonably be viewed as surrendering a particular equivalent." *Id.* First, "[t]he equivalent may have been unforeseeable at the time of the application." *Id.* Second, "the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question." *Id.* Third, "there may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question." *Id.* at 740-41.

In this case, the relevant facts about what transpired during prosecution are as follows. Claim 1 as originally filed recited two alternative conditions for the claimed protein:

> a protein as defined in the following (A) or (B) in a cell of said bacterium:
>
> (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 in Sequence listing.

J.A. 5047. The examiner rejected that claim as anticipated by a reference disclosing the *E. coli* "*yfiK* gene product" *(i.e.*, the *E. coli* YfiK protein)—which differed from SEQ ID NO: 2 by deletion, substitution, insertion, or addition of several amino acids and, therefore, did not come within the (A) alternative but did come within the (B) alternative. J.A. 5378. In response, the applicants left the (A) alternative alone but replaced the language following (B) with new language: "a protein which comprises an amino acid sequence that is encoded by a nucleotide sequence that hybridizes with the nucleotide sequence of SEQ ID NO: 1 under stringent conditions." J.A. 5609.[7]

As an initial matter, CJ's argument for prosecution history estoppel in this case involves an unusual circumstance. The infringement determination does not rest on finding an equivalent of the new claim language—namely, the (nucleotide) SEQ ID NO: 1 language now in claim 15. Rather, it rests on finding an equivalent of the (amino-acid) SEQ ID NO: 2 language now in claim 9, which was not itself altered by the amendment at issue. That is, the original claim provided two alternatives; only the second was modified by amendment; and only the first is asserted as the basis for infringement by CJ's

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[7] As previously noted, claims 9 and 15 issued from new claims added at the same time as this amendment. *See supra* note 6. Claims 9 and 15 respectively contain the same language as the (A) and (B) limitations in claim 1 after it was amended. Claim 20, the claim at issue, treats claims 9 and 15 as alternatives in the same way that original and amended claim 1 treated (A) and (B).

second later strain. But we need not reach Ajinomoto's contention 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. The Commission did not so rule, instead concluding that the "tangential relation" exception applied, so that Ajinomoto did not surrender the protein produced by the codon-randomized non-*E. coli yddG* gene of CJ's second later strain. J.A. 41-44. We agree with that conclusion.[8]

In applying the "tangential relation" exception, we "ask[] whether the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1369 (Fed. Cir. 2003). "[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.* 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. In that situation, there is no surrender of the equivalent by that amendment.

For instance, in *Insituform Technologies, Inc. v. CAT Contracting, Inc.*, the patent claimed a method of

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[8] CJ contends that Ajinomoto forfeited invocation of the "tangential relation" exception because it did not invoke the exception before the ALJ or in its request for review by the full Commission. CJ cites no authority that barred the Commission from exercising discretion to raise the issue and give the parties an adequate opportunity to address it, as the Commission did here.

using a vacuum to impregnate a flexible tube with resin. 385 F.3d 1360, 1362-63 (Fed. Cir. 2004). The claims were originally rejected over a prior-art reference that disclosed a single vacuum source located far away from the resin source. *Id.* at 1369. The applicant amended the claim at issue to require a single vacuum source placed near the resin source. *See id.* at 1368-70. The alleged equivalent used multiple vacuum sources. *Id.* at 1369-70. We held that the "tangential relation" exception applied, observing that the purpose of the narrowing amendment was to distinguish the invention from the prior art based on the location of the vacuum source relative to the resin, not to limit the number of vacuum sources. *Id.* at 1370.

Similarly, in *Regents of the University of California v. Dakocytomation California, Inc.*, the patented method involved using DNA testing to detect chromosomal abnormalities. 517 F.3d 1364, 1369-70 (Fed. Cir. 2008). The claim at issue originally recited "disabling the hybridization capacity of repetitive sequences" generally. *Id.* at 1377. The examiner rejected the claim over several prior-art references, one of which disclosed disabling hybridization using unique sequence probes. *Id.* at 1378. In response, the applicants amended the claim to recite a particular technique of disabling hybridization using blocking nucleic acids. *Id.* The parties stipulated that the added "blocking nucleic acid" limitation was limited to human nucleic acids, but the alleged equivalent used synthetic nucleic acids. *Id.* at 1376. We concluded that the narrowing amendment was tangential to how the equivalent differed from the literal claim limitation: "[I]n narrowing the claim to overcome the prior art rejections, the focus of the patentees' arguments centered on the method of blocking— not on the particular type of nucleic acid that could be used for blocking." *Id.* at 1378.

Indeed, we noted, "the 'nucleic acid' limitation was never narrowed during prosecution and was not at issue in the office action rejecting the claims," and "none of the cited references concerned the type of nucleic acid that could perform the blocking, or mentioned the accused equivalent." *Id.*

Our decision in *Intervet Inc. v. Merial Ltd.* is to similar effect. In that case, the patent claimed DNA constructs encoding a type of porcine circovirus. 617 F.3d 1282, 1284 (Fed. Cir. 2010). The claim at issue originally recited DNA sequences from a group of thirteen open reading frames, which are portions of a gene that encode a protein. *Id.* at 1285-86, 1291. The examiner rejected the claim over open reading frames from another organism, noting that the claim as written could cover open reading frames from any organism. *Id.* at 1291. The applicants then amended the claim to require that the open reading frames be "of porcine circovirus type II." *Id.* The alleged equivalent was a nucleotide sequence that was over 99% homologous to one of the claimed sequences. *Id.* at 1286. The "tangential relation" exception applied to that equivalent, we held, because "[t]he rationale for the amendment was to narrow the claimed universe of [open reading frames] down to those of [porcine circovirus type II], and bore only a tangential relation to the question of which DNA sequences are and are not properly characterized as [porcine circovirus type II]." *Id.* at 1292.

This understanding of the "tangential relation" exception also underlies cases in which we have held that the patentee failed to establish that a narrowing amendment was tangential to the equivalent at issue. For example, in *Biagro Western Sales, Inc. v. Grow More, Inc.*, the claims at issue, which claimed buffered phosphorus

fertilizers, were rejected over a prior-art reference disclosing a fertilizer that was buffered only when diluted. 423 F.3d 1296, 1299, 1306 (Fed. Cir. 2005). In response, the applicant amended the claims by adding the limitation "wherein said phosphorous-containing acid or salt thereof is present in an amount of about 30 to about 40 weight percent," explaining that the fertilizer must be concentrated and that the amendment specified a range for the concentration. *Id.* at 1305-06. The alleged equivalent contained phosphorus compounds at a concentration of between 59% and 62%. *Id.* at 1305. We concluded that the "tangential relation" exception did not apply, reasoning that it was "clear from the prosecution history that the reason for adding the range limitation was to overcome a prior art fertilizer that was not concentrated," and "both the reason for the amendment and the asserted equivalent relate to the concentration of the fertilizer." *Id.* at 1306.

Here, we conclude, the Commission correctly concluded that Ajinomoto had rebutted the *Festo* presumption because the amendment was tangential to the equivalent in question. The 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." J.A. 5047. 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.

Indeed, 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.

Accordingly, 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. Under *Festo*'s express provision for a "tangential relation" exception to the presumption as to the scope of surrender by amendment during prosecution, this conclusion about the reason for the amendment at issue does not "ignore[] how the patentee deliberately elected to narrow the claims" (Dissent at 6); rather, it identifies what was not within the "scope disclaimed" *(id.* at 7), so that it may be proved to infringe by satisfying the other requirements of the doctrine of equivalents. We therefore reject CJ's contention that prosecution history estoppel precludes the Commission's finding of infringement under the doctrine of equivalents for the second later strain.

2

CJ's second challenge to the Commission's finding regarding the protein limitation and CJ's second later strain is that the non-*E. coli* YddG protein of CJ's second later strain could not properly be found to be equivalent to the claimed *E. coli* YddG protein. Ajinomoto presented its equivalence case within the function-way-result framework, under which a product or process that

does not literally satisfy a claim limitation may nevertheless infringe "if it performs substantially the same function in substantially the same way to obtain the same result." *Duncan Parking Techs., Inc. v. IPS Grp., Inc.*, 914 F.3d 1347, 1362 (Fed. Cir. 2019) (quoting *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950)). We conclude that substantial evidence supports the Commission's finding of equivalence under that test.

As to "function": Ajinomoto's expert, Dr. Gregory Stephanopoulos, testified that both *E. coli* and non-*E. coli* YddG proteins function as "export protein[s] that actively export[] aromatic L-amino acids and aromatic L-amino acid analogs" out of the bacterial cell. J.A. 545-46. A 2007 article by Doroshenko et al. similarly explains that both proteins are involved in exporting aromatic compounds. *See* J.A. 9451. And Dr. So Young Kim, a CJ employee, testified during a deposition that both proteins would be expected to have similar functions based on similarities in the organisms from which they are derived. *See* J.A. 10641 ("Q. Based on the similarity between E. coli and [the non-*E. coli* organism], you would suspect that the protein coded by the [non-*E. coli]* yddG gene would be useful for whatever it does in E. coli, right? A. I think that way too."). Thus, the Commission's finding that both proteins perform the same function is supported by substantial evidence.

As to "way": Dr. Stephanopoulos testified that the two proteins are 85% to 95% identical in structure. J.A. 546. This range was corroborated by a 2002 article by Santiviago et al., which indicates an 85% structural identity, *see* J.A. 9444, and the Doroshenko article, which notes a 95% identity in amino-acid sequence, J.A. 9451.

On the record here, substantial evidence supports a finding that the two proteins perform the membrane-transport function in substantially the same way. *See also Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 868 (Fed. Cir. 2017) (noting that the "function" and "way" inquiries often overlap or are synonymous).

As to "result": Dr. Stephanopoulos testified that, by exporting L-tryptophan out of the bacterial cell, both proteins increase the ability of bacteria to "produce and accumulate L-tryptophan." *See* J.A. 547. That statement is supported by CJ's fermentation data, which showed that strains containing the *E. coli yddG* gene but with a stronger promoter, and strains containing the non-*E. coli yddG* gene with a strong promoter, both showed greater production of L-tryptophan than did strains containing the *E. coli yddG* gene with the native promoter. *See* J.A. 7957; J.A. 10053. In other words, enhancing the expression of either the *E. coli* or the non-*E. coli yddG* gene had the effect of increasing production of L-tryptophan, which supports an inference that the proteins encoded by those genes both result in increased L-tryptophan production. The Commission's findings regarding result are supported by substantial evidence.

CJ argues that the two proteins do not perform the same function in the same way because the *E. coli* YddG protein exports aromatic L-amino acids such as L-tryptophan, whereas the non-*E. coli* YddG protein exports a different compound—namely, paraquat (also known as methyl viologen). But a 2012 article by Liu et al. explains that YddG proteins can export both types of compounds. *See* J.A. 9751 ("YddG is classified as aromatic

amino acid/paraquat exporter . . . ."). And Dr. Stephanopoulos, relying on the Santiviago article, testified that the non-*E. coli* YddG protein must be coupled to the OmpD protein, which is present in the non-*E. coli* organism but not *E. coli*, to export paraquat. J.A. 762 (citing J.A. 9439). The fact that the non-*E. coli* YddG protein may be involved in exporting compounds other than L-tryptophan in the non-*E. coli* organism does not undermine the Commission's well-supported finding that the non-*E. coli* YddG protein is involved in exporting L-tryptophan in the *E. coli* bacteria used by CJ.

B

CJ challenges the Commission's finding of infringement of *both* later strains on one additional ground. The Commission found that CJ's later strains met the resistance limitation. CJ argues that substantial evidence does not exist to support that finding.[9] We reject that argument.

Several pieces of evidence indicate that, as a general matter, enhancing the activity of the YddG protein increases bacteria's resistance to L-tryptophan. Table 1 of the '655 patent shows that *E. coli* bacteria with multiple copies of the *yddG* gene introduced through plasmids demonstrated better growth on a tryptophan substrate, and thus more resistance, than unmodified *E. coli* bacteria. *See* '655 patent, col. 9, lines 50-65 (bottom row, compare column "pUC19" (-) with column "pYDDG1" (+)).

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[9] CJ does not challenge the finding that CJ's first later strain meets the protein limitation of the claim 15 alternative of claim 20. Specifically, CJ's first later strain uses a non-*E. coli yddG* gene without codon randomization, which hybridizes with the complement of SEQ ID NO: 1 *(i.e.*, the nucleotide sequence of the *E. coli yddG* gene), and thus falls within the literal scope of claim 15.

Similarly, the Doroshenko article, mentioned above, describes an experiment in which *E. coli* bacteria with a stronger promoter preceding the *yddG* gene demonstrated enhanced resistance to L-tryptophan. *See* J.A. 9455 (row DV036, column DL-5-f-Trp).

CJ's fermentation data, mentioned above, also provides direct evidence that CJ's later strains have increased resistance to L-tryptophan. That data shows a greater volume of tryptophan with both of CJ's later strains than with unmodified *E. coli* bacteria. *See* J.A. 7957 (first later strain: middle table, row F4, column "Volume produced"); J.A. 10053 (second later strain: row "Product (g)" toward middle of table). Dr. Stephanopoulos indicated that a strain's ability to overproduce L-tryptophan necessarily meant that the strain had increased resistance to L-tryptophan. *See* J.A. 1448 ("[I]f that product feedback inhibits its own synthesis, clearly, this is not going to work."); *see also* J.A. 521 (stating that bacteria that "exhibit enhanced resistance to an aromatic L-amino acid or an aromatic L-amino acid analog" also "overproduce the corresponding aromatic L-amino acid analog").

CJ's objections to the sufficiency or even relevance of this evidence are unpersuasive. CJ points out that the bacteria used to generate the data in Table 1 of the '655 patent contained plasmids with more than the two copies of the *yddG* gene in CJ's later strains. *See* J.A. 1229. The Doroshenko article, however, indicates that enhancing the activity of even a single copy of the *yddG* gene can increase resistance to L-tryptophan. CJ responds that the strain studied in Doroshenko used a strong λP_L promoter, while CJ's later strains use relatively weaker non-*E. coli* native *yddG*, *rmf*, and *rhtB* promoters. *See* J.A. 9454. But Dr. Stephanopoulos testified that at least

the *rmf* promoter in both of CJ's later strains also is more potent than the native *E. coli yddG* promoter. J.A. 554. Thus, even if CJ is correct that its later strains do not contain tandem promoters, the Commission could reasonably infer that the promoters used in CJ's later strains enhance the activity of the *yddG* genes relative to unmodified *E. coli* bacteria and thereby increase those strains' resistance to L-tryptophan.

CJ also cites Ajinomoto's 2002 Progress Report as evidence that enhancing a single copy of the *yddG* gene is insufficient to enhance resistance to L-tryptophan. That report states that an experiment using "only one copy" of the *yddG* gene with a PL promoter "does not correctly model[]" an earlier experiment using a "moderate-copy-number" plasmid with the *yddG* gene, which had shown a "positive effect" of the *yddG* gene on tryptophan production. J.A. 10268. No more need be inferred from the report than that enhancing a single copy of the *yddG* gene increases resistance to L-tryptophan less than using a greater number of copies. The Commission did not need to infer that enhancing a single copy as in CJ's later strains does not enhance resistance at all.

Further, CJ asserts that the increased production of L-tryptophan, and thus the enhanced resistance to L-tryptophan, observed in its later strains could be attributable to the presence of other genetic mutations rather than to increased YddG protein activity alone. *See* J.A. 442. But the claims require only that the protein "has the activity to make the bacterium resistant" to L-tryptophan, not that the protein be the sole cause of the bacterium's enhanced resistance to L-tryptophan. *See* '655 patent, col. 22, lines 57-59. Considering the already-mentioned evidence that the YddG protein gener-

ally has the effect of increasing resistance to L-tryptophan, the Commission had substantial evidence from which to find that it was more likely than not that increased activity of the YddG protein at least partly contributed to the enhanced resistance of CJ's later strains.

C

CJ's final contention in its cross-appeal seeks reversal of the Commission's rejection of CJ's invalidity challenge to claim 20. CJ argues that substantial evidence does not support the Commission's finding that CJ did not prove lack of an adequate written description for the genus of "more potent promoter[s]" recited in claims 9 and 15 and, by incorporation, in claim 20. We reject CJ's argument.

"[A] sufficient description of a genus . . . requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010) (en banc). The Commission found both that the '655 patent discloses a representative number of species of more potent promoters and that there are structural features common to the genus of more potent promoters. Both of those findings are supported by substantial evidence, and they suffice to uphold the Commission's rejection of CJ's written-description challenge.

1

As to a representative number of species, we have recognized that the amount of disclosure necessary to satisfy the written-description requirement "will necessarily vary depending on the context," considering such

facts as "the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology," and "the predictability of the aspect at issue." *Ariad*, 598 F.3d at 1351 (quoting *Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005)). In some circumstances, we have added, "a patentee may rely on information that is 'well-known in the art' for purposes of meeting the written description requirement," because "the specification is viewed from the perspective of one of skill" in the relevant art. *Bos. Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1366 (Fed. Cir. 2011).

The '655 patent discloses four examples of "potent promoters": "P*L* promoter of lambda phage," the "lac promoter," the "trp promoter," and the "trc promoter." '655 patent, col. 6, lines 21-24. The patent also cites the 1986 article by Deuschle et al. as disclosing "examples of potent promoters" and "[m]ethods for [the] evaluation [of] the strength of promoter[s]." *Id.*, col. 6, lines 16-21. That article provides data about the relative strength of fourteen promoters and describes a general methodology for determining promoter strength in *E. coli* bacteria. J.A. 617477. This evidence supports the Commission's finding that "enhancing promoter activity was well-known" and that a skilled artisan "would have been able to identify more potent promoters by employing common tools for measuring RNA transcription." J.A. 46.

The '655 patent also makes clear that its invention was "identifying the yddG gene encoding a membrane protein" and discovering that the gene "conferred on a microorganism resistance to phenylalanine and several amino acid analogues" when the gene was amplified or its expression enhanced, *see* '655 patent, col. 2, lines 46-57, not the well-known techniques for performing the

amplification or expression enhancement, *see id.*, col. 5, line 57, through col. 6, line 33. We have explained that the representative-species inquiry is directed to whether the inventor "has truly invented the genus" as opposed to "a research plan, leaving it to others to explore the unknown contours of the claimed genus." *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1300 (Fed. Cir. 2014). Here, the genus of more potent promoters was already well explored in the relevant art by the time of the '655 patent's invention. In these circumstances, the Commission permissibly found in the specification, read in light of the background knowledge in the art, a representative number of species for the genus of more potent promoters.

2

As to a common structural feature, the Commission found that a skilled artisan could "identify more potent *yddG* promoters given the well-known link between consensus sequence and promoter strength," *i.e.*, that promoters having fewer departures from a "consensus sequence" in a promoter are generally stronger than promoters with more departures from such a sequence. J.A. 46.[10] Substantial evidence supports that finding. For instance, a 1983 article by Hawley and McClure describes a study demonstrating that most "mutations that decrease initiation frequency also decrease the homology of the promoter to the consensus sequence, while up-mutations increase the homology in" most instances. J.A.

[10] The consensus sequence is a specific nucleotide sequence that appears in the promoters associated with many different genes in the genome of a particular organism. In *E. coli*, the consensus sequence has two parts: TTGACA at the -35 region and TATAAT at the -10 region.

6237. Similarly, a 1986 article by Horwitz and Loeb explains that "mutations that increase transcription, 'up mutations,' usually increase homology with the consensus sequence and spacing," while "mutations that decrease transcription, 'down mutations,' usually decrease homology with the consensus sequence and spacing." J.A. 6251.

CJ disputes that similarity to the consensus sequence defines a common structural feature, citing several articles as indicating that a promoter closer to the consensus sequence will not always be stronger than one farther from that sequence. For instance, a 1998 article by Jensen and Hammer reports that a pattern observed in another organism—that "the relatively strong promoters were the perfect ones," *i.e.*, those closer to the consensus sequence—"did not hold true for *E. coli:* here the promoters which had either an error in the consensus sequence or a shorter spacer were relatively strong." J.A. 9149. Moreover, a 1985 article by Aoyama and Takanami states that similarity to the consensus sequence "is still not enough to predict the site and strength of promoter from a given sequence," J.A. 6215, and a 1999 book edited by Fernandez and Hoeffler notes that "the strongest promoters in *E. coli* do not necessarily adhere to the consensus sequence," J.A. 9113.

CJ's argument both assumes too strict a legal standard and reads too much into its cited references. Adequate written description does not require a perfect correspondence between the members of the genus and the asserted common structural feature; for a functionally defined genus like the one at issue here, we have spoken more modestly of a "*correlation* between structure and function." *Ariad*, 598 F.3d at 1350 (emphasis added). In

any event, CJ's evidence at most establishes that, starting with the consensus sequence, deviations from that sequence do not *always* decrease promoter strength, at least in *E. coli*. But the genus at issue here is "more potent promoter[s]" than the native promoter, not less potent promoters than the consensus sequence. And the Commission had substantial evidence from which to find that, starting from the native *E. coli yddG* promoter, deviations toward the consensus sequence generally increase promoter strength.

The cases cited by CJ in which we have held genus claims to lack an adequate written description are inapposite. In *Boston Scientific*, the specification contained "no examples of macrocyclic lactone analogs of rapamycin" (the claimed genus) and essentially "no guidance on how to properly determine whether a compound is a macrocyclic lactone analog of rapamycin." 647 F.3d at 1364. In *AbbVie*, there was "no evidence to show any described antibody to be structurally similar to, and thus representative of," an antibody accused of coming within the claim, nor was there "evidence to show whether one of skill in the art could make predictable changes to the described antibodies to arrive at other types of antibodies such as" the accused antibody. 759 F.3d at 1301. And in *Regents of the University of California v. Eli Lilly & Co.*, the specification described "a process for obtaining human insulin-encoding cDNA" (such cDNA required by the claim at issue) but not any "sequence information indicating which nucleotides constitute human cDNA" or "further information in the patent pertaining to that cDNA's relevant structural or physical characteristics." 119 F.3d 1559, 1567 (Fed. Cir. 1997). Here, by contrast, the '655 patent expressly provides four examples of

"more potent promoters," and the Commission supportably found that a skilled artisan could make relatively predictable changes to the native promoter to arrive at a more potent promoter.

IV

For the foregoing reasons, we affirm the Commission's decision.

No costs.

AFFIRMED

APPENDIX B

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

Nos. 2018-1590, 2018-1629

AJINOMOTO CO., INC., AJINOMOTO HEARTLAND INC.,
APPELLANTS

v.

INTERNATIONAL TRADE COMMISSION, APPELLEE

CJ CHEILJEDANG CORP., CJ AMERICA, INC.,
PT CHEIJEDANG INDONESIA, INTERVENORS

CJ CHEILJEDANG CORP., CJ AMERICA, INC.,
PT CHEIJEDANG INDONESIA, APPELLANTS

v.

INTERNATIONAL TRADE COMMISSION, APPELLEE,

AJINOMOTO CO., INC., AJINOMOTO HEARTLAND INC.,
INTERVENORS

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

Decided: August 6, 2019

JOHN D. LIVINGSTONE, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Atlanta, GA, argued for Ajinomoto Co., Inc., Ajinomoto Heartland Inc. Also represented by MARTIN DAVID WEINGARTEN; CHARLES E. LIPSEY, Reston, VA; MAREESA ARNITA FREDERICK, CORA RENAE HOLT, BARBARA RUDOLPH, Washington, DC.

HOUDA MORAD, Office of General Counsel, United States International Trade Commission, Washington, DC, argued for appellee. Also represented by SIDNEY A. ROSENZWEIG, DOMINIC L. BIANCHI, WAYNE W. HERRINGTON.

JAMES F. HALEY, JR., Haley Guiliano LLP, New York, NY, argued for CJ CheilJedang Corp., CJ America, Inc., PT CheilJedang Indonesia. Also represented by STEVEN PEPE, Ropes & Gray LLP, New York, NY; MATTHEW RIZZOLO, Washington, DC.

Before DYK, MOORE, and TARANTO, *Circuit Judges*.

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

DYK, *Circuit Judge*, concurring-in-part and dissenting-in-part.

I join the majority as to parts I, II, III (B) (as it relates to Strain A, corresponding to the "first later strain" in the majority) and (C). I respectfully dissent from the majority's conclusion that Ajinomoto successfully rebutted the presumption of prosecution history estoppel under the tangential exception as to respondent's recombinant bacterial Strain B, which corresponds to the "second later strain" referred to by the majority, *see* Majority Op. at 15.

On appeal, the only asserted claim is claim 20 of U.S. Patent No. 7,666,655 ('655 patent). It covers "[a] method for producing an [amino acid,] which comprises cultivating the bacterium according to any one of claims 9[, or 15]." '655 patent, col. 24, ll. 4-6. In relevant part, claim 9 covers a recombinant bacteria having a "protein consist[ing] of the amino acid sequence of SEQ ID NO: 2." *Id.* col. 22, ll. 56-57. This corresponds to the amino acid

sequence of *E. coli* YddG protein (a membrane-bound protein involved in the cellular export of aromatic amino acids). Strain B does not literally infringe claim 9 because it produces a protein with an amino acid sequence that differs from SEQ ID NO: 2. *See* J.A. 37. Instead, Ajinomoto asserts infringement under the doctrine of equivalents, arguing that Strain B's non-*E. coli* YddG protein is equivalent to the *E. coli* YddG protein (SEQ ID NO: 2) in claim 9.

The prosecution history shows that claim language was amended such that the accused equivalent is excluded.[1] Originally, the claim language covered variations of SEQ ID NO: 2, stating that it covered "deletion, substitution, insertion or addition of one or several amino acids" of SEQ ID NO: 2. J.A. 5609. During prosecution, the examiner rejected the claim as anticipated by prior art (Livshits) that disclosed a recombinant *E. coli* bacteria producing YfiK protein, encoded by the *yfiK* gene, which had an amino acid sequence different from the SEQ ID NO: 2 but still satisfied the claim limitations. J.A. 5378. Specifically, the examiner stated "Livshits et al. anticipate claims 1-4 because the *yfiK* gene product can be considered a protein" meeting the claim limitation above. *Id.* In response to this rejection, the patentee narrowed the claim language (which now appears in claim 15) to only cover protein variants differing from SEQ ID NO: 2 when they are "encoded by a nucleotide sequence that hybridizes with the nucleotide

[1] Everyone agrees that the relevant prosecution history for the analysis focuses on the language in claim 1, which was later utilized in claims 9 and 15 that were added later in prosecution.

sequence of SEQ ID NO: 1[, the *E. coli yddG* gene,] under stringent conditions comprising 60°C, 1 x SSC, 0.1% SDS." J.A. 5609; *see* '655 patent, col. 23, ll. 19-22.[2] The patentee stated that "[i]n view of this amendment, Livshits et al no longer anticipates the claimed invention." J.A. 5617.

The majority assumes that prosecution history estoppel presumptively applies in this case. Majority Op. at 18. But the majority concludes that Ajinomoto is still not precluded from arguing infringement under the doctrine of equivalents based on the tangential exception.

We have consistently described this exception as "very narrow." *Integrated Tech. Corp. v. Rudolph Techs., Inc.*, 734 F.3d 1352, 1358 (Fed. Cir. 2013) (quoting *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 480 F.3d 1335, 1342 (Fed. Cir. 2007)). Under this exception, the question is "whether the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1369 (Fed. Cir. 2003) (en banc). The inquiry "focuses on the patentee's objectively apparent reason for the narrowing amendment," which "should be discernible from the prosecution history record." *Id.* (emphasis added). In my view the "reason for the narrowing amendment" in this case is directly related to the equivalent.

Originally, the claim covered proteins with amino acid sequence variations from SEQ ID NO: 2, which would have included the non-*E. coli* YddG protein at issue here. The examiner rejected the original claim

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[2] Strain B does not literally infringe claim 15 because the non-*E. coli* YddG protein's encoding nucleotide sequence does not hybridize with SEQ ID NO: 1 under the claimed conditions.

based on anticipating prior art, and the patentee responded with a narrowing amendment. Instead of continuing to define the covered proteins in terms of amino acid sequence variations from SEQ ID NO: 2,[3] the patentee deliberately chose to redefine the claimed proteins in terms of the ability of their encoding nucleotide sequences to hybridize with SEQ ID NO: 1 under the claimed conditions. The amended claim language excluded the prior art protein (Livshits) because it was made based on a nucleotide sequence that did not meet the newly added hybridization requirement. The 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. Thus, I do not see how the reason for the narrowing amendment is tangential to the accused equivalent.

Ajinomoto argues that "[t]o the extent anything was given up during prosecution, it was the YfiK protein [disclosed in Livshits] . . . and, possibly, other non-YddG proteins." Ajinomoto Response & Reply Br. at 41 (emphasis omitted). Ajinomoto's argument that prosecution history estoppel would only apply to the specific prior art protein (or possibly other non-YddG proteins) is not only inconsistent with how the patentee amended the claims but also our caselaw. Specifically, "[Ajinomoto's] representations convey to the public that it was relying on [the claimed hybridization requirement] to overcome the prior art. The public is entitled to rely on those representations." *Integrated Tech.*, 734 F.3d at 1359. "The

[3] The patentee later added claim language that covered other, more limited, variations from the amino acid sequence of SEQ ID NO: 2, by "one to five amino acids," but that claim language is not at issue here. '655 Patent, col. 21, l. 42.

fact that the inventors may have thought after the fact that they could have relied on other distinctions in order to defend their claims[, e.g., by limiting the claim to only YddG-type proteins,] is irrelevant and speculative . . . ." *Schwarz Pharma, Inc. v. Paddock Labs., Inc.*, 504 F.3d 1371, 1377 (Fed. Cir. 2007). "It is not relevant to the determination of the scope of the surrender that the applicant did not need to amend the claims" in the way that it chose to do so "in order to overcome the prior art." *Lucent Techs., Inc. v. Gateway*, 525 F.3d 1200, 1218 (Fed. Cir. 2008) (citing *Norian Corp v. Stryker Corp.*, 432 F.3d 1356, 1361-62 (Fed. Cir. 2005)).

The majority adopts a slightly different version of Ajinomoto's untenable argument. The majority concludes that the "objectively evident rationale" for the narrowing amendment was "to limit the set of proteins within the claim's scope so that it no longer included the prior-art [protein], and, more generally, no longer allowed as wide a range of *amino acid* alterations." Majority Op. at 21 (emphasis in original). The majority reasons that because Strain A, which makes the same protein as Strain B but with a different nucleotide sequence, literally infringes claim 15, somehow Strain B should be found to infringe claim 9 under the doctrine of equivalents. It theorizes 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" (i.e., the accused equivalent). *Id.* at 21. In this way, the majority concludes that the reason for the narrowing amendment—limiting the range of proteins covered by the claim—is unrelated to the way in which the equivalent departs from the literal claim limitation—differences among the several DNA sequences that encode a given protein.

The problem with the majority's analysis is that it ignores how the patentee deliberately elected to narrow the claims. The anticipating prior art disclosed *E. coli* YfiK protein, encoded by the *yfiK* gene, and this prior art was avoided by narrowing the claim to only cover certain encoding nucleotide sequences. That rationale is directly related to the accused equivalent, which does not infringe because it does not use a covered encoding nucleotide sequence. In other words, the rationale for the narrowing amendment (avoiding a prior art protein based on its encoding nucleotide sequence that does not meet the newly claimed hybridization requirement) directly relates to the accused equivalent (a protein made by an encoding nucleotide sequence that does not meet the newly claimed hybridization requirement).

The cases cited by the majority also do not support its approach. In *Insituform Technologies, Inc. v. CAT Contracting, Inc.*, 385 F.3d 1360 (Fed. Cir. 2004), and *Regents of the University of California v. Dakocytomation California*, 517 F.3d 1364 (Fed. Cir. 2008), multiple limitations were added with a narrowing amendment but only one of those limitations related to what was taught in the prior art cited by the examiner. We held that the equivalent to the other limitation was permitted under the tangential exception. In *Insituform*, the rationale for the amendment was to limit the location of the vacuum source, not the number of vacuum sources (the accused equivalent). 385 F.3d at 1370. In *Regents*, the rationale for the amendment was to limit the type of blocking method, not the particular types of nucleic acids that could be used in that method (the accused equivalent). 517 F.3d at 1378. These cases cannot be read as allowing the patentee to recapture scope disclaimed in order to

distinguish the prior art, which is exactly what the patentee is attempting to do here. The anticipating prior art cited by the examiner specifically taught a protein made by a particular gene, and the patentee narrowed the claim to avoid this prior art by limiting the claim to only cover proteins made by particular nucleotide sequences (which neither the prior art nor Strain B have).

Our decision in *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282 (Fed. Cir. 2010), is also inapposite. There, the claims were "narrow[ed from] the claimed universe of [nucleotide sequences] down to those of [porcine circovirus type II ('PCV-2')]," but there remained the tangential "question of which DNA sequences are and are not properly characterized as PCV-2." *Id.* at 1292 (emphasis added). In contrast, there is no question here of which nucleotide sequences are "properly characterized" as being included under the claim language—only those that hybridize with SEQ ID NO: 1 "under stringent conditions comprising 60°C, 1 x SSC, 0.1% SDS" are covered. J.A. 5609. There is no dispute that CJ's bacterial strain does not satisfy this specific and unambiguous limitation.

In my view the tangential exception cannot apply. The equivalent is directly related to the reason for the amendment—to exclude those proteins made by an encoding nucleotide sequence that does not hybridize with SEQ ID NO: 1 under the specified conditions. I respectfully dissent from the majority's contrary conclusion.

APPENDIX C

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of CERTAIN L-TRYPTOPHAN, L-TRYPTOPHAN PRODUCTS, AND THEIR METHODS OF PRODUCTION,

Inv. No. 337-TA-1005

COMMISSION OPINION

On August 11, 2017, the presiding Administrative Law Judge ("ALJ") in the above-identified investigation issued his final initial determination ("FID") finding no violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 ("section 337"), by Respondents CJ CheilJedang Corp., CJ America, Inc. ("CJ America"), and PT CheilJedang Indonesia (collectively, "CJ" or "Respondents"). Having considered the FID, the parties' petitions, responses, and written submissions, and the record in this investigation, the Commission has determined to reverse the FID's finding of no section 337 violation with respect to both U.S. Patent No. 7,666,655 ("the '655 patent") and U.S. Patent No. 6,180,373 ("the '373 patent"). All findings in the FID that are consistent with this opinion are affirmed.

I. BACKGROUND

A. Procedural Background

By publication in the Federal Register on June 14, 2016, the Commission instituted Investigation No. 337-TA-1005, based on a complaint filed by Complainants Ajinomoto Co., Inc. of Tokyo, Japan and Ajinomoto

Heartland Inc. of Chicago, Illinois (collectively, "Ajinomoto" or "Complainants"). *See* 81 *Fed. Reg.* 38735-36 (June 14, 2016). The complaint, as supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain L-tryptophan, L-tryptophan products, and their methods of production, by reason of infringement of claims 4, 7, 8, and 20 of the '655 patent and claim 10 of the '373 patent (collectively, "the asserted patents"). *Id.* The notice of investigation identified CJ CheilJedang Corp. of Seoul, Republic of Korea; CJ America, Inc. of Downers Grove, Illinois; and PT CheilJedang Indonesia of Jakarta, Indonesia as respondents in this investigation. *Id.* The Office of Unfair Import Investigations is not a party to the investigation. *Id.*

On April 17, 2017, the ALJ issued an initial determination ("ID") granting Complainants' unopposed motion for summary determination that they satisfy the economic prong of the domestic industry requirement under 19 U.S.C. § 1337(a)(3)(A) (significant investment in plant and equipment) and (B) (significant employment of labor or capital) for both asserted patents. *See* Order No. 18, *unreviewed*, Comm'n Notice (May 17, 2017).

On May 16, 2017, the ALJ issued an ID granting Complainants' unopposed motion to terminate the investigation with respect to certain claims of the '655 patent. *See* Order No. 30, *unreviewed*, Comm'n Notice (June 2, 2017). Claim 20 of the '655 patent and claim 10 of the '373 patent (hereinafter, "the asserted claims") remain at issue in the investigation.

On May 15-19, 2017, the ALJ conducted an evidentiary hearing and on August 11, 2017, the ALJ issued his FID finding no violation of section 337. Specifically, the FID finds that: (1) Respondents' accused products do not infringe the asserted claims of the '373 or the '655 patents either literally or under the doctrine of equivalents; (2) claim 10 of the '373 patent is invalid for indefiniteness and lack of written description; (3) claim 20 of the '655 patent is invalid for lack of written description; and (4) complainants do not satisfy the technical prong of the domestic industry requirement with respect to the '655 and the '373 patents. In addition, the ALJ issued a Recommended Determination ("RD") recommending, should the Commission find a violation of section 337, that the Commission issue: (1) an LEO against Respondents' accused products; and (2) a CDO against Respondent CJ America. The RD further recommends setting a zero percent bond during the Presidential review period. On August 14, 2017, the Commission issued a Notice requesting written submissions on the public interest. *See* 82 *Fed. Reg.* 39456-57 (Aug. 18, 2017). On September 20, 2017, Respondents filed a written submission in response to the Commission's August 14, 2017 Notice ("CJ's PI Submission"). No other submissions were received.

On August 28, 2017, Complainants filed a petition for review urging reversal of the FID's findings on non-infringement and invalidity ("Ajinomoto's Pet."), and Respondents filed a contingent petition for review of the FID's adverse infringement and validity findings ("CJ's Contingent Pet."). On September 5, 2017, the parties filed responses to each other's petition ("Ajinomoto's Pet. Resp." and "CJ's Pet. Resp.").

On October 12, 2017, the Commission issued a Notice determining to review the FID in its entirety. *See* 82 *Fed. Reg.* 48528-29 (Oct. 18, 2017). The October 12, 2017 Notice requested briefing in response to certain questions relating to the FID's finding of no section 337 violation. *See id.* In addition, the October 12, 2017 Notice solicited written submissions on issues of remedy, the public interest, and bonding. *See id.* On October 27, 2017, the parties filed written submissions in response to the October 12, 2017 Notice ("Ajinomoto's Suppl. Br." and "CJ's , Suppl. Br."), and on November 3, 2017, the parties filed responses to each other's submissions ("Ajinomoto's Suppl. Resp." and "CJ's Suppl. Resp.").

B. The Asserted Patents

1. The '373 Patent

The '373 patent, entitled "Microorganisms for the Production of Tryptophan and Process for the Preparation thereof," issued on January 30, 2001. The '373 patent generally relates to "[a] tryptophan producing strain of microorganism [that] is selected from *E. coli* and Corynebacteria and [that] is tryptophan feedback resistant and serine feedback resistant." *See* JX-1, '373 patent at Abstract. The '373 patent explains that "[t]he combination according to the invention of at least one feedback-resistant serA allele with a micro-organism with deregulated tryptophan metabolism results in an increase in the tryptophan yield . . . compared with the yield achievable with the same microorganism without the feedback-resistant serA allele under culturing conditions which are otherwise the same." *See* JX-1, '373 patent at 2:15-21. For example, "tryptophan yields were around 12.5 g/l [with *E. coli* strain SV164 (with trypto-

phan feedback-resistant trpE8 allele) modified with serine feedback-resistant serA5 allele)],[1] compared with 3.5 g/l using the same strain without serA5." *See id.* at 11:60-12:36 (Example 3); *see also id.* at 12:37-13:10 (Example 4) ("Fermentation reveals that the [tryptophan-producing *Corynebacterium glutamicum*] strain which harbours the serA5 allele on a plasmid achieves the highest tryptophan yields.").

The asserted claim of the '373 patent (claim 10) recites:

> 10. In a method for producing tryptophan comprising
>
> culturing a tryptophan producing strain of microorganism in a culture medium; and recovering the produced tryptophan from the culture medium; the improvement which comprises
>
> utilizing a tryptophan producing strain of microorganism selected from the group consisting of *E. coli* and Corynebacteria which is tryptophan feedback resistant and serine feedback resistant and wherein said serine feedback resistance is by a mutation in a serA allele, where the mutated serA allele codes for a protein which has a K_i value for serine between 0.1 mM and 50 mM to produce said tryptophan; and

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[1] *See* JX-1, '373 patent at 9:57-59 ("The resulting strains were called PD103 (trpEO), KB862 (trpE5), SV164 (trpE8) and SV163 (trpE6)."), 12:29-30 ("This homogeneous serA5 λ lysate was used to infect the tryptophan producer strain SV164.").

> wherein said tryptophan feedback resistance is by a trpE allele which codes for a protein which has a K_i value for tryptophan between 0.1 mM and 20 mM.

2. The '655 Patent

The '655 patent, entitled "*Escherichia* Bacteria Transformed with the *yddG* Gene to Enhance L-Amino Acid Producing Activity," issued on February 23, 2010. The '655 patent generally relates to: "a method for producing L-amino acid, such as L-phenylalanine and L-tryptophan . . . using bacterium belonging to the genus *Escherichia* wherein the L-amino acid productivity of said bacterium is enhanced by enhancing an activity of protein encoded by the *yddG* gene from *Escherichia coli*, wherein said protein has an activity to make said bacterium resistant to L-phenylalanine, a phenylalanine analogue, or a tryptophan analogue." *See* JX-3, '655 patent at Abstract.

The '655 patent explains that "'[r]esistance to L-phenylalanine and/or an amino acid analog' means [the] ability for [the] bacterium to grow on a minimal medium containing L-phenylalanine or the amino acid analog in [a] concentration under which [the] unmodified or the wild type, or the parental strain of the bacterium cannot grow, or [the] ability for [the] bacterium to grow faster on a medium containing L-phenylalanine or the amino acid analog than [the] unmodified or the wild type, or the parental strain of the bacterium." *See* JX-3, '655 patent at 4:49-56. For example, the '655 patent discloses that *yddG* gene amplification enhanced *E. coli's* resistance to the presence of amino acid and amino acid analogs and improved phenylalanine productivity. *See id.* at 9:31 -

11:3 (Examples 2-3). Similarly, enhanced *yddG* gene expression improved tryptophan productivity of *E. coli* strain SV164. *See id.* at 12:47-14:28 (Example 5).

The asserted claim of the '655 patent (claim 20) 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.[2]

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[2] Claims 9 and 15 are independent and claims 10-14 and 16-20 depend thereon, respectively. Independent claims 9 and 15 recite:

> **9.** A recombinant *Escherichia coli* bacterium, which has the ability to accumulate aromatic L-amino acid in a medium, wherein the aromatic L-amino acid production by said bacterium is enhanced by enhancing activity of a protein in a cell of said bacterium beyond the levels observed in a wild-type of said bacterium, and in which said protein consists of the amino acid sequence of SEQ ID NO: 2 and said protein has the activity to make the bacterium resistant to L-phenylalanine, fluoro-phenylalanine or 5-fluoro-DL-tryptophan, wherein the activity of the protein is enhanced by transformation of the bacterium with a DNA encoding the protein to express the protein in the bacterium, by replacing the native promoter which precedes the DNA on the chromosome of the bacterium with a more potent promoter, or by introduction of multiple copies of the DNA encoding said protein into the chromosome of said bacterium to express the protein in said bacterium.
>
> **15.** A recombinant *Escherichia coli* bacterium, which has the ability to accumulate aromatic L-amino acid in a medium, wherein the aromatic L-

C. The Domestic Industry Products

Ajinomoto defines its domestic industry products as [redacted] As explained in the FID, tryptophan is an amino acid that is formulated as a dietary supplement for livestock feed or human consumption. *Id.* at 5, 116.

D. The Accused Products

Ajinomoto defines the accused products as "certain bulk L-tryptophan or L-tryptophan products and the

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amino acid production by said bacterium is enhanced by enhancing activity of a protein in a cell of said bacterium beyond the levels observed in a wild-type of said bacterium, and in which 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., lxSSC, 0.1% SDS and said protein has the activity to make the bacterium resistant to L-phenylalanine, fluorophenylalanine or 5-fluoro-DL-tryptophan, wherein the activity of the protein is enhanced by transformation of the bacterium with a DNA encoding the protein to express the protein in the bacterium, by replacing the native promoter which precedes the DNA on the chromosome of the bacterium with a more potent promoter, or by introduction of multiple copies of the DNA encoding said protein into the chromosome of said bacterium to express the protein in said bacterium.

use of particular bacterial strains to produce certain bulk L-tryptophan or L-tryptophan products." *See* FID at 8. CJ categorizes the accused products based on whether they were made with CJ's "earlier" or "later" production strains of bacteria. *Id.* CJ identifies the "earlier production strains" as [redacted], -3368, [redacted] ("Earlier Strains"), and the "later production strains" as [redacted] ("Later Strains"). *Id.* at 7-8.

II. LEGAL STANDARDS

A. Standard on Review

Commission Rule 210.45(c) provides that "[o]n review, the Commission may affirm, reverse, modify, set aside or remand for further proceedings, in whole or in part, the initial determination of the administrative law judge" and that "[t]he Commission also may make any findings or conclusions that in its judgment are proper based on the record in the proceeding." *See* 19 C.F.R. § 210.45(c). In addition, as explained in *Certain Polyethylene Terephthalate Yarn and Products Containing Same*, "[o]nce the Commission determines to review an initial determination, the Commission reviews the determination under a *de novo* standard." Inv. No. 337-TA-457, Comm'n Op., 2002 WL 1349938, *5 (June 18, 2002) (citations omitted). This is "consistent with the Administrative Procedure Act which provides that once an initial agency decision is taken up for review, 'the agency has all the powers which it would have in making the initial decision except as it may limit the issues on notice or by rule." *Id.* (citing 5 U.S.C. § 557(b).

B. Infringement

"An infringement analysis entails two steps. The first step is determining the meaning and scope of the

patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996) (citations omitted). A complainant must prove either literal infringement or infringement under the doctrine of equivalents. And infringement must be proven by a preponderance of the evidence. *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988). The preponderance of the evidence standard "requires proving that infringement was more likely than not to have occurred." *See Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F.3d 1326, 1341 n.15 (Fed. Cir. 2005).

Literal infringement requires the patentee to prove that the accused device contains each and every limitation of the asserted claim(s). *Frank's Casing Crew & Rental Tools, Inc. v. Weatherford Int'l, Inc.*, 389 F.3d 1370, 1378 (Fed. Cir. 2004). If any claim limitation is absent, there is no literal infringement of that claim as a matter of law. *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000). Where literal infringement is not found, infringement can still be found under the doctrine of equivalents. According to the Federal Circuit:

> Infringement under the doctrine of equivalents may be found when the accused device contains an "insubstantial" change from the claimed invention. Whether equivalency exists may be determined based on the "insubstantial differences" test or based on the "triple identity" test, namely, whether the element of the accused device "performs

> substantially the same function in substantially the same way to obtain the same result." The essential inquiry is whether "the accused product or process contain elements identical or equivalent to each claimed element of the patented invention[.]"

TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc., 529 F.3d 1364, 1376-77 (Fed. Cir. 2008) (citations omitted). "The doctrine of equivalents, however, is not a tool for expanding the protection of a patent after examination has been completed." *Southwall Technologies, Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1579 (Fed. Cir. 1995) (citation omitted). Rather, "prosecution history estoppel limits the range of equivalents available to a patentee by preventing recapture of subject matter surrendered during prosecution of the patent." *Id.* (citation omitted). In particular, "[a] patentee's decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim." *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 740 (2002) (citation omitted). The patentee, however, can rebut the presumption that estoppel bars a claim of equivalence where "[t]he equivalent may have been unforeseeable at the time of the application; the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question; or there may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question." *Id.* at 740-41.

C. Domestic Industry - Technical Prong

The technical prong of the domestic industry requirement is satisfied when the complainant in a patent-based section 337 investigation establishes that it is practicing or exploiting the patents at issue. *See* 19 U.S.C. §1337 (a)(2) and (3); *Certain Microsphere Adhesives, Process for Making Same and Prods. Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, Comm'n Op. at 8 (Jan. 16, 1996).

The test for the technical prong of the domestic industry requirement is the same as that for infringement. *Certain Doxorubicin and Preparations Containing Same*, Inv. No. 337-TA-300, Initial Determination at 109, (May 21, 1990), *aff'd*, Views of the Commission at 22 (October 31, 1990) ("*Doxorubicin*"); *see also Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1375 (Fed. Cir. 2003). "First, the claims of the patent are construed. Second, the complainant's article or process is examined to determine whether it falls within the scope of the claims." *Doxorubicin*, Initial Determination at 109. The patentee must establish by a preponderance of the evidence that the domestic product practices one or more claims of the patent. And the technical prong of the domestic industry can be satisfied either literally or under the doctrine of equivalents. *Certain Dynamic Sequential Gradient Devices and Component Parts Thereof*, Inv. No. 337-TA-335, Initial Determination at 44, Pub. No. 2575 (May 11, 1992).

D. Invalidity

1. Generally

It is Respondents' burden to prove invalidity, and the burden of proof never shifts to the patentee to prove validity. *Scanner Techs. Corp. v. ICOS Vision Sys.*

Corp. N.V., 528 F.3d 1380 (Fed. Cir. 2008). "Under the patent statutes, a patent enjoys a presumption of validity, *see* 35 U.S.C. § 282, which can be overcome only through facts supported by clear and convincing evidence[.]" *SRAM Corp. v. AD-II Eng'g, Inc.*, 465 F.3d 1351, 1357 (Fed. Cir. 2006).

2. Indefiniteness

Statutory definiteness requires that the patent "specification [] conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." *See* 35 U.S.C. § 112, ¶ 2.[3] "[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014).

3. Written Description

"A determination that a patent is invalid for failure to meet the written description requirement of 35 U.S.C. § 112, ¶ 1 is a question of fact." *Ariad Pharm., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010). The test for the written description requirement under 35 U.S.C. § 112, ¶1, is "whether the disclosure conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1285 (Fed. Cir. 2012) (citation omitted). "This test

[3] The effective dates of the asserted patents pre-date the America Invents Act ("AIA") enacted by Congress on September 16, 2011. Thus, the pre-AIA version of the cited statute applies to the asserted patents.

requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Id.* (citation omitted). "Given this perspective, in some instances, a patentee can rely on information that is 'well-known in the art' to satisfy written description." *Id.* (citing *Boston Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1366 (Fed. Cir. 2011)). However, "[t]he knowledge of ordinary artisans may be used to inform what is actually in the specification, . . . , but not to teach limitations that are not in the specification, even if those limitations would be rendered obvious by the disclosure in the specification." *Rivera v. Int'l Trade Comm'n*, 857 F.3d 1315, 1322 (Fed. Cir. 2017).

III. ANALYSIS

A. The '373 Patent

1. Ki Value Assays

As explained below, the Commission finds that the reverse McKitrick[4] assay and the Bauerle[5] assay are acceptable methods of measurement for the terms "K_i value for serine" and "K_i value for tryptophan," respectively.[6] This is not to say that the McKitrick and Bauerle assays *must* be used or are the only means of measure-

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[4] McKitrick, *Regulation of Phosphoglycerate Dehydrogenase Levels and Effect on Serine Synthesis in Escherichia coli K-12*, Journal of Bacteriology, Jan. 1980, pp. 235-245, Vol. 141, No. 1 (JX-5).

[5] Bauerle et al., *Anthranilate Synthase-Anthranilate Phosphoribosyltransferase Complex and Subunits of Salmonella typhimurium*, 142 Methods in Enzymology 366 (1987) (JX-37).

[6] The FID construes the term "K_i value" as "the concentration of an inhibiting substance for an enzyme which reduces the activity of the enzyme to 50%." *See* FID at 21.

ment; rather, Complainants are only required to establish by a preponderance of the evidence that the asserted claim would be infringed under the conditions of McKitrick and Bauerle. *See MeadWestVaco Corp. v. Rexam Beauty and Closures, Inc.*, 731 F.3d 1258, 1268-69 (Fed. Cir. 2013) (affirming the district court's denial of motion to exclude expert's testimony where "[the expert] opined that using his testing parameters, which differed slightly from the claim construction, he was able to conclude that the [accused] tubes infringed the [asserted] patent when applying the court's construction"); *see also Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 449 F.3d 1209, 1219 (Fed. Cir. 2006) ("A patentee may prove direct infringement or inducement of infringement by either direct or circumstantial evidence.") (citation omitted).

(i) K_i value for serine

Complainants contend that "one of skill in the art following the teaching of the '373 patent would use the reverse assay described in McKitrick to determine serine sensitivity." *See* Ajinomoto's Suppl. Br. at 2. Complainants recognize that "[t]he McKitrick reference does not explicitly disclose an assay for measuring serine sensitivity" but "disclose[s] forward and reverse assays for measuring phosphoglycerate dehydrogenase ('PGD') activity, and [that] those of skill were readily aware that to measure serine sensitivity you first needed to measure PGD activity." *Id.* Indeed, the '373 patent explains that "[t]he PGD activity was determined by detection of the forward or reverse reaction of the enzyme by the method of McKitrick" and that "[t]he said assay (*i.e.*, the forward or reverse McKitrick assay)] is suitable for determining the serine sensitivity of any phosphoglycerate dehydrogenase." *See* JX-1, '373 patent at 6:29-35. The

'373 patent also provides that "[i]t is likewise possible to employ any other method for measuring the PGD activity," *i.e.*, other than "the method of McKitrick." *Id.* at 6:35-37. The '373 patent explains that "enzyme activity is measured in this case without serine and with various concentrations of serene[sic]" and that the K_i value is "the serine concentration []which inhibit the activity of the enzyme by 50%."[7] *Id.* at 6:32-40. Thus, the '373 patent provides that the forward and reverse McKitrick assays and any other method may be used to determine PGD activity (and therefore serine sensitivity). This analysis does not conflate PGD activity and serine sensitivity. Rather, as Complainants admit, PGD activity is closely related to serine sensitivity, and PGD activity must be measured at various serine concentrations to determine serine sensitivity.

Nevertheless, while the record evidence includes the assay conditions for the reverse McKitrick assay (Tris buffer, pH 8.5, room temperature, hydroxypyruvic acid phosphate substrate, *see, e.g.*, Ajinomoto's Suppl. Br. at 16; JX-5 (McKitrick) at 237; JX-1, '373 patent at 6:29-37), the parties' briefs are conspicuously silent about the conditions of the forward McKitrick assay. In other words, no party presents any evidence that the forward and reverse McKitrick assays use different conditions and/or yield different K_i values. In fact, Complainants persuasively establish that the "the coupled [forward] assay . . . gives approximately the same en-

[7] As noted by Complainants, "the word 'enzyme' is referring to PGD, and the 'activity of the enzyme' means PGD activity." *See* Ajinomoto's Suppl. Br. at 2.

zyme activity as the spectrophotometric [reverse] assay." *See* Ajinomoto's Suppl. Resp. at 6 (citing JX-5 (McKitrick) at 244) (alteration in original).[8] The intrinsic evidence also provides no assay conditions for "any other method for measuring the PGD activity," *see* JX-1, '373 patent at 6:35-37. Furthermore, as discussed further *infra* section III.A.4(i), while the '373 patent specification provides that other methods for measuring PGD activity may be used, the record also shows that a POSITA[9] is aware that certain parameters (*e.g.*, pH) can affect the assay results, and therefore, the POSITA can analyze the results accordingly (as Ajinomoto's expert did in this case, *see* Ajinomoto's Pet. at 71-72). *See*, *e.g.*, RX-221C, Grant[10] WS[11] at Q/A 150-172; *see also In re GPAC Inc.*, 57 F.3d 1573,1579 (Fed. Cir. 1995) ("The person of ordinary skill in the art is a hypothetical person who is presumed to know the relevant prior art.") (citation omitted).

Accordingly, the Commission finds that the assay conditions disclosed in the context of the reverse McKitrick assay are acceptable for determining infringement in connection with the term "K_i value for serine." As discussed further *infra* section III.A.4(i), the Commission also finds that Respondents have failed to prove by clear

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[8] Respondents argue that "there is no dispute that the two McKitrick assays give different results and K_i values for the PGD of a given allele," *see* CJ's Suppl. Br. at 5, but Respondents provide no citation to evidence of record in support of their argument.

[9] "POSITA" means a "person of ordinary skill in the art."

[10] Dr. Gregory A. Grant is one of Respondents' experts in this investigation.

[11] "WS" refers to "Witness Statement."

and convincing evidence that the term "K_i value for serine" is indefinite.

(ii) K_i value for tryptophan

Complainants also contend that the evidence of record demonstrates "an express intent on the part of the patentee to define K_i such that it must be measured by the methods of McKitrick and Bauerle for serine and tryptophan, respectively." *See* Ajinomoto's Pet. at 82 (citing FID at 50). Complainants' contention is contradicted by the '373 patent specification which provides that tryptophan sensitivity may be determined by any method and that the Bauerle assay is an exemplary (not required) method. *See* JX-1, '373 patent at 3:43-49 (emphasis added):

> The tryptophan sensitivity of the anthranilate synthase can be determined by *any method* which permits the activity of this enzyme to be determined in the presence of tryptophan. *For example,* chorismate can be reacted in a suitable buffer system with glutamine, which is its partner in the reaction, under enzyme catalysis (Bauerle R. et al., 1987, Methods in Enzymology Vol. 142:366-386).

Nevertheless, while the record evidence includes the assay conditions for the Bauerle assay (potassium phosphate buffer, pH 7.0, room temperature, 0.25 mM chorismic acid substrate, *see, e.g.*, Ajinomoto's Suppl. Br. at 20; JX-37 (Bauerle) at 369; JX-1, '373 patent at 3:46-49), the intrinsic evidence provides no assay conditions for any other "method which permits the activity of this enzyme to be determined in the presence of tryptophan," *see* JX-1, '373 patent at 3:43-46.

Accordingly, the Commission finds that the assay conditions disclosed in the context of the Bauerle assay are acceptable for determining infringement in connection with the term "K_i value for tryptophan." As discussed further *infra* section III.A.4(i), the Commission also finds that Respondents failed to prove by clear and convincing evidence that the term "K_i valué for tryptophan" is indefinite.

2. Infringement

The parties' dispute with respect to infringement centers around the following portion of claim 10 of the '373 patent (emphasis added):

> where the mutated ***serA allele*** codes for a protein which has a K_i value for serine between 0.1 mM and 50 mM to produce said tryptophan; and wherein said tryptophan feedback resistance is by a ***trpE allele*** which codes for a protein which has a K_i value for tryptophan between 0.1 mM and 20 mM.

The FID finds that Ajinomoto has not met its burden to show that proteins encoded by [redacted][12] have a K_i value for serine between 0.1 mM and 50 mM when measured according to the reverse McKitrick assay. *See* FID at 40-44. The FID does not address whether CJ's tryptophan production strains satisfy the K_i value limitation relating to the *trpE* allele. *See id.* at 44. We address this limitation below.

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[12] [redacted] *See, e.g.*, FID at 38, 42.

(i) *SerA* Allele Limitation

(a) [redacted]

The Commission finds that Dr. Stephanopoulos[13] credibly established that [redacted] codes for a protein with a K_i value for serine that is within the claimed range of 0.1 mM to 50 mM. *See* Ajinomoto's Pet. at 69-70 (citing CX-1529C, Stephanopoulos WS at Q/As 201-20, 272-300). Relying on scientific publications by CJ's own expert, Dr. Grant, Dr. Stephanopoulos also testifies that [redacted] *See* CX-1529C, Stephanopoulos WS at Q/As 289-90 (citing Grant 2000 (CX-765)[14] and Grant 2001 (CX-464)[15]). While the Grant 2000 and Grant 2001 publications used a pH of 7.5 instead of McKitrick's pH of 8.5, Complainants persuasively established that "one of skill in the art would not have expected a materially different K_i value for serine of [redacted]." *See* Ajinomoto's Pet. at 71-72. Indeed, Complainants' expert, Dr. Stephanopoulos, credibly testified that at a pH 8.5, the K_i value would be higher and "[m]ore into the

[13] Dr. Gregory Stephanopoulos is Complainants' expert in this investigation.

[14] Grant et al., *Role of an Interdomain Gly-Gly Sequence at the Regulatory-Substrate Domain Interface in the Regulation of Escherichia coli. D-3-Phosphoglycerate Dehydrogenase*, Biochemistry 2000, Vol. 39, 7316-19 (CX-765).

[15] Grant et al., *Amino Acid Residue Mutations Uncouple Cooperative Effects in Escherichia coli D-3-Phosphoglycerate Dehydrogenase*, 276 J. Biological Chemistry 17844-50 (2001) (CX-464).

range of the claims." *See, e.g.*, Hearing Tr.[16] at 482:3-8 (Stephanopoulos). The FID and CJ do not dispute the K_i value would be higher at McKitrick's pH of 8.5, but the FID surmises that it could "elevate the K_i beyond the upper limit of the K_i range for serine in claim 10," *i.e.*, beyond the 50 mM value. *See* FID at 41. However, the FID's suggestion is inconsistent with the evidence of record that [redacted] is highly unlikely, particularly when the record does not show a significant increase of the K_i value from a pH of 7.5 to a pH of 8.5. *See*, e.g., Ajinomoto's Pet. at 73 (Table 1) (showing similar K_i values for serine at pH 8.5 (McKitrick) and at pH 7.5 (RX-101[17] and RX-135C[18])); *see also* RX-221C, Grant WS at Q/A 166 (reporting a "20%" increase of the IC50 value[19] from a pH of 7.5 to a pH of 8.5).

The FID also errs in finding that "the record is [] silent on how multiple changes to the conditions of the

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[16] "Hearing Tr." refers to "Hearing Transcript," as corrected on July 7, 2017

[17] Grant et al., *Specific Interactions at the Regulatory Domain-Substrate Binding Domain Interface Influence the Cooperativity of Inhibition and Effector Binding in Escherichia coli D-3-Phosphoglycerate Dehydrogenase*, Journal of Biological Chemistry, Vol. 276, No. 2, pp. 1078-83,2001 (RX-101).

[18] [redacted] *See* CJ's Pet. Resp. at 55.

[19] Dr. Stephanopoulos testified (and Respondents do not dispute) that Dr. Grant defines "IC_{50}" the same way as "K_i" is used in the '373 patent. *See* CX-1529C, Stephanopoulos WS at Q/A 281 (citing RX-101).

reverse McKitrick assay would interact to affect measured K_i values." *See* FID at 41. In fact, the evidence shows that variations of the conditions (including temperature, substrate, and enzyme or buffer concentration) are unlikely to materially affect the K_i value. *See* Ajinomoto's Pet. at 72 (citing Hearing Tr. at 472:24-473:2 (Stephanopoulos)). First, the Grant articles used the same temperature (room temperature) and buffer (Tris) as the reverse McKitrick assay.[20] *See id.* at 72-73 (citing JX-5.3 (McKitrick); CX-765.1 (Grant 2000); CX-464.1 (Grant 2001)). Second, with respect to the substrate and buffer concentration, Complainants persuasively establish that "three different exhibits of record studying the [redacted] indicate that using ana-ketoglutarate substrate rather than hydroxyl pyruvic acid phosphate and different concentration of Tris buffer does not materially change the resulting K_i value for serine" . . . and [redacted] *Id.* at 72-73 (citing '373 patent, JX-1 at Table 1; RX-101; RX-135C). Third, with respect to enzyme concentration, Respondents' expert argues that "different enzyme concentration under otherwise identical conditions would yield different K, values for serine," but as noted by Complainants, Respondents provide no evidence that any variation of enzyme concentration would push the K_i value outside the claimed

[20] CJ's arguments with respect to the effects of temperature, substrate, and enzyme or buffer concentration, were raised in connection with CJ's indefiniteness claim and under CJ's theory that "any other method for measuring the PGD activity" is possible. *See* CJ's Pet. Resp. at 40. However, while such arguments have merit in the context of indefiniteness, they are irrelevant in the context of infringement where the assay used is the reverse McKitrick assay.

range and "no evidence... suggest[ing] any effect of enzyme concentration on the *relevant* K_i assays." *Id.* at 72 (citing RX-113.7[21]) (emphasis added); RX-221C, Grant WS at Q/A 158.

Finally, we also agree with Complainants that the FID's (and CJ's) reliance on Grant 2005 (RX-133)[22] is misplaced. The Grant 2005 publication which uses a lower pH and a different buffer (phosphate buffer) does not establish that the K_i value would be outside of the claimed range under the reverse McKitrick assay conditions. Rather, the record evidence (including the Grant 2000 and 2001 publications and the testimony of Dr. Stephanopoulos) shows it is more likely than not that at McKitrick's higher pH and with McKitrick's Tris buffer, the K_i value [redacted] fall within the claimed range of 0.1 mM to 50 mM. *See, e.g.*, Hearing Tr. at 482:3-8 (Stephanopoulos); CX-1529C, Stephanopoulos WS at Q/As 289-90 (citing Grant 2000 (CX-765) and Grant 2001 (CX-464)).

In sum, Complainants have offered credible evidence that the K_i value would be within the claimed range under the reverse McKitrick assay conditions. On the other hand, the FID and Respondents theorize that various parameters can affect the K_i value but offer no evidence to persuasively rebut Complainants' evidence. Thus, the Commission has determined to reverse the

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[21] Sugimoto et al., *The Mechanism of End Product Inhibition of Serine Biosynthesis*, The Journal of Biological Chemistry, Vol., 243, No. 9, pp. 2081-89, 1968 (RX-113).

[22] Grant et al., *Identification of Amino Acid Residues Contributing to the Mechanism of Cooperativity in E. coli D-3-Phosphoglycerate Dehydrogenase*, Biochemistry 2005, 44(51), 16844-52 (RX-133).

FID's funding of non-infringement with respect to CJ's strains with [redacted]

(b) [redacted]

With respect to [redacted], the FID finds that "Ajinomoto's reliance on the Grant articles to establish the K_i range fails for the same reason it failed in the context of [redacted]" *See* FID at 42. The Commission disagrees and finds that the record evidence supports a finding of infringement by CJ's strains with [redacted] (also called [redacted][23]).

Initially, we note that [redacted] is one of the preferred embodiments disclosed in the'373 specification and in that respect, it is likely within the scope of claim 10. *See* JX-1, '373 patent at 6:45-55 (Table 1); *Accent Packaging, Inc. v. Leggett & Platt, Inc.*, 707 F.3d 1318, 1326 (Fed. Cir. 2013) ("We have held that 'a claim interpretation that excludes a preferred embodiment from the scope of the claim is rarely, if ever, correct.'") (citing *On-Line Techs., Inc. v. Bodenseewerk Perkin-Elmer GmbH*, 386 F.3d 1133, 1138 (Fed. Cir. 2004)).

The FID rejects the disclosure in the '373 patent on the basis that "[t]he '373 specification lacks intrinsic detail as to the conditions under which the K_i values were measured." *See* FID at 42. The FID reasons that "the specification text [] indicates usage of the forward or reverse McKitrick assay, but also follows a portion of text indicating that any other method could be used to determine PGD activity." *Id.* (citing JX-1, '373 patent at 6:27-43). We disagree. As discussed *supra* section III.A.2(i)(a), it does not matter for purposes of infringement that it is possible to measure enzyme activity

[23] *See, e.g.*, CJ's Pet. Resp. at 41, 55.

and/or serine sensitivity through a forward or reverse McKitrick reaction or any other method (RX-302C, Grant RWS[24] at Q/As 45, 61, 74); what matters here, is whether Complainants can persuasively establish that the K_i value of [redacted] was obtained in accordance with the McKitrick reverse assay.

The record evidence supports a finding that the K_i value for serine of [redacted] was determined in accordance with the reverse McKitrick assay. [redacted][25] JX-5 (McKitrick) at 237; *see also* Ajinomoto's Pet. at 75; CX-1977C, Stephanopoulos RWS at Q/A 212; CJ's Suppl. Br. at 4 ("[I]n McKitrick, under Materials and Methods, item (i) describes the forward assay (3-Phosphoglycerate dehydrogenase coupled assay), and item (ii) describes the reverse assay (Phosphoglycerate dehydrogenase spectrophotometric assay)."). [redacted] But the standard for infringement is preponderance not definitive evidence. [redacted]

[24] "RWS" refers to "Rebuttal Witness Statement."

[25] [redacted]

[redacted] However, [redacted] does not change our conclusion that the K_i value for serine of [redacted] is more likely than not within the claimed range under the McKitrick reverse conditions. [redacted] By contrast, Respondents provide no evidence that [redacted] would materially affect the K_i value or push it outside of the claimed range.

We also agree with Complainants that Dr. Grant's RX-101 publication and RX-135C experimental report provide further support for finding that [redacted] codes for a protein with a K_i value for serine between 0.1 mM and 50 mM as required by claim 10. *See* [redacted] As discussed above, the variation in pH from 7.5 to 8.5 does not alter our analysis but moves the K_i value further into the claimed range and does not cause the K_i value to fall outside of the claimed range. *See supra* section III.A.2(i)(a). Nor is there any evidence that the parameters identified by Respondents (temperature, substrate, and enzyme or buffer concentration) materially affect the K_i value. *See id.*

Thus, the Commission has determined to reverse the FID's findings with respect to [redacted] limitation.

(ii) *TrpE* Allele Limitation

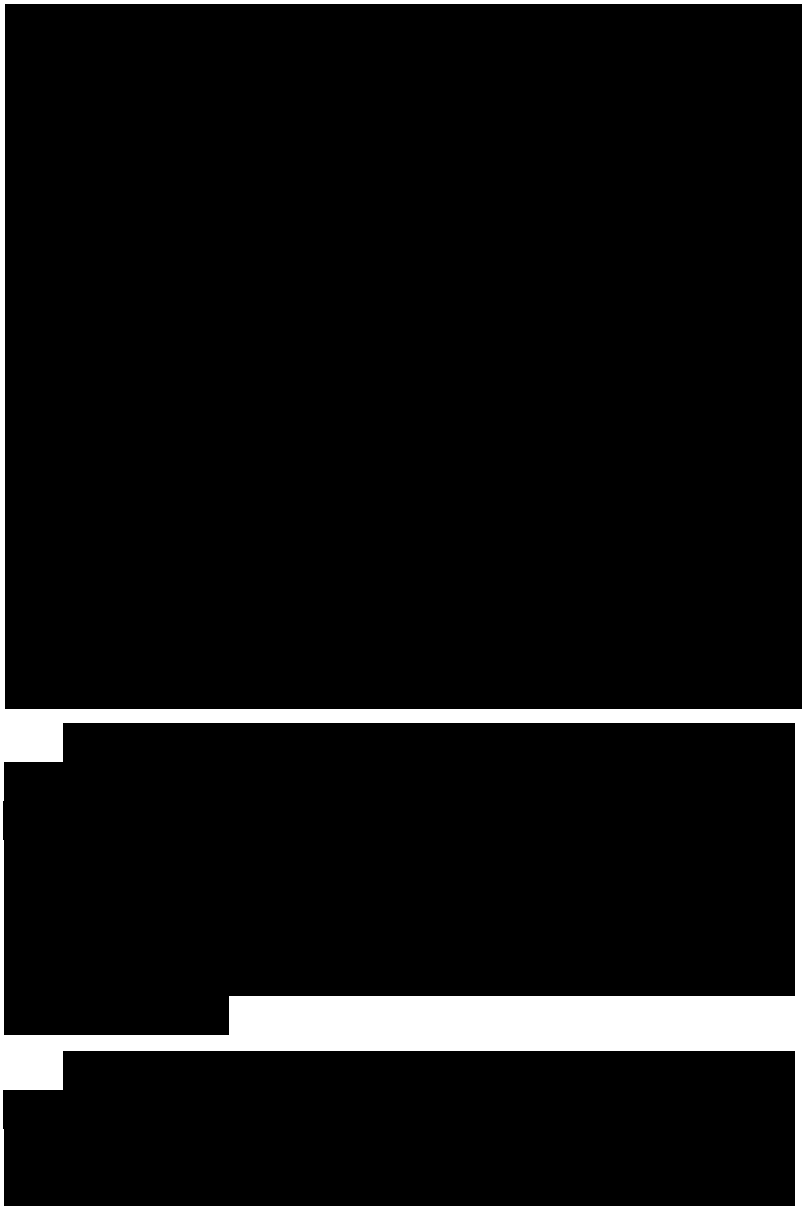
Because we disagree with the FID that Complainants have failed to prove infringement by a preponderance of the evidence with respect to the *serA* allele, the Commission must also determine infringement with respect to the K_i value limitation relating to the *trpE* allele.[26] As explained below, the Commission finds that CJ's strains satisfy that limitation.

(a) [redacted]

The Commission finds that Complainants credibly established, through Dr. Stephanopoulos, their expert, [redacted][27] [redacted], that the *trpE* allele that contains [redacted] yields a K_i value of [redacted] *i.e.*, within the claimed range of 0.1 mM to 20 mM. *See* Ajinomoto's Pet. at 77 (citing CX-1529C, Stephanopoulos WS at Q/As 189-93, 301-09, 328-29; CX-1534C, [redacted]; CX-497C22, Ajinomoto Experimental Report). [redacted]

[26] [redacted] *See* Ajinomoto's Pet. at 68 (citing CX-1529C, Stephanopoulos WS at Q/As 182-183, 328).

[27] [redacted]



[28] Hagino et al., *Regulatory Properties of Anthranilate Synthetase from Corynebacterium glutamicum*, Agr. Biol. Chem., 39 (2), 323-330 (1975) (CX-1543).

[redacted] The Commission finds that Respondents' attorney arguments are insufficient to rebut Ajinomoto's factual and expert evidence. Thus, the Commission has determined that CJ's strains with [redacted] satisfy the K_i value limitation relating to the *trpE* allele.

(b) [redacted]

With respect to the [redacted] which corresponds to [redacted] the Commission finds that Complainants credibly established that [redacted] encodes for a protein having a K_i value of [redacted] for tryptophan, within the claimed range of 0.1 mM and 20 mM. *See* Ajinomoto's Pet. at 78; CX-1529C, Stephanopoulos WS at Q/As 163-64, 303 [redacted]

In addition, we note that [redacted] is one of the preferred embodiments disclosed in the '373 specification and in that respect, it is likely within the scope of claim 10. [redacted] *Accent*

Packaging, 707 F.3d at 1326 ("We have held that 'a claim interpretation that excludes a preferred embodiment from the scope of the claim is rarely, if ever, correct.'") (citation omitted). Respondents fail to properly rebut Complainants' evidence with respect to [redacted].

Thus, the Commission has determined that CJ's strains with [redacted] satisfy the K_i value limitation relating to the *trpE* allele.

(iii) Conclusion

Accordingly, the Commission has determined to reverse the FID's finding of non-infringement of claim 10 of the '373 patent with respect to CJ's production strains.

3. Domestic Industry - Technical Prong

The Commission finds that the record evidence supports a conclusion that Complainants satisfied the technical prong of the domestic industry requirement with respect to the '373 patent.

With respect to the K_i value relating to the *serA* allele, [redacted]

We disagreed with those reasons, and we further find that the record evidence supports the conclusion that Complainants established by a preponderance of the evidence that the K_i value limitation is satisfied [redacted]

With respect to the K_i value relating to the *trpE* allele (which the FID does not reach), [redacted] *See* Ajinomoto's Pet. at 96 (citing CX-1529C, Stephanopoulos WS at Q/As 330, 340, 346-47, 349, 357; [redacted] However, Respondents argue that [redacted][29] Respondents further argue that [redacted]

The Commission finds that the evidence does not support Respondents' arguments that the K_i value [redacted] Respondents provide no factual or technical evidence to support such theories. [redacted]

[redacted]

[29] [redacted]

[redacted]

[redacted][30]

[redacted]

[30] [redacted]

[redacted] As such, the evidence of record supports the conclusion that Ajinomoto's [redacted] are within the scope of claim 10. *See Accent Packaging*, 707 F.3d at 1326 ("We have held that 'a claim interpretation that excludes a preferred embodiment from the scope of the claim is rarely, if ever, correct.'") (citation omitted).

Thus, the Commission has determined to reverse the FID's finding that Complainants failed to satisfy the

technical prong of the domestic industry requirement with respect to the '373 patent

4. Invalidity

(i) Indefiniteness

The Commission finds that the FID errs in finding that clear and convincing evidence of indefiniteness for the "K_i value" limitations supports a finding of invalidity. *See* FID at 49-53. The FID reasons that "[l]ike the claim at issue in *Teva*,[31] claim 10 offers no guidance on its face [] as to which assay or conditions should be used to measure K_i." *Id.* at 50.

As discussed *supra* section III.A.l, the '373 patent specification provides that "the forward or reverse [McKitrick] reaction of the enzyme" may be used to determine PGD activity and that "[t]he said assay [(*i.e.*, the forward or reverse assay)] is suitable for determining the serine sensitivity [(*i.e.*, the K_i value)] of any phosphoglycerate dehydrogenase." *See* JX-1, '373 patent at 6:29-35. The '373 patent also provides that "[i]t is likewise possible to employ any other method for measuring the PGD activity." *Id.* at 6:35-37. Similarly, the '373 patent specification states that tryptophan sensitivity may be determined by any method and that the Bauerle assay is an exemplary method. *See* JX-1, '373 patent at 3:43-49.

Complainants do not dispute that the "K_i values are assay-dependent." *See* FID at 49 (citing Ajinomoto's Reply Post-Hearing Br. at 44). However, as explained *supra* section III.A. 1, the intrinsic evidence includes assay conditions for the reverse McKitrick and the Bauerle assays, but appears silent on the assay conditions for any

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[31] *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1337 (Fed. Cir. 2015).

other method for measuring serine or tryptophan sensitivity. Also conspicuously absent from the record, is any evidence that the forward and reverse McKitrick assays use different conditions and/or yield different K_i values. *See supra* section III.A.1. In fact, Complainants persuasively establish that the "the coupled [forward] assay ... gives approximately the same enzyme activity as the spectrophotometric [reverse] assay." *See* Ajinomoto's Suppl. Resp. at 6 (citing JX-5 (McKitrick) at 244) (alteration in original).[32]

Thus, the facts in the present case are distinguishable from *Teva* where the patent specification failed to mention *any* method for determining "molecular weight." *See Teva*, 789 F.3d at 1344-45 ("To summarize, it is undisputed that 'molecular weight' or average molecular weight can be ascertained by any of three possible measures: M_p, M_n, and M_w. The claims do not indicate which measure to use. The specification never defines molecular weight or even mentions M_p, M_n, and M_w.").

Because Respondents fail to establish that the intrinsic record includes assay conditions for measuring serine sensitivity, other than those disclosed in the reverse McKitrick assay, the Commission finds that Respondents do not carry their burden to prove that the term "K, value for serine" is indefinite by clear and convincing evidence. *See Akzo Nobel Coatings, Inc. v. Dow Chem. Co.*, 811 F.3d 1334,1344 (Fed. Cir. 2016) (affirming district court's conclusion that claims were not indefinite

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[32] Respondents argue that "there is no dispute that the two McKitrick assays give different results and K_i values for the PGD of a given allele," *see* CJ's Suppl. Br. at 5, but we discern no adequate support for this argument in Respondents' papers.

where "neither the claim language nor the specification indicates a temperature for the final viscosity measurement" but "room temperature is the only temperature mentioned at all in the [] patent in connection with a viscosity measurement').[33] And while the '373 patent specification provides that other methods for measuring PGD activity may be used, the record also shows that a POSITA is aware that certain parameters *(e.g.*, pH) can affect the assay results and the POSITA can evaluate the results accordingly (as Ajinomoto's expert did in this case, *see* Ajinomoto's Pet. at 71-72). *See*, *e.g*, RX-221C, Grant WS at Q/A 150-172; *see also In re GPAC*, 57 F.3d at 1579 ("The person of ordinary skill in the art is a hypothetical person who is presumed to know the relevant prior art.") (citation omitted). Thus, there is no clear and convincing evidence that the specification and the prosecution history do not inform a POSITA with reasonable certainty with respect to the term "K_i value for serine."

Similarly, Respondents fail to satisfy their burden to establish by clear and convincing evidence that the term "K_i value for tryptophan" is indefinite. Respondents fail to explain why the specification and the prosecution history do not inform a POSITA with reasonable

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[33] We also agree with Complainants that the FID incorrectly conflates the law of claim construction and indefiniteness when stating that "the law governing claim construction would preclude the [FID] from importing a limitation from an exemplary embodiment in the specification into claim 10." *See* FID at 51 (citation omitted). Indeed, the standard for statutory definiteness requires "reasonable certainty" and is distinct from the claim construction standard, and the claims are not indefinite where only one set of assay conditions is exemplified in the specification. *See Akzo*, 811 F.3d at 1344; *One-E-Way, Inc. v. Int'l Trade Comm'n*, 859 F.3d 1059, 1065 (Fed. Cir. 2017) (finding claims not indefinite based on exemplary statement in the prosecution history).

certainty with respect to the term "K_i value for tryptophan," when Bauerle is the only method exemplified for measuring the K_i value for tryptophan. *See, e.g.*, '373 patent at 8:32-34 (Example 1).

Thus, the Commission has determined to reverse the FID's findings with respect to indefiniteness.

(ii) Written Description

The Commission has also determined reverse the FID's findings with respect to lack of written description.

There is no legal support for the FID's conclusion (and Respondents' position) that a claimed feature ("recovering the produced tryptophan from the culture medium") that is undisputedly well-known in the art and appears in the preamble portion of a Jepson claim[34] (claim 10) lacks written description support. Rather, "a patentee may rely on information that is 'well-known in the art' for purposes of meeting the written description requirement." *See Boston Scientific Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1366 ((Fed. Cir. 2011); *compare id.* ("[H]owever, when the four corners of the specification directly contradict information that the patentee alleges is 'well-known' to a person of skill at the effective filing date, no reasonable jury could conclude that the patentee possessed the invention").

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[34] The Jepson format is a claim structure including: "(1) a preamble ... describ[ing] [] all the elements or steps of the claimed combination which are conventional or known, (2) [a] phrase such as 'wherein the improvement comprises,' and (3) [t]hose elements, steps, and/or relationships which constitute that portion of the claimed combination which the applicant considers as the new or improved portion." *See* MPEP § 2129; 37 C.F.R. § 1.75(e).

We also agree with Complainants that the specification provides sufficient examples of known processes for tryptophan production, which requires recovering the produced tryptophan. *See* Ajinomoto's Pet. at 95 (citing JX-1, '373 patent at 1:19-43 (citing CX-830; CX-865; CX-1207); CX-1977C, Stephanopoulos RWS at Q/As 246-50).

Thus, the Commission has determined to reverse the FID's findings with respect to lack of written description.

B. The '655 Patent

1. Infringement

The Commission has determined to affirm the FID's construction of the term "replacing the native promoter" and the FID's finding that CJ's Earlier Strains do not satisfy that limitation under the FID's construction. However, the Commission has determined to reverse the FID's finding that Ajinomoto has failed to establish by a preponderance of the evidence that CJ's Later Strains [redacted] infringe claim 20 of the '655 patent.

(i) CJ's [redacted]

(a) "Resistance" Limitation

The Commission has determined that the FID errs in finding that "Ajinomoto has failed to establish by a preponderance of the evidence that [redacted] meets the resistance limitation of claim 20."[35] *See* FID at 75. While we agree with the FID that commercial viability

[35] Specifically, claim 20 recites that "said protein has the activity to make the bacterium resistant to L-phenylalanine, fluoro-phenylalanine or 5-fluoro-DL-tryptophan." *See supra* section I.B.2.

is insufficient by itself to establish that the "protein has the activity to make the bacterium resistant" as required by claim 20, the Commission finds that Complainants showed that [redacted] satisfies this limitation by a preponderance of the evidence.

In particular, Complainants relied on disclosure in the '655 patent showing that *yddG* gene amplification conferred resistance to L-phenylalanine, fluoro-phenylalanine or 5-fluoro-DL-tryptophan. In particular, the '655 patent explains that:

> [T]he *yddG* gene encoding a membrane protein . . . conferred on a microorganism resistance to phenylalanine and several amino acid analogues when the wild type allele of the gene was amplified on a multi copy vector in the microorganism. Besides, the *yddG* gene can enhance L-phenylalanine production when its additional copies are introduced into the cells of the respective producing strain. And the *yddG* gene can enhance L-tiyptophan production when its expression in the cells of the respective producing strain is enhanced.

JX-3, '655 patent at 2:40-57. As noted by Complainants, Example 2 of the '655 patent shows that increasing the activity of YddG makes bacteria resistant to high concentrations of L-phenylalanine, fluoro-phenylalanine, or 5fluoro-DL-tryptophan. *See* Ajinomoto's Pet. at 38 (citing JX-3, '655 patent at 9:32-66 (Table 1); CX-1529C, Stephanopoulos WS at Q/As 387-88, 545-47). Complainants also point to several publications, including JX-17 at pages 4-5, to argue that "enhancement of a single

chromosomal *yddG* gene copy (using a stronger promoter) results in bacterial resistance to aromatic amino acid analogues." *Id.* at 41 (citing JX-17.4-5; *see also* CX-475.4; CX-476.3; CX-478.1; CX-471). CJ responds that any inference from Table 1 of the '655 patent is inappropriate because "Table 1 [] contains data from bacteria expressing *yddG* from a high copy-number plasmid (more than 100 copies per cell) and a moderate copy-number plasmid (20-50 copies per cell)," while [redacted] *See* CJ's Pet. Resp. at 17 (citing RX-303C (Roepe[36] RWS) at Q/As 290-91, 293; JX-3, '655 patent at 9:11-16, Table 1). CJ also rejects Complainants' reliance JX-17 arguing that it "suffer[s] the same defect as Table 1, they rely [redacted], and are, therefore, inapposite to CJ's strains. *Id.* at 18 (citing, *inter alia*, JX-17 (high copy-number plasmid pUC19-yddG; more than 100 copies).

We disagree with Respondents' suggestion that [redacted] are insufficient to provide the resistance recited in claim 20. Respondents fail to properly rebut Complainants' infringement evidence. First, Respondents mischaracterize JX-17 as only showing a high copy-number plasmid pUC19-yddG; more than 100 copies. Respondents do not address Complainants' argument and testimony from Dr. Stephanopoulos with respect to the DV036 Example in JX-17 which discloses [redacted]

[36] Dr. Paul Roepe is one of Respondents' experts in this investigation.

[redacted] and which results in bacterial resistance to aromatic amino acid analogues. *See* Ajinomoto's Pet. at 41; CX-1529C, Stephanopoulos WS at Q/As 551-54; [redacted]

In addition, Respondents' argument that the Later Strains are [redacted] is contradicted by the evidence, which shows that [redacted] in both of CJ's Later Strains was replaced. *See* Ajinomoto's Pet. at 44 (citing CX-1529C, Stephanopoulos WS at Q/A 694). In particular, [redacted] was replaced with a [redacted] was replaced with [redacted] *See* CX-1529C, Stephanopoulos WS at Q/A 694. Dr. Stephanopoulos also testified that [redacted] *Id.*

Furthermore, Respondents do not deny that the ability of a bacterium to overproduce amino acids means that it is necessarily resistant to such amino acids. However, Respondents argue that Ajinomoto did not "establish[] the required causality of any resistance to the enhanced activity of YddG." *See* CJ's Pet. Resp. at 16. We

disagree. Complainants persuasively established that enhancing the activity of the YddG protein in [redacted] causes the bacterium to overproduce tryptophan, and thus confers bacterial resistance. *See* Ajinomoto's Pet. at 40; *see also* CX-1529C, Stephanopoulos WS at Q/A 681. We also note the broad definition of "[resistance to L-phenylalanine and/or an amino acid analog" in the '655 patent as the ability of the bacterium to grow on a minimal medium containing L-phenylalanine or the amino acid analog at a concentration under which the wild type or parental strain of the bacterium cannot grow, or the ability of the bacterium to grow faster on a medium containing L-phenylalanine or the amino acid analog than the wild type or parental strain of the bacterium. *See* JX-3, '655 patent at 4:49-56.

[redacted]

Thus, the Commission finds that Complainants established by a preponderance of the evidence that [redacted] satisfies the "resistance" limitation. Accordingly, the Commission has determined to reverse the FID's findings with respect to the "resistance" limitation.

(b) Other Limitations

Because we disagree with the FID that CJ's [redacted] does not satisfy the "resistance" limitation, the Commission must determine infringement with respect to the other limitations of claim 20, which the FID does not reach.[37] In particular, Respondents do not dispute infringement of the claim limitation requiring "cultivating the bacterium according to any one of claims 9-12, 13, 14, 15-18, or 19" or the claim limitation requiring that the bacterium is "recombinant *Escherichia coli* bacterium, which has the ability to accumulate aromatic L-amino acid in a medium." See JX-3, claim 20; CX-1529C, Stephanopoulos WS at Q/As 703-06. However, Respondents dispute the "enhanced activity" limitation of claims 9 and 15. *See* CJ's Pet. Resp. at 20-21. The Commission finds that Complainants satisfied their burden to establish infringement of the "enhanced activity" limitation by [redacted], as follows.

Claim 20 (via claims 9 and 15) requires that the activity of the protein is enhanced by: (1) "transformation of the bacterium with a DNA encoding the protein to express the protein in the bacterium," (2) "replacing the native promoter which precedes the DNA on the chromosome of the bacterium with a more potent promoter," or (3) "introduction of multiple copies of the DNA encoding said protein into the chromosome of said bacterium

[37] The Commission agrees with the FID that "Ajinomoto has established, by a preponderance of the evidence, that the use of [redacted] meets the protein definition of claim 15 [("said protein is encoded by the nucleotide sequence which hybridizes with the complement of the nucleotide sequence of SEQ ID NO: l under stringent conditions comprising 60° C., lxSSC, 0.1% SDS")], which is incorporated by reference into claim 20." *See* FID at 73.

to express the protein in said bacterium." *See supra* section I.B.2. The Commission finds that CJ's [redacted] satisfies at least option (1) of the "enhanced activity" limitation.

Specifically, with respect to the first option, we agree that "CJ's Later Strains have [redacted] which [redacted] and has thus been 'transformed' into CJ's Later Strains." *See* Ajinomoto's Pet. at 43 (citing CX-1529C, Stephanopoulos WS at Q/A 693). Respondents argue that the first method requires "'transformation' with additional [redacted]" *See* CJ's Pet. Resp. at 21 (emphasis in original). Respondents cite no support in the claim language or anywhere in the intrinsic record for such a narrow interpretation of the claim. Respondents also argue that [redacted] in CJ's Later Strains [redacted] *Id.* (emphasis in original). We disagree. Although the claim requires "transform[ing]," "replacing," or "introduce[ing]," which are presumed to have different meanings or scopes, nothing precludes some overlap between those scopes such that a method can satisfy both the "transform[ing]" and "introduc[ing]" options.

Thus, the Commission finds that the record evidence supports a finding of infringement by a preponderance of the evidence with respect to CJ's [redacted]. Accordingly, the Commission has determined to reverse the FID's finding of non-infringement of claim 20 of the '655 patent with respect to CJ's [redacted].

(ii) CJ's [redacted]

(a) "Protein" Limitation

The Commission has determined that the FID errs in finding that [redacted] does not satisfy the protein limitation of claim 9 ("said protein consists of the amino acid sequence of SEQ ID NO: 2") under the doctrine of equivalents, *i.e.*, that [redacted] is not equivalent to the *E. coli* YddG protein under the function-way-result test.

We agree with Complainants that a preponderance of the evidence supports a finding that [redacted] satisfies the protein limitation of claim 9 under the doctrine of equivalents. Complainants argue that [redacted] ... is functionally equivalent to *E. coli* YddG." *See* Ajinomoto's Pet. at 49. Complainants explain that [redacted] *Id.* at 48 (citations omitted). In addition, Complainants continue, "[b]oth serve as [redacted] *Id.* at 48-49. Complainants further contend that "CJ's fermentation documents show [redacted] *Id.* at 48.

The Commission finds that Complainants persuasively establish that [redacted] protein performs substantially the same function, in the same way, to obtain the same result and is therefore equivalent to the *E. coli* YddG protein. Complainants have estab-

lished that [redacted] and *E. coli* YddG proteins are highly homologous *(see* CX-1529C, Stephanopoulos WS at Q/As 671, 699; [redacted]). Without pointing to any evidence, Respondents do not dispute the [redacted] assertion. Respondents' unsupported attorney arguments do not rebut Complainants' high homology assertion [redacted] which is supported by documentary evidence and expert testimony. *See also* JX-3, '655 patent at 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.").

Complainants also persuasively established that both [redacted] and *E. coli* YddG proteins function as [redacted] *See* Ajinomoto's Pet. at 48-49 (citations omitted). Respondents do not challenge this characterization but they (and the FID) argue that the evidence shows that the *E. coli* YddG protein exports aromatic amino acids, but that [redacted] *See* CJ's Pet. Resp. at 24 [redacted]. However, as Complainants note, [redacted] *See* Ajinomoto's Pet. at 49. We agree with Complainants that "[there is no evidence tha [redacted] *Id.* To the contrary, as Dr. Stephanopoulos testified, [redacted] function of [redacted] depends on the [redacted], which is present in [redacted] but not *E. coli*. *See* CX-2115C Stephanopoulos Suppl. RWS at Q/As 112-120.

Furthermore, Complainants persuasively argue that CJ's fermentation evidence shows that [redacted] when incorporated into the claimed *E. coli* bacterium, has the exact same tryptophan-increasing effect as the *E. coli* YddG protein." *See* Ajinomoto's Pet. at 50. As Dr. Stephanopoulos testified, the strain having the native expression levels of the *yddG* gene exhibits almost [redacted] tryptophan production [redacted] than the strain having CJ's [redacted] *See* CX-1529C, Stephanopoulos WS at Q/A 681 (citing CX-628C; CX-635C). Thus, Complainants establish by a preponderance of the evidence that [redacted] when incorporated in the *E. coli* bacterium increases tryptophan production (compare tryptophan productions of [redacted] Complainants also establish by a preponderance of the evidence that [redacted] (which is undisputedly the same for Strains 4127 and 4151) increased the tryptophan production in the same way as the *E. coli* YddG protein, as both are highly homologous export proteins, *i.e.*, they "facilitate[] the export of . . . tryptophan, across the bacterial cell membrane and out of the cell [thereby] . . . lowering intracellular concentrations of tryptophan, in turn reducing

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[38] [redacted] CX-1529C, Stephanopoulos WS at Q/A 686 (citing CX-1530C, Rigoutsos WS).

feedback inhibition by tryptophan, and increasing tryptophan production." *See, e.g.*, Ajinomoto's Pet. at 14 (citing JX-3, '655 patent at 1:31-39, 1:54-2:36, 2:40-57; CX-1529C, Stephanopoulos WS at Q/As 370-89; CX-2115C, Stephanopoulos Suppl. RWS at Q/As 297-348, 350-57). Accordingly, the Commission finds that the evidence supports a finding [redacted] is equivalent to the *E. coli* YddG protein or SEQ ID NO: 2 and that the FID errs in concluding otherwise.

With respect to Respondents' prosecution history estoppel argument, the Commission finds that while prosecution history estoppel applies indirectly to the "SEQ ID No: 2" element of claim 9 and limits the range of equivalents that is available for that claim term, the narrowing amendment bears no more than a tangential relation to the alleged equivalent such that any presumption of estoppel is rebutted as to that equivalent. The claim term "SEQ ID No: 2," appears in claim 1 (which was amended) and must be interpreted consistently in all the '655 patent claims. *See Glaxo Wellcome, Inc. v. Impax Laboratories, Inc.*, 356 F.3d 1348, 1356 (Fed. Cir. 2004) ("This court has noted that subject matter surrendered via claim amendments during prosecution is also relinquished for other claims containing the same limitation. This court follows this rule to ensure consistent interpretation of the same claim terms in the same patent.") (citation omitted).

Claim 1 was amended during prosecution of the '655 patent, impacting the scope of that claim and the terms recited therein. 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 . . ..

See JX-4 ('655 File History) at 48. The Examiner rejected claim 1 over the Livshits prior art which discloses the *yfiK* gene (not yddG*)* and satisfies limitation (B). *Id.* at 378-80. After the Examiner's rejection, the patentee amended limitation (B) of claim 1 as follows:

> [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~~ of 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 in~~ ~~Sequence~~ ~~listing~~ that is encoded by a nucleotide sequence that hybridizes with the nucleotide sequence of SEO ID NO: 1 . . ..

See id. at 610.[39] The patentee also subsequently amended claim 1 to include an additional limitation as follows:

> [A] . . . bacterium . . . enhanced . . . by enhancing activity of a protein ... as defined in the following ~~(A) or (B)~~ (A), (B) or (C)
>
> (A) a protein which comprises the amino acid sequence of SEQ ID NO: 2;
>
> (B) a protein which comprises the amino acid sequence of SEO ID NO: 2 having deletion, substitution, insertion or addition of one to five amino acids: or
>
> (C) a protein which comprises ~~an~~ the amino acid that is encoded by a nucleotide sequence that hybridizes with the complement of the nucleotide sequence of SEQ ID NO: 1 . . ..

See id. at 692.

While limitation (A) ("SEQ ID NO: 2") of claim 1 was not amended in response to the Examiner's rejection, it

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[39] The nucleotide sequence of the *yddG* gene (i.e., SEQ ID NO: 1) encodes the amino acid sequence of the YddG protein (*i.e.*, SEQ ID NO: 2). *See, e.g.*, CX-1530C, Rigoutsos WS at Q/A 172; CX-1529C, Stephanopoulos WS at Q/A 576. Hybridization 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. *See, e.g.*, JX-3, '655 patent at 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."); see also CX-1530C, Rigoutsos WS at Q/As 33-34.

is also impacted by the claim amendment because there is overlap with original limitation (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 other words, any range of equivalents afforded to limitation (A) cannot recapture subject matter surrendered through the amendment of limitation (B). *See Southwall*, 54 F.3d at 1579 ("[P]rosecution history estoppel limits the range of equivalents available to a patentee by preventing recapture of subject matter surrendered during prosecution of the patent.") (citation omitted). The patentee is presumed to have surrendered the territory between original limitation (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") and the amended limitation ("a protein which comprises the amino acid that is encoded by a nucleotide sequence that hybridizes with the complement of the nucleotide sequence of SEQ ID NO: l").[40] *See Festo*, 535 U.S. at 740 ("A patentee's decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim.") (citation omitted).

Having found that Complainants may be constrained by a range of equivalents including "a protein which comprises the amino acid that is encoded by a nucleotide sequence that hybridizes with the complement

[40] The range of equivalents also includes "a protein which comprises the amino acid sequence of SEQ ID NO: 2 having deletion, substitution, insertion or addition of one to five amino acids."

of the nucleotide sequence of SEQ ID NO: 1," two key questions remain: (1) whether CJ's [redacted] is within the range of equivalents; and (2) whether Complainants properly rebut the prosecution history estoppel presumption with respect to the accused equivalent.

With respect to the first question, Complainants' own expert admits that the nucleotide sequence of [redacted] is not likely to hybridize with the complement of the [nucleotide sequence of] SEQ ID NO: l."[41] *See* CX-1530C, Rigoutsos[42] WS at Q/A 100. Moreover, Complainants do not argue that the protein in [redacted] differs from SEQ ID NO: 2 by "having deletion, substitution, insertion or addition of one to five amino acids." Thus, the protein of [redacted] is presumably outside the range of equivalents.

However, with respect to the second question, the Commission finds that Complainants properly rebut the presumption of prosecution history estoppel by showing that the narrowing amendment bears no more than a tangential relationship to the accused equivalent, *i.e.*, [redacted] and the protein encoded by that gene. *See Festo*, 535 U.S. at 740-41 [redacted]

[41] To be clear, [redacted] *See* CX-1529C, Stephanopoulos WS at Q/A 686 (citing CX-1530C, Rigoutsos WS). But while [redacted]

[42] Dr. Isidore Rigoutsos is one of Complainants' experts in this investigation.

[redacted][43] The [redacted] sufficiently alters its sequence such that it is not likely to "hybridize with the complement of the [nucleotide sequence of] SEQ ID NO: 1." However, as described above [redacted] And [redacted] includes [redacted] which hybridizes with the complement of the nucleotide sequence of SEQ ID NO: 1 and as such, it is within the scope of asserted claim 20. *See* FID at 73; CX-1530C, Rigoutsos WS at Q/A 97. In effect, what takes [redacted] out of the range of equivalents is not the presence of [redacted] but [redacted]

The Commission finds that the narrowing amendment limits the range of equivalents to certain types of genes (*i.e.*, genes that hybridize with the complement of the [nucleotide sequence of] SEQ ID NO: 1, which excludes the *yfiK* gene) but is unrelated to [redacted] of genes that would otherwise be within the scope of the asserted claim or range of equivalents *(e.g.*, [redacted].[44] Thus, the narrowing amendment bears no more than a tangential relation to the accused equivalent [redacted] and the presumption of estoppel

[43] Complainants explain that [redacted] *See* Ajinomoto's Pet. at 47 (citations omitted).

[44] *See* Ajinomoto's Suppl. Resp. at 25 [redacted]

is rebutted such that the range of equivalents may extend to cove [redacted].[45] *See Insituform Techs., Inc. v. CAT Contracting, Inc.*, 385 F.3d 1360, 1370 (Fed. Cir. 2004).

Accordingly, the Commission has determined to reverse the FID's findings of non-infringement of claim 20 of the '655 patent with respect to CJ's [redacted].

(b) Other Limitations

Because we disagree with the FID that [redacted] does not satisfy the "protein" limitation, the Commission must also determine infringement with respect to the other limitations of claim 20. As explained below, the Commission finds that CJ's [redacted] satisfies the other limitations of claim 20 of the '655 patent.

In particular, Respondents do not dispute infringement of the claim limitation requiring "cultivating the bacterium according to any one of claims 9-12, 13, 14, 15-18, or 19" or the claim limitation requiring that the bacterium is "recombinant *Escherichia coli* bacterium, which has the ability to accumulate aromatic L-amino acid in a medium," and complainants have adduced sufficient evidence to satisfy these limitations. *See* JX-3, claim 20; CX-1529C, Stephanopoulos WS at Q/As 703-06. However, Respondents dispute the "resistance" and "enhanced activity" limitation of claims 9 and 15. The

[45] We disagree with Complainants that the alleged equivalent was unforeseeable. Like the prior art's *yfiK* gene, the patentee could have foreseen that other genes could be excluded by its narrowing amendment. Complainants also do not dispute that [redacted] was known at the time of the amendment.

Commission finds that Complainants satisfied their burden to establish infringement of the "resistance" and "enhanced activity" limitation by [redacted] for the same reasons as for [redacted] (indeed, [redacted]. *See supra* section III.B.l(i)(a)-(b). Additionally, the Commission finds that CJ's [redacted] also satisfies option (2) of the "enhanced activity" limitation because "[i]n [redacted]" *See* CX-1529C, Stephanopoulos WS at Q/A 694.

Thus, the Commission finds that the record evidence supports a finding of infringement by a preponderance of the evidence with respect to CJ's [redacted]. Accordingly, the Commission has determined to reverse the FID's findings of non-infringement as to CJ's [redacted].

2. Domestic Industry - Technical Prong

The Commission finds that the FID errs in finding that Complainants did not satisfy their burden with respect to the technical prong of the domestic industry requirement with respect to the '655 patent. See FID at 118.

The FID notes that "the sole dispute regarding the technical prong of Ajinomoto's domestic industry case as it relates to the '655 patent [redacted]

Thus, the Commission has determined to reverse the FID's findings with respect to the technical prong of the domestic industry requirement for the '655 patent.

3. Invalidity - Written Description

The Commission finds that the FID errs in finding that clear and convincing evidence supports invalidity for lack of written description for the term "more potent promoter." Specifically, the Commission finds that Complainants persuasively show that: (1) enhancing promoter activity was well-known (undisputed by Respondents); (2) the specification includes sufficient examples of more potent *yddG* promoters; (3) a POSITA would have been able to identify more potent promoters by employing common tools for measuring RNA transcription (undisputed by Respondents); and (4) a POSITA can identify more potent *yddG* promoters given the well-known link between consensus sequence and promoter strength. *See* Ajinomoto's Pet. at 57-58.

Respondents contend "nothing was known in the art or reported in the '655 Patent about the strength of the *yddG* promoter, [therefore] the skilled artisan at the filing date would not know which, if any, of the potent promoters known in the art was more potent than the *yddG* promoter." *See* CJ's Pet. Resp. at 29-30. Respondents' unsupported assertion is contradicted by the record evidence, including the '655 patent specification which provides that the "[s]trength of [a] promoter is defined by [the] frequency of acts of the RNA synthesis initiation" and "[m]ethods for evaluation [of] the strength of promoter and [] examples of potent promoters are described by Deuschle . . . (Promoters in *Escherichia coli*: a hierarchy of *in vivo* strength indicates alternate structures) . . . ." *See* JX-3, '655 patent at 6:15-21; CX-794.

The FID and Respondents do not explain why the examples provided in the specification are not sufficiently representative of the genus of more potent promoters for the *yddG* gene. Respondents' argument that "claim 20 [] encompasses an infinite genus of possible promoters" is not clear and convincing evidence of lack of written description where the specification includes multiple examples of more potent *yddG* promoters (including the P_L promoter of lambda phage, the lac promoter, the trp promoter, and the trc promoter, *see* JX-3, '655 patent at 6:21-24) and a POSITA would know how to identify more potent promoters and assess promoter strength. *See LizardTech, Inc.* v. *Earth Resource Mapping, Inc.*, 424 F.3d 1336,1345 (Fed. Cir. 2005) ("A claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language.") (citation omitted).

In addition, while Respondents may be able establish that the consensus sequence does not necessarily provide the *most* potent promoter for *the yddG* gene of *E. coli* bacteria, Respondents do not show by clear and convincing evidence that the consensus sequence is unrelated to promoter strength or fails to yield a *more* potent promoter relative to the native *yddG* promoter. Furthermore, the FID's reasoning that "the relationship between consensus sequence and promoter potency is found nowhere in the '655 patent" does not support lack of written description where such link was well-known by a POSITA and where the main example of a "more potent promoter" in the '655 patent (the P_L promoter) itself has the consensus sequence at the -35 region. *See Capon*, 418 F.3d 1357; JX-3, '655 patent at 11:5-12:65 (Examples 4-5); CX-794.2, 6.

Importantly, the cases cited by the FID and Respondents are inapposite.[46] Unlike *Ariad*, there is no clear and convincing evidence that the '655 patent disclosure fails to convey to those skilled in the art that the inventors had possession of the claimed subject matter as of the filing date. *See Hynix Semiconductor Inc.* v. *Rambus Inc.*, 645 F.3d 1336, 1352 (Fed. Cir. 2011) ("There is no special rule for supporting a genus by the disclosure of a species; so long as disclosure of the species is sufficient to convey to one skilled in the art that the inventor possessed the subject matter of the genus, the genus will be supported by an adequate written description."). For example, Respondents have not identified any example of a "more potent promoter" that is not sufficiently disclosed or represented in the '655 patent

[46] *See, e.g.*, *Ariad*, 598 F.3d at 1350 (cited in FID at 89 and CJ's Pet. Resp. at 28).

specification and/or would fail to enhance the activity of the protein as required by claim 20 of the '655 patent. In contrast, in *Ariad*, "the specification at best describes decoy molecule structures and hypothesizes with no accompanying description that they could be used to reduce NF-κB activity." *See Ariad*, 598 F.3d at 1351; *see also Rivera* v. *Int'l Trade Comm'n*, 857 F.3d 1315, 1321 (Fed. Cir. 2017) (finding that the asserted claims lacked written description support where the specification's disclosure of a "pod" failed to support the claimed "container" because "without a separate 'pod,' the assemblies shown in the [asserted] patent would not function, because inserting loose-grain coffee or loose-leaf tea into the containers shown in the embodiments would clog the brewing chamber"); *compare Honeywell Int'l Inc. v. United States*, 609 F.3d 1292, 1301 (Fed. Cir. 2010) (reversing the lower court's invalidity finding where the disclosure of a CRT display provided written description support for other types of monitors and the disclosure provided that the invention could be applied to a wide variety of display and vision aid devices).

Thus, the Commission has determined to reverse the FID's findings with respect to lack of written description of the term "more potent promoter."

IV. REMEDY, PUBLIC INTEREST, AND BONDING

A. Limited Exclusión Order

Section 337 requires the Commission to issue limited exclusion orders against named respondents that are found to have imported, sold for importation, or sold after importation infringing articles:

> If the Commission determines, as a result of an investigation under this section, that there is a violation of this section, it shall direct that the articles concerned, imported by any person violating the provision of this section, be excluded from entry into the United States . . . .

See 19 U.S.C. § 1337(d)(l). *See also Spansion, Inc.* v. *Int'l Trade Comm'n*, 629 F.3d 1331, 1358 (Fed. Cir. 2010) ("[T]he Commission is required to issue an exclusion order upon the finding of a Section 337 violation absent a finding that the effects of one of the statutorily-enumerated public interest factors counsel otherwise.").

The ALJ recommended that the Commission issue a limited exclusion order ("LEO") against Respondents' accused products, should the Commission find a violation of section 337. *See* RD at 124. However, the ALJ found "no meaningful justification in CJ's briefing for including a certification provision in any LEO that may issue." *Id.* Respondents argue that no remedy should issue as to the '373 patent which expires on January 30, 2018, two weeks before the end of the Presidential review period. *See* CJ's Suppl. Br. at 29. With respect to the '655 patent, which expires on June 15, 2023, Respondents request that the LEO contain a certification provision because Respondents also "import [] and/or manufacture [] products that are not accused of infringement (*i.e.* non-tryptophan products) and also tryptophan products produced from various strains, some but not all of which may be subject to the order." *Id.* at 30. Complainants respond that the expiration of the '373 patent should not preclude the issuance of an LEO in this investigation. *See* Ajinomoto's Suppl. Resp. at 41. With respect to the

'655 patent, Complainants argue that a certification provision is not appropriate. *Id.* at 42.

The Commission finds that a limited exclusion order is proper with respect to the '373 patent even though the '373 patent expires during the Presidential review period. *See Certain Air Mattress Systems, Components Thereof and Methods of Using The Same*, Inv. No. 337-TA-971, Comm'n Op. at 49, 54 (June 20, 2017) (finding that an LEO was an appropriate remedy even where the asserted patent was set to expire 11 days after the end of the Presidential review period). As to the '655 patent, the Commission has determined that the LEO should include the standard certification provision that CBP typically requests. In addition, the Commission finds that the certification provision is justified because not all of CJ's accused strains infringe the '655 patent. Indeed, only CJ's [redacted] would be subject to the LEO after the expiration date of the '373 patent (but not CJ's Earlier Strains which do not infringe the '655 patent, *see supra* section III.B.l). *See Certain Air Mattress Systems*, Comm'n Op. at 49 (including a certification provision in the LEO).

Accordingly, the Commission has determined to issue a limited exclusion order covering Respondents' infringing products. The Commission has also determined to include a certification provision in the LEO.

B. Cease and Desist Order

Section 337 provides that in addition to, or in lieu of, the issuance of an exclusion order, the Commission may issue a cease and desist order ("CDO") as a remedy for violation of section 337. *See* 19 U.S.C. § 1337(f)(l). The Commission generally issues a cease and desist order di-

rected to a domestic respondent when there is a "commercially significant" amount of infringing, imported product in the United States that could be sold so as to undercut the remedy provided by an exclusion order. *See Certain Condensers, Parts Thereof and Products Containing Same, Including Air Conditioners for Automobiles*, Inv. No. 337-TA-334, Comm'n Op. at 26-28 (Aug. 27, 1997); *Certain Crystalline Cefadroxil Monohydrate*, Inv. No. 337-TA-293, USITC Pub. 2391, Comm'n Op. at 37-42 (June 1991); *see also Certain Table Saws Incorporating Active Injury Mitigation Technology and Components Thereof*, Inv. No. 337-TA- 965, Comm'n Op. at 6-7, n.2 (Feb. 1, 2017). Complainants bear the burden of proving that a respondent has a commercially significant inventory in the United States. *Certain Integrated Repeaters, Switches, Transceivers & Products Containing Same*, Inv. No. 337-TA-435, Comm'n Op.,2002WL 31359028 (Aug. 16, 2002).

The ALJ recommended a CDO against Respondent CJ America, should the Commission find a section 337 violation. *See* RD at 124. Respondents argue that Complainants fail to establish that "the inventory held by CJ America is 'commercially significant.'" *See* CJ's Suppl. Resp. at 29. Complainants argue that "CJ America held approximately [redacted] of Accused Products in inventory in the U.S." and "CJ America maintains inventory in the ordinary course of business in the United States for feed-grade tryptophan." *See* Ajinomoto's

Suppl. Br. at 37 (citing RX-300C, Kim[47] WS at Q/A 73; Hearing Tr. at 678:7-10 (Kim))[48]

The Commission finds that a CDO is justified because CJ America maintains a commercially significant inventory. CJ America notes that it holds about [redacted] of Accused Products which is not insignificant compared to CJ's "[redacted] sold annually in the United States." *See* CJ's Suppl. Br. at 33. Accordingly, the Commission has determined to issue a cease and desist order against Respondent CJ America.[49]

C. Bonding

The ALJ and the Commission must also determine the amount of bond to be required of a respondent, pursuant to section 337(j)(3), during the 60-day Presidential review period following the issuance of permanent relief, in the event that the Commission determines to order a remedy. *See* 19 U.S.C. § 1337(j)(3). The purpose of the bond is to protect the complainant from any injury. *See* 19 C.F.R. §§ 210.42(a)(l)(ii), 210.50(a)(3). The complain-

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[47] Dr. So Young Kim is an employee of CJ CheilJedang Corp. *See* RX-300C, Kim WS at Q/A 3.

[48] Complainants seek a CDO against CJ America but not Respondents CJ CheilJedang Corp. and PT CheilJedang Indonesia. *See* Ajinomoto's Suppl. Br. at 37-37, Ex. 2.

[49] Chairman Schmidtlein supports issuance of the CDO in this investigation for reasons similar to those offered by her in previous investigations. *See, e.g., Certain Table Saws Incorporating Active Injury Mitigation Technology and Components Thereof,* Inv. No. 337-TA- 965, Comm'n Op. at 6-7, n.2 (Feb. 1, 2017) (public version). Specifically, she finds that the presence of some infringing domestic inventory, regardless of the commercial significance, provides a basis to issue the CDO against CJ America.

ant has the burden of supporting any bond amount it proposes. *See Certain Rubber Antidegradants, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-533, Comm'n Op. at 40 (July 21, 2006).

The ALJ recommended against setting a bond during Presidential review. *See* RD at 125. [redacted] Complainants argue that "[a] 100% bond is appropriate to protect Ajinomoto from any injury." *See* Ajinomoto's Suppl. Br. at 38. Complainants reason that "a price differential is impracticable here because it does not represent the true difference between the price of the infringing and domestic industry products." *Id.* Respondents note that "[Complainants] did not introduce any evidence—fact or expert, testimonial or documentary— regarding an appropriate bond." *See* CJ's Suppl. Resp. at 29.

The Commission finds that the ALJ correctly recommended a zero percent bond. Complainants fail to satisfy their burden to support a 100% bond or to properly explain why a reasonable royalty or price differential would be impractical. Accordingly, the Commission has determined to set a zero bond during the Presidential review period.

D. The Public Interest

In determining the remedy, if any, for a violation of Section 337, the Commission must consider the effect of the remedy on certain public interest considerations: (1) the public health and welfare; (2) competitive conditions in the United States economy; (3) the production of like or directly competitive products in the United States;

and (4) United States consumers. *See* 19 U.S.C. § 1337(d) and (f).

Respondents argue that "any remedy should be deferred by six months to allow CJ's customers to switch to non-excluded tryptophan products or for CJ to change its strains pursuant to the Commission decision." *See* CJ's Suppl. Br. at 32. Respondents reason that "CJ accounts for more than [redacted] of the U.S. feed-grade tryptophan market, or roughly [redacted], sold annually in the United States" and that "[a]n exclusion order barring CJ's market-leading products from the United States would, therefore, immediately create a significant shortfall of more than one-third of the feed-grade tryptophan market, resulting in shortages and price hikes for animal feed supplements, animal feed, and downstream products in the U.S. food supply chain." *Id.* at 33-34 (citations omitted). Complainants respond that "not a single member of the public has publicly expressed any concerns regarding the impact of the ALJ's recommended remedial orders for the tryptophan products at issue." *See* Ajinomoto's Suppl. Resp. at 45. Complainants also note that [redacted] such that "Ajinomoto, as well as other competitors, have the capacity to meet the demand in the U.S. marketplace." *Id.* at 46 (citations omitted). Complainants further argue that "[t]he products at issue are dietary supplements for animal feed—they are not prescription pharmaceuticals, they are not medical devices, they do not affect the public health and safety." *See* Ajinomoto's Suppl. Br. at 39.

Based on the evidence presented, the Commission finds that a limited exclusion order directed against L-tryptophan products infringing the '373 and '655 patents,

and the cease and desist order against Respondent CJ America, would cause little to no harm to the public health and welfare, the competitive conditions in the United States economy, the production of like or directly competitive products in the United States, and United States consumers. Accordingly, the Commission has determined that the public interest factors do not preclude issuance of remedial orders.

V. CONCLUSION

For the foregoing reasons, the Commission has determined to find a section 337 violation with respect to the '373 and '655 patents. All findings in the FID that are consistent with this opinion are affirmed.

By order of the Commission

Lisa R. Barton
Secretary to the Commission

Issued: January 11, 2018

APPENDIX D

NOTE: This order is nonprecedential.

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

Nos. 2018-1590, 2018-1629

AJINOMOTO CO., INC., AJINOMOTO HEARTLAND INC.,
APPELLANTS

v.

INTERNATIONAL TRADE COMMISSION, APPELLEE

CJ CHEILJEDANG CORP., CJ AMERICA, INC.,
PT CHEIJEDANG INDONESIA, INTERVENORS

CJ CHEILJEDANG CORP., CJ AMERICA, INC.,
PT CHEIJEDANG INDONESIA, APPELLANTS

v.

INTERNATIONAL TRADE COMMISSION, APPELLEE,

AJINOMOTO CO., INC., AJINOMOTO HEARTLAND INC.,
INTERVENORS

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

ON PETITIONS FOR PANEL REHEARING AND REHEARING EN BANC

Before PROST, *CHIEF JUDGE*, NEWMAN, LOURIE, DYK, MOORE, O'MALLEY, REYNA, WALLACH, TARANTO, CHEN, and HUGHES, *Circuit Judges*[1].

PER CURIAM.

ORDER

CJ CheilJedang Corp., CJ America, Inc. and PT CheilJedang Indonesia and Ajinomoto Co., Inc. and Ajinomoto Heartland Inc. separately filed combined petitions for panel rehearing and rehearing en banc. Responses to CJ's petition were invited by the court and filed by Ajinomoto Co., Inc., Ajinomoto Heartland Inc. and the International Trade Commission. The petitions were referred to the panel that heard the appeal, and thereafter the petitions for rehearing en banc were referred to the circuit judges who are in regular active service.

Upon consideration thereof,

IT IS ORDERED THAT:

The petitions for panel rehearing are denied.

The petitions for rehearing en banc are denied.

The mandate of the court will issue on December 2, 2019.

Date November 25, 2019

FOR THE COURT

/s/ Peter R. Marksteiner

Peter R. Marksteiner
Clerk of Court

[1] Circuit Judge Stoll did not participate.

APPENDIX E

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

Nos. 2018-1590, 2018-1629

AJINOMOTO CO., INC., AJINOMOTO HEARTLAND INC.,
APPELLANTS

v.

INTERNATIONAL TRADE COMMISSION, APPELLEE

CJ CHEILJEDANG CORP., CJ AMERICA, INC.,
PT CHEIJEDANG INDONESIA, INTERVENORS

CJ CHEILJEDANG CORP., CJ AMERICA, INC.,
PT CHEIJEDANG INDONESIA, APPELLANTS

v.

INTERNATIONAL TRADE COMMISSION, APPELLEE,

AJINOMOTO CO., INC., AJINOMOTO HEARTLAND INC.,
INTERVENORS

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

JUDGMENT

This Cause having been considered, it is Ordered and Adjudged:

AFFIRMED

Entered By Order Of The Court

August 6, 2019

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court