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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

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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 tryptophan 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

[1] *See* JX-1, '373 patent at 9:57-59 ("The resulting strains were called PD103 (trpE0), KB862 (trpE5), SV164 (trpE8) and SV163 (trpE6)."), 12:29-30 ("This homogeneous serA5 λ lysate was used to infect the tryptophan producer strain SV164.").

> 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
>
> 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]

[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-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., 1xSSC, 0.1% SDS 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.

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C. The Domestic Industry Products

Ajinomoto defines its domestic industry products as [

]. 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 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 [ ], -3368, [ ] ("Earlier Strains"), and the "later production strains" as [ ] ("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,

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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 15, 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 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

[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.

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. K_i 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 measurement; 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).

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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.

(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,

[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.

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 enzyme 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

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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."

Respondents have failed to prove by clear 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 value for tryptophan" is indefinite.

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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 [ ][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.

(i) *SerA* Allele Limitation

(a) [ ]

The Commission finds that Dr. Stephanopoulos[13] credibly established that [ ] 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 [ ] *See* CX-1529C, Stephanopoulos

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

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

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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 [ ]." *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 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 [

] 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

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[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).

[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).

RX-135C[18]); *see also* RX-221C, Grant WS at Q/A 166 (reporting a "20%" increase of the IC_{50} 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 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 [ ] indicate that using an α-ketoglutarate substrate rather than hydroxyl pyruvic acid phosphate and different concentrations of Tris buffer does not materially change the resulting K_i value for serine" . . . and [ ] *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 concentrations under otherwise identical conditions would yield different K_i values for serine," but as noted by Complainants, Respondents provide no evidence that any variation of enzyme

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[18] [ ] *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).

[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.

concentration would push the K_i value outside the claimed 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 [

] 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 FID's finding of non-infringement with respect to CJ's strains with [ ].

(b) [ ]

With respect to [ ], 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 [

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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).

]." *See* FID at 42. The Commission disagrees and finds that the record evidence supports a finding of infringement by CJ's strains with [ ] (also called [ ][23]).

Initially, we note that [ ] 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 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 [ ] was obtained in accordance with the McKitrick reverse assay.

The record evidence supports a finding that the K_i value for serine of [ ] was determined in accordance with the reverse McKitrick assay. [

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

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

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]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)."). [

] But the standard for infringement is preponderance not definitive evidence. [

]

However, [ ] does not change our conclusion that the K_i value for serine of [ ] is more likely than not within the claimed range under the McKitrick reverse conditions. [

]. By contrast, Respondents provide no evidence that [ ] 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 [ ] codes for a protein

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25 [ ]

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with a K_i value for serine between 0.1 mM and 50 mM as required by claim 10. *See* [

]. 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 [

] 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) [ ]

The Commission finds that Complainants credibly established, through Dr. Stephanopoulos, their expert, [ ][27] [ ], that the *trpE* allele that contains [ ] yields a K_i value of [ ], *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, [ ]; CX-497C.22, Ajinomoto Experimental Report). [

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

[27] [ ]

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]28 [

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

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[

] 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 [ ] satisfy the K_i value limitation relating to the *trpE* allele.

(b) [ ]

With respect to the [ ] which corresponds to [ ], the Commission finds that Complainants credibly established that [ ] encodes for a protein having a K_i value of [ ] 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 [

]

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

]; *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 [ ].

Thus, the Commission has determined that CJ's strains with [ ] 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, [

]. 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 [

].

With respect to the K_i value relating to the *trpE* allele (which the FID does not reach), [

] *See* Ajinomoto's Pet. at 96 (citing CX-1529C, Stephanopoulos WS at Q/As 330, 340, 346-47, 349,

357; [

] However,

Respondents argue that [

][29] Respondents further argue

that [

].

The Commission finds that the evidence does not support Respondents' arguments that the K_i value [

]. Respondents provide no factual or technical evidence to support such

theories. [

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[29] [

]

[30] [ ]

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[

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[

] As such, the evidence of record supports the conclusion that Ajinomoto's [ ] 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.1, 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,

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

but appears silent on the assay conditions for any 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_i 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 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

[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.

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 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.

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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).

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").

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

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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).

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finding that Ajinomoto has failed to establish by a preponderance of the evidence that CJ's Later Strains [ ] infringe claim 20 of the '655 patent.

(i) CJ's [ ]

(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 [ ] meets the resistance limitation of claim 20."[35] *See* FID at 75. While we agree with the FID that commercial viability 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 [ ] 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-tryptophan 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,

[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.

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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 [

] *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 on JX-17 arguing that it "suffer[s] the same defect as Table 1, they rely [

], 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 [ ] 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 [

] 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; [

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

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In addition, Respondents' argument that the Later Strains are [

] is contradicted by the evidence, which shows that [

] 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, [

] was replaced with a [

] was replaced with [ ] *See* CX-1529C, Stephanopoulos WS at Q/A 694. Dr. Stephanopoulos also testified that [

] *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 [ ] 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 "[r]esistance to L-phenylalanine and/or an amino acid analog" in the '655 patent as the ability of

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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.

[

]

Thus, the Commission finds that Complainants established by a preponderance of the evidence that [ ] 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 [ ] 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

[37] The Commission agrees with the FID that "Ajinomoto has established, by a preponderance of the evidence, that the use of [ ] 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: 1 under stringent conditions comprising 60° C., 1xSSC, 0.1% SDS")], which is incorporated by reference into claim 20." *See* FID at 73.

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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 [ ], 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 to express the protein in said bacterium." *See supra* section I.B.2. The Commission finds that CJ's [ ] 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 [ ] which [ ] 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 [ ]" *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 [ ] in CJ's Later Strains [ ] *Id.* (emphasis in original). We disagree. Although the claim requires "transform[ing]," "replacing," or "introduc[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 [ ]. 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 [ ].

(ii) CJ's [ ]

(a) "Protein" Limitation

The Commission has determined that the FID errs in finding that [ ] 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 [ ] 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 [ ] satisfies the protein limitation of claim 9 under the doctrine of equivalents. Complainants argue that [ ] . . . is functionally equivalent to *E. coli* YddG." *See* Ajinomoto's Pet. at 49. Complainants explain that [ ] *Id.* at 48 (citations omitted). In addition, Complainants continue, "[b]oth serve as [ ] *Id.* at 48-49. Complainants further contend that "CJ's fermentation documents show [ ] *Id.* at 48.

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The Commission finds that Complainants persuasively establish that [ ] 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 established that [ ] and *E. coli* YddG proteins are highly homologous (*see* CX-1529C, Stephanopoulos WS at Q/As 671, 699; [ ]). Without pointing to any evidence, Respondents do not dispute the [ ] assertion. Respondents' unsupported attorney arguments do not rebut Complainants' high homology assertion [ ] 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 [ ] and *E. coli* YddG proteins function as [ ] *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 [ ]. *See* CJ's Pet. Resp. at 24 [ ]. However, as Complainants note, [ ]. *See* Ajinomoto's Pet. at 49. We agree with Complainants that "[t]here is no evidence that [ ] *Id.* To the contrary, as Dr. Stephanopoulos testified, [ ] function of [ ] depends on the [ ], which is present in [ ] but not *E. coli*. *See* CX-2115C, Stephanopoulos Suppl. RWS at Q/As

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112-120. Furthermore, Complainants persuasively argue that CJ's fermentation evidence shows that [ ] 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 [ ] tryptophan production [ ] than the strain having CJ's [

[38]

]. *See* CX-1529C, Stephanopoulos WS at Q/A 681 (citing CX-628C; CX-635C). Thus, Complainants establish by a preponderance of the evidence that [ ] when incorporated in the *E. coli* bacterium increases tryptophan production (compare tryptophan productions of [ ]). Complainants also establish by a preponderance of the evidence that [ ] 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 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 [

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

] 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 SEQ 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 SEQ 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 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

---

[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.

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: 1").[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 of the nucleotide sequence of SEQ ID NO: 1," two key questions remain: (1) whether CJ's [ ] 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 [ ] is not likely to hybridize with the

[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."

complement of the [nucleotide sequence of] SEQ ID NO: 1."[41] *See* CX-1530C, Rigoutsos[42] WS at Q/A 100. Moreover, Complainants do not argue that the protein in [ ] differs from SEQ ID NO: 2 by "having deletion, substitution, insertion or addition of one to five amino acids." Thus, the protein of [ ] 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.*, [ ] and the protein encoded by that gene. *See Festo*, 535 U.S. at 740-41. [ ][43] The [ ] 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, [ ]. And [ ] includes [ ] 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 [ ] out of the range of equivalents is not the presence of [ ] but [ ].

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

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

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

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 [ ] of genes that would otherwise be within the scope of the asserted claim or range of equivalents (*e.g.*, [ ]).[44] Thus, the narrowing amendment bears no more than a tangential relation to the accused equivalent [ ], and the presumption of estoppel is rebutted such that the range of equivalents may extend to cover [ ][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 [ ].

(b) Other Limitations

Because we disagree with the FID that [ ] 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 [ ] 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

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

[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 [ ] was known at the time of the amendment.

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 Commission finds that Complainants satisfied their burden to establish infringement of the "resistance" and "enhanced activity" limitation by [ ] for the same reasons as for [ ] (indeed, [ ]). *See supra* section III.B.1(i)(a)-(b). Additionally, the Commission finds that CJ's [ ] also satisfies option (2) of the "enhanced activity" limitation because "[i]n [

]" *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 [ ]. Accordingly, the Commission has determined to reverse the FID's findings of non-infringement as to CJ's [ ].

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 [

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[

]

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 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

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

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 Exclusion 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 [ ] 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.1). *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)(1). The Commission generally issues a cease and desist order directed 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., 2002 WL 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 [ ] 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 [ ] of

[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.

Accused Products which is not insignificant compared to CJ's "[ ] 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)(1)(ii), 210.50(a)(3). The complainant 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. [

] 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]

[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.

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 [ ] of the U.S. feed-grade tryptophan market, or roughly [ ], 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 [

] 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.

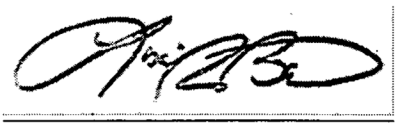
Lisa R. Barton
Secretary to the Commission

Issued: January 11, 2018

CERTAIN L-TRYPTOPHAN, L-TRYPTOPHAN PRODUCTS, AND THEIR METHODS OF PRODUCTION **Inv. No. 337-TA-1005**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **OPINION** has been served on the following parties, as indicated, on **January 11, 2018**.



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