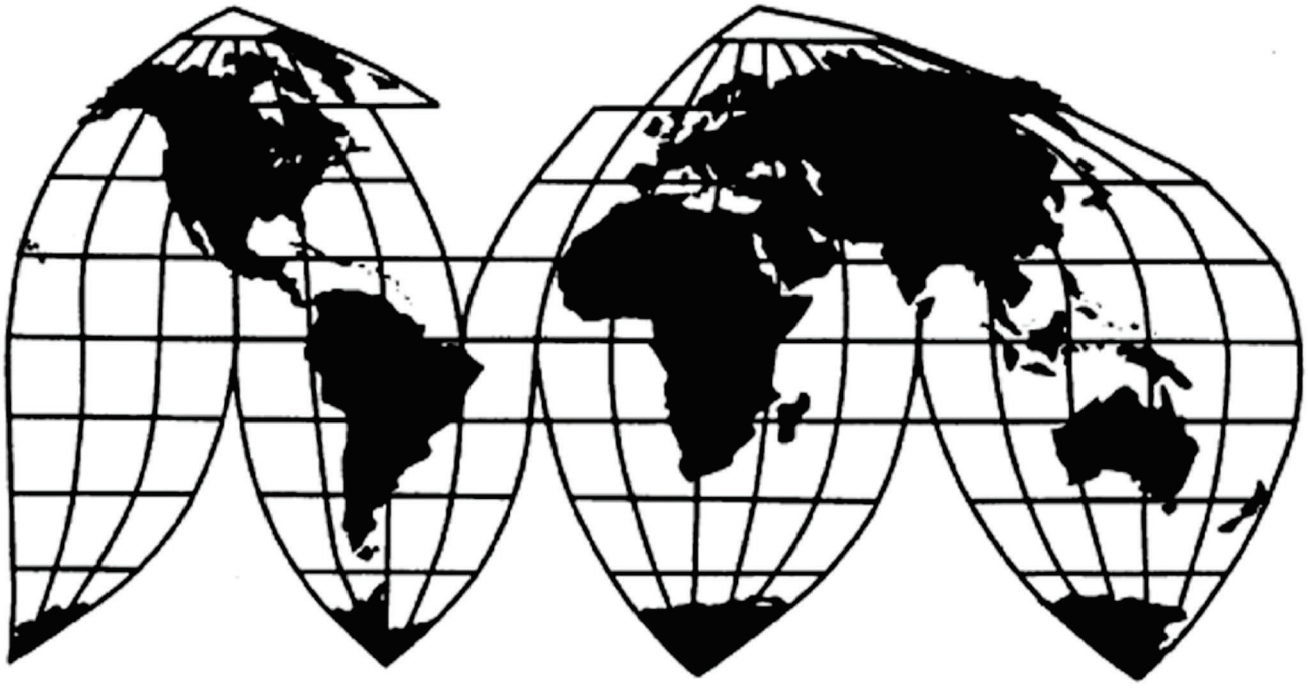
In the Matter of

CERTAIN L-TRYPTOPHAN, L-TRYPTOPHAN PRODUCTS, AND THEIR METHODS OF PRODUCTION

Investigation No. 337-TA-1005

Publication 4933 **September 2019**

U.S. International Trade Commission



Washington, DC 20436

U.S. International Trade Commission

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In the Matter of

CERTAIN L-TRYPTOPHAN, L-TRYPTOPHAN PRODUCTS, AND THEIR METHODS OF PRODUCTION

Investigation No. 337-TA-1005

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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	Investigation No. 337-TA-1005

NOTICE OF COMMISSION FINAL DETERMINATION FINDING A SECTION 337 VIOLATION; ISSUANCE OF A LIMITED EXCLUSION ORDER AND CEASE AND DESIST ORDER; TERMINATION OF THE INVESTIGATION

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has found a violation of section 337 of the Tariff Act of 1930 ("section 337"), as amended, in this investigation. The Commission has issued a limited exclusion order prohibiting the importation of certain L-tryptophan and L-tryptophan products that infringe claim 10 of U.S. Patent No. 6,180,373 ("the '373 patent") or claim 20 of U.S. Patent No. 7,666,655 ("the '655 patent"). The Commission has also issued a cease and desist order directed to the domestic respondent. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Houda Morad, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 708-4716. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server at *https://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted Investigation No. 337-TA-1005 on June 14, 2016, 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 FR 38735-6 (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 certain claims of the '655 patent and the '373 patent (collectively, "the asserted patents"). *Id.* The notice of investigation identified CJ CheilJedang Corp. of Seoul, Republic of Korea; CJ America, Inc. ("CJ America") of Downers Grove, Illinois; and PT CheilJedang Indonesia of Jakarta, Indonesia (collectively "CJ" or "Respondents") as respondents in this investigation. *See id.* The Office of Unfair Import Investigations is not a party to the investigation.

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) and (B) for both asserted patents. *See* Order No. 18, *unreviewed*, Comm'n Notice (May 17, 2017).

On August 11, 2017, the ALJ issued his final initial determination ("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' products do not satisfy the technical prong of the domestic industry requirement with respect to the '655 or the '373 patents. In addition, the ALJ issued a Recommended Determination ("RD") recommending, should the Commission find a section 337 violation, that the Commission issue: (1) a limited exclusion order against Respondents' accused products; and (2) a cease and desist order against Respondent CJ America. The RD further recommends no bond during the Presidential review period.

On August 14, 2017, the Commission issued a Notice requesting written submissions on the public interest. *See* 82 FR 39456-57 (Aug. 18, 2017). On September 20, 2017, Respondents filed a written submission in response to the Commission's August 14, 2017 Notice. No other submissions were received.

On October 12, 2017, the Commission issued a Notice determining to review the FID in its entirety. *See* 82 FR 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, and on November 3, 2017, the parties filed responses to each other's submissions.

Having examined the record of this investigation, including the FID, the RD, and the parties' submissions, the Commission has determined to:

(1) reverse the FID's finding that the accused products do not infringe claim 10 of the '373 patent;

(2) reverse the FID's finding that the domestic industry requirement is not satisfied for the '373 patent.

(3) reverse the FID's finding that claim 10 of the '373 patent is invalid under 35 U.S.C. § 112, second paragraph, for indefiniteness;

(4) reverse the FID's finding that claim 10 of the '373 patent is invalid under 35 U.S.C. § 112, first paragraph, for lack of written description;

(5) affirm the FID's finding that claim 10 of the '373 patent is not invalid under 35 U.S.C. § 112, first paragraph, for lack of enablement;

(6) affirm the FID's finding that claim 10 of the '373 patent is not invalid under 35 U.S.C. § 103 for obviousness;

(7) affirm in part and reverse in part the FID's finding that the accused products do not infringe claim 20 of the '655 patent;

(8) reverse the FID's finding that the domestic industry requirement is not satisfied for the '655 patent.

(9) affirm the FID's finding that claim 20 of the '655 patent is not invalid under 35 U.S.C. § 112, second paragraph, for indefiniteness.

(10) reverse the FID's finding that claim 20 of the '655 patent is invalid under 35 U.S.C. § 112, first paragraph, for lack of written description; and

(11) affirm all other findings in the FID that are not inconsistent with the Commission's determination.

Accordingly, the Commission finds that there is a violation of section 337 with respect to both asserted patents. The Commission has determined the appropriate remedy is a limited exclusion order against Respondents' accused products, and a cease and desist order against Respondent CJ America. The Commission has also determined that the public interest factors enumerated in subsections 337(d)(l) and (f)(1) (19 U.S.C. 1337(d)(l), (f)(1)) do not preclude issuance of the limited exclusion order and cease and desist order. The Commission has further determined to set a bond at zero (0) percent of entered value during the Presidential review period (19 U.S.C. 1337(j)).

The Commission's orders and opinion were delivered to the President and to the United States Trade Representative on the day of their issuance.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: December 18, 2017

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 **NOTICE** has been served on the following parties, as indicated, on **December 18, 2017**.

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainants Ajinomoto Co., Inc. and Ajinomoto Heartland, Inc.:

Mareesa A. Frederick, Esq.
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001

- ☐ Via Hand Delivery
- ☒ Via Express Delivery
- ☐ Via First Class Mail
- ☐ Other:_____

On Behalf of Respondents CJ CheilJedang Corp., CJ America, Inc., and PT CheilJedang Indonesia:

Matthew J. Rizzolo, Esq.
ROPES & GRAY LLP
2099 Pennsylvania Ave., NW
Washington, DC 20006

- ☐ Via Hand Delivery
- ☒ Via Express Delivery
- ☐ Via First Class Mail
- ☐ Other:_____

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN L-TRYPTOPHAN, L-TRYPTOPHAN PRODUCTS, AND THEIR METHODS OF PRODUCTION**	**Investigation No. 337-TA-1005**

LIMITED EXCLUSION ORDER

The United States International Trade Commission ("Commission") has determined that there is a violation of Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), in the unlawful importation, sale for importation, or sale within the United States after importation by Respondents CJ CheilJedang Corp., CJ America, Inc., and PT CheilJedang Indonesia (collectively, "Respondents") of certain L-tryptophan and L-tryptophan products covered by claim 20 of U.S. Patent No. 7,666,655 or claim 10 of U.S. Patent No. 6,180,373.

Having reviewed the record of this investigation, including the written submissions of the parties, the Commission has made its determination on the issues of remedy, public interest, and bonding. The Commission has determined that the appropriate form of relief is a limited exclusion order prohibiting the unlicensed entry into the United States of covered L-tryptophan and L-tryptophan products manufactured by or on behalf of the Respondents or any of their affiliated companies, parents, subsidiaries, or other related business entities, or their successors or assigns.

The Commission has also determined that the public interest factors enumerated in 19 U.S.C. 1337(d) do not preclude the issuance of the limited exclusion order, and that the bond

during the Presidential review period shall be in the amount of zero (0) percent of the entered value of the covered products.

Accordingly, the Commission hereby **ORDERS** that:

1. L-tryptophan and L-tryptophan products that infringe claim 20 of U.S. Patent No. 7,666,655 or claim 10 of U.S. Patent No. 6,180,373 that are manufactured by or on behalf of, or are imported by or on behalf of the Respondents or any of their affiliated companies, parents, subsidiaries, agents, or other related business entities, or their successors or assigns are excluded from entry for consumption into the United States, entry for consumption from a foreign-trade zone, or withdrawal from a warehouse for consumption, for the remaining term of the patents, except under license of the patent owner or as provided by law.

2. Notwithstanding paragraph 1 of this Order, the aforesaid L-tryptophan and L-tryptophan products are entitled to entry into the United States for consumption, entry for consumption from a foreign trade zone, or withdrawal from a warehouse for consumption, under bond in the amount of zero (0) percent of the entered value of the covered products pursuant to subsection (j) of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337(j)), and the Presidential Memorandum for the United States Trade Representative of July 21, 2005, (70 FR 43251), from the day after this Order is received by the United States Trade Representative, and until such time as the United States Trade representative notifies the Commission that this action is approved or disapproved but, in any event, not later than sixty (60) days after the issuance of receipt of this action.

3. At the discretion of U.S. Customs and Border Protection ("CBP") and pursuant to the procedures it establishes, persons seeking to import L-tryptophan and L-tryptophan products that are potentially subject to this Order may be required to certify that they are familiar with the terms of this Order, that they have made appropriate inquiry, and thereupon state that, to the best of their knowledge and belief, the products being imported are not excluded from entry under paragraph 1 of this Order. At its discretion, CBP may require persons who have provided the certification described in this paragraph to furnish such records or analyses as are necessary to substantiate this certification.

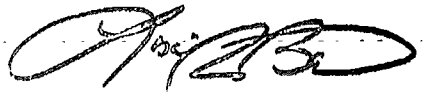
4. In accordance with 19 U.S.C. 1337(l), the provisions of this Order shall not apply to infringing L-tryptophan and L-tryptophan products that are imported by or for the use of the United States, or imported for and to be used for, the United States with the authorization or consent of the Government.

5. The Commission may modify this Order in accordance with the procedures described in Rule 210.76 of the Commission's Rules of Practice and Procedure (19 CFR 210.76).

6. The Secretary shall serve copies of this Order upon each party of record in this Investigation and upon CBP.

7. Notice of this Order shall be published in the Federal Register.

By Order of the Commission.



Lisa R. Barton
Secretary to the Commission

Issued: December 18, 2017

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 **ORDER, COMMISSION** has been served on the following parties, as indicated, on **December 18, 2017**.

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainants Ajinomoto Co., Inc. and Ajinomoto Heartland, Inc.:

Mareesa A. Frederick, Esq.
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001

☐ Via Hand Delivery
☒ Via Express Delivery
☐ Via First Class Mail
☐ Other:_____

On Behalf of Respondents CJ CheilJedang Corp., CJ America, Inc., and PT CheilJedang Indonesia:

Matthew J. Rizzolo, Esq.
ROPES & GRAY LLP
2099 Pennsylvania Ave., NW
Washington, DC 20006

☐ Via Hand Delivery
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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	Investigation No. 337-TA-1005

CEASE AND DESIST ORDER

IT IS HEREBY ORDERED THAT RESPONDENT CJ America, Inc. ("Respondent"), 3500 Lacey Road, Suite 230, Downers Grove, Illinois 60515-5423, cease and desist from conducting any of the following activities in the United States: importing, selling, marketing, advertising, distributing, transferring (except for exportation), and soliciting U.S. agents or distributors for, certain L-tryptophan and L-tryptophan products covered by claim 20 of U.S. Patent No. 7,666,655 or claim 10 of U.S. Patent No. 6,180,373 ("the Asserted Patents") in violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337).

I.
Definitions

As used in this Order:

(A) "Commission" shall mean the United States International Trade Commission.

(B) "Complainants" shall Ajinomoto Co., Inc. of Tokyo, Japan, and Ajinomoto Heartland, Inc. of Chicago, Illinois.

(C) "Respondent" shall mean CJ America, Inc.

(D) "Person" shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than Respondent or its majority owned or controlled subsidiaries, successors, or assigns.

(E) "United States" shall mean the fifty States, the District of Columbia, and Puerto Rico.

(F) The terms "import" and "importation" refer to importation for entry for consumption under the Customs laws of the United States.

(G) The term "covered products" shall mean L-tryptophan and L-tryptophan products covered by claim 20 of U.S. Patent No. 7,666,655 or claim 10 of U.S. Patent No. 6,180,373. Covered products shall not include articles for which a provision of law or license avoids liability for infringement of certain claims of the Asserted Patents.

II.
Applicability

The provisions of this Cease and Desist Order shall apply to Respondent and to any of its principals, stockholders, officers, directors, employees, agents, distributors, controlled (whether by stock ownership or otherwise) and majority-owned business entities, successors, and assigns, and to each of them insofar as they are engaging in conduct prohibited by section III, *infra*, for, with, or otherwise on behalf of, Respondent.

III.
Conduct Prohibited

The following conduct of Respondent in the United States is prohibited by this Order. For the remaining terms of the Asserted Patents, Respondent shall not:

(A) import or sell for importation into the United States covered products;

(B) market, distribute, sell, or otherwise transfer (except for exportation), in the United States imported covered products;

(C) advertise imported covered products;

(D) solicit U.S. agents or distributors for imported covered products; or

(E) aid or abet other entities in the importation, sale for importation, sale after importation, transfer, or distribution of covered products.

IV.
Conduct Permitted

Notwithstanding any other provision of this Order, Respondent shall be permitted:

(A) to engage in specific conduct otherwise prohibited by the terms of this Order if, in a written instrument, the owner of the Asserted Patents licenses or authorizes such specific conduct; or

(B) to engage in specific conduct otherwise prohibited by the terms of this Order if such specific conduct is related to the importation or sale of covered products by or for the United States.

V.
Reporting

For purposes of this requirement, the reporting periods shall commence on July 1 of each year and shall end on the subsequent June 30. The first report required under this section shall cover the period from the date of issuance of this Order through June 30, 2018. This reporting requirement shall continue in force until such time as Respondent has truthfully reported, in two consecutive timely filed reports, that it has no inventory of covered products in the United States.

Within thirty (30) days of the last day of the reporting period, Respondent shall report to the Commission: (a) the quantity in units and the value in dollars of covered products that it has

(i) imported and/or (ii) sold in the United States after importation during the reporting period, and (b) the quantity in units and value in dollars of reported covered products that remain in inventory in the United States at the end of the reporting period. When filing written submissions, Respondent must file the original document electronically on or before the deadlines stated above and submit eight (8) true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the investigation number ("Inv. No. 337-TA-1005") in a prominent place on the cover pages and/or the first page. (*See* Handbook for Electronic Filing Procedures, https://www.usitc.gov/secretary/documents/handbook_on_filing_procedures.pdf). Persons with questions regarding filing should contact the Office of the Secretary (202-205-2000). If Respondent desires to submit a document to the Commission in confidence, it must file the original and a public version of the original with the Office of the Secretary and must serve a copy of the confidential version on Complainants' counsel. [1]

Any failure to make the required report or the filing of any false or inaccurate report shall constitute a violation of this Order, and the submission of a false or inaccurate report may be referred to the U.S. Department of Justice as a possible criminal violation of 18 U.S.C. 1001.

VI.
Recordkeeping and Inspection

(A) For the purpose of securing compliance with this Order, Respondent shall retain any and all records relating to the sale, offer for sale, marketing, or distribution in the United States of covered products, made and received in the usual and ordinary course of business,

[1] Complainants must file a letter with the Secretary identifying the attorney to receive reports associated with this Order. The designated attorney must be on the protective order entered in the investigation.

whether in detail or in summary form, for a period of three (3) years from the close of the fiscal year to which they pertain.

(B) For the purposes of determining or securing compliance with this Order and for no other purpose, subject to any privilege recognized by the federal courts of the United States, and upon reasonable written notice by the Commission or its staff, duly authorized representatives of the Commission shall be permitted access and the right to inspect and copy, in Respondent's principal office during office hours, and in the presence of counsel or other representatives if Respondent so chooses, all books, ledgers, accounts, correspondence, memoranda, and other records and documents, in detail and in summary form, that must be retained under subparagraph VI(A) of this Order.

VII.
Service of Cease and Desist Order

Respondent is ordered and directed to:

(A) Serve, within fifteen days after the effective date of this Order, a copy of this Order upon each of its respective officers, directors, managing agents, agents, and employees who have any responsibility for the importation, marketing, distribution, or sale of imported covered products in the United States;

(B) Serve, within fifteen days after the succession of any persons referred to in subparagraph VII(A) of this Order, a copy of this Order upon each successor; and

(C) Maintain such records as will show the name, title, and address of each person upon whom the Order has been served, as described in subparagraphs VII(A) and VII(B) of this Order, together with the date on which service was made.

The obligations set forth in subparagraphs VII(B) and VII(C) shall remain in effect until the Asserted Patents expire.

VIII.
Confidentiality

Any request for confidential treatment of information obtained by the Commission pursuant to section V - VI of this Order should be made in accordance with section 201.6 of the Commission's Rules of Practice and Procedure (19 CFR 201.6). For all reports for which confidential treatment is sought, Respondent must provide a public version of such report with confidential information redacted.

IX.
Enforcement

Violation of this Order may result in any of the actions specified in section 210.75 of the Commission's Rules of Practice and Procedure (19 CFR 210.75), including an action for civil penalties under section 337(f) of the Tariff Act of 1930 (19 U.S.C. 1337(f)), as well as any other action that the Commission deems appropriate. In determining whether Respondent is in violation of this Order, the Commission may infer facts adverse to Respondent if it fails to provide adequate or timely information.

X.
Modification

The Commission may amend this Order on its own motion or in accordance with the procedure described in section 210.76 of the Commission's Rules of Practice and Procedure (19 CFR 210.76).

XI.
Bonding

The conduct prohibited by Section III of this Order may be continued during the sixty-day period in which this Order is under review by the United States Trade Representative, as

delegated by the President (70 FR 43251 (July 21, 2005)), subject to the Respondent's posting of a bond in the amount of zero (0) percent of the entered value of the covered products. This bond provision does not apply to conduct that is otherwise permitted by section IV of this Order. Covered products imported on or after the date of issuance of this Order are subject to the entry bond set forth in the exclusion order issued by the Commission, and are not subject to this bond provision.

The bond is to be posted in accordance with the procedures established by the Commission for the posting of bonds by complainants in connection with the issuance of temporary exclusion orders. *See* 19 CFR 210.68. The bond and any accompanying documentation are to be provided to and approved by the Commission prior to the commencement of conduct that is otherwise prohibited by section III of this Order. Upon the Secretary's acceptance of the bond, (a) the Secretary will serve an acceptance letter on all parties, and (b) Respondent must serve a copy of the bond and any accompanying documentation on Complainants' counsel.[2]

The bond is to be forfeited in the event that the United States Trade Representative approves this Order (or does not disapprove it within the review period), unless the U.S. Court of Appeals for the Federal Circuit, in a final judgment, reverses any Commission final determination and Order as to Respondent on appeal, or unless Respondent exports or destroys the products subject to this bond and provides certification to that effect that is satisfactory to the Commission.

The bond is to be released in the event the United States Trade Representative disapproves this Order and no subsequent order is issued by the Commission and approved (or

[2] *See* Footnote 1.

not disapproved) by the United States Trade Representative, upon service on Respondent of an order issued by the Commission based upon application therefore made by Respondent to the Commission.

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: December 18, 2017

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 **ORDER, COMMISSION** has been served on the following parties, as indicated, on **December 18, 2017**.

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
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On Behalf of Complainants Ajinomoto Co., Inc. and Ajinomoto Heartland, Inc.:

Mareesa A. Frederick, Esq.
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001

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On Behalf of Respondents CJ CheilJedang Corp., CJ America, Inc., and PT CheilJedang Indonesia:

Matthew J. Rizzolo, Esq.
ROPES & GRAY LLP
2099 Pennsylvania Ave., NW
Washington, DC 20006

☐ Via Hand Delivery
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PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

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

COMMISSION OPINION

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

I. BACKGROUND

A. Procedural Background

By publication in the Federal Register on June 14, 2016, the Commission instituted Investigation No. 337-TA-1005, based on a complaint filed by Complainants Ajinomoto Co., Inc. of Tokyo, Japan and Ajinomoto Heartland Inc. of Chicago, Illinois (collectively, "Ajinomoto" or "Complainants"). *See* 81 *Fed. Reg.* 38735-36 (June 14, 2016). The complaint, as supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), based upon the importation into the United States, the sale for importation, and the sale within the United

States after importation of certain L-tryptophan, L-tryptophan products, and their methods of production, by reason of infringement of claims 4, 7, 8, and 20 of the '655 patent and claim 10 of the '373 patent (collectively, "the asserted patents"). *Id.* The notice of investigation identified CJ CheilJedang Corp. of Seoul, Republic of Korea; CJ America, Inc. of Downers Grove, Illinois; and PT CheilJedang Indonesia of Jakarta, Indonesia as respondents in this investigation. *Id.* The Office of Unfair Import Investigations is not a party to the investigation. *Id.*

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

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

On May 15-19, 2017, the ALJ conducted an evidentiary hearing and on August 11, 2017, the ALJ issued his FID finding no violation of section 337. Specifically, the FID finds that: (1) Respondents' accused products do not infringe the asserted claims of the '373 or the '655 patents either literally or under the doctrine of equivalents; (2) claim 10 of the '373 patent is invalid for indefiniteness and lack of written description; (3) claim 20 of the '655 patent is invalid for lack of written description; and (4) complainants do not satisfy the technical prong of the domestic industry requirement with respect to the '655 and the '373 patents. In addition, the ALJ issued a Recommended Determination ("RD") recommending, should the Commission find a

violation of section 337, that the Commission issue: (1) an LEO against Respondents' accused products; and (2) a CDO against Respondent CJ America. The RD further recommends setting a zero percent bond during the Presidential review period. On August 14, 2017, the Commission issued a Notice requesting written submissions on the public interest. *See* 82 *Fed. Reg.* 39456-57 (Aug. 18, 2017). On September 20, 2017, Respondents filed a written submission in response to the Commission's August 14, 2017 Notice ("CJ's PI Submission"). No other submissions were received.

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

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

B. The Asserted Patents

1. The '373 Patent

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

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

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

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,

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.

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.

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."

][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

[25] [ ]

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). [

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

[27] [ ]

]

[

]28 [

]

[

]

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

[

] 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. [

30

[29] [

]

[30] [ ]

]

[

]

[

] 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).

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.

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.

]

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

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.

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.

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

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 [

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[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

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[39] The nucleotide sequence of the *yddG* gene (*i.e.*, SEQ ID NO: 1) encodes the amino acid sequence of the YddG protein (*i.e.*, SEQ ID NO: 2). *See, e.g.*, CX-1530C, Rigoutsos WS at Q/A 172; CX-1529C, Stephanopoulos WS at Q/A 576. Hybridization allows some flexibility in the nucleotide sequence such that the exact SEQ ID NO: 1 sequence is not required, but a highly homologous nucleotide sequence could still be within the scope of the claim. *See, e.g.*, JX-3, '655 patent at 5:40-43 ("For example, the stringent conditions includes a condition under which DNAs having high homology, for instance DNAs having homology no less than 70% to each other, are hybridized."); *see also* CX-1530C, Rigoutsos WS at Q/As 33-34.

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. <u>Domestic Industry - Technical Prong</u>

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 [

]

[

]

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]

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[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**.

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainants Ajinomoto Co., Inc. and Ajinomoto Heartland, Inc.:

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☒ Via Express Delivery
☐ Via First Class Mail
☐ Other:_____

On Behalf of Respondents CJ CheilJedang Corp., CJ America, Inc., and PT CheilJedang Indonesia:

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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	Investigation No. 337-TA-1005

NOTICE OF COMMISSION DETERMINATION TO REVIEW A FINAL INITIAL DETERMINATION FINDING NO SECTION 337 VIOLATION; SCHEDULE FOR FILING WRITTEN SUBMISSIONS ON THE ISSUES UNDER REVIEW AND ON REMEDY, THE PUBLIC INTEREST, AND BONDING

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review a final initial determination ("FID") of the presiding administrative law judge ("ALJ") finding no violation of section 337 of the Tariff Act of 1930, as amended. The Commission requests certain briefing from the parties on the issues under review, as indicated in this notice. The Commission also requests briefing from the parties and interested persons on the issues of remedy, the public interest, and bonding.

FOR FURTHER INFORMATION CONTACT: Houda Morad, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 708-4716. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server at *https://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted Investigation No. 337-TA-1005 on June 14, 2016, 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 FR 38735-6 (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 certain claims of U.S. Patent No. 7,666,655 ("the '655 patent") and U.S. Patent No. 6,180,373 ("the '373 patent"). *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 (collectively "CJ" or "Respondents") as respondents in this investigation. *See id.* The Office of Unfair Import Investigations is not a party to the investigation.

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' products do not satisfy the technical prong of the domestic industry requirement with respect to the '655 or the '373 patents. In addition, should the Commission find a violation of section 337, the RD recommends that the Commission issue: (1) a limited exclusion order against Respondents' accused products; and (2) a cease and desist order against Respondent CJ America.

The Commission has determined to review the FID in its entirety. In connection with its review, the parties are requested to brief their positions with reference to the applicable law and the evidentiary record regarding the questions provided below:

1. Please explain, with textual support from the McKitrick reference (JX-5), discussed at column 6, lines 29-37 of the '373 patent, whether McKitrick discloses measuring serine sensitivity via a forward assay, a reverse assay, or both.

2. Please explain whether and why the specific conditions and methods of McKitrick (JX-5) and Bauerle (JX-37), discussed in the '373 patent specification, were not closely followed to establish infringement of the '373 patent. Please provide factual as well as legal support to explain whether the methods employed provide adequate proof of infringement.

3. Assuming prosecution history estoppel arising from the amendment of the term a "protein that has several amino acid deletions, substitutions, insertions, or additions as compared to SEQ ID NO:2" during prosecution of the '655 patent, is relevant to the scope of the term "said protein consists of the amino acid sequence of SEQ ID NO: 2" in claim 9, please explain whether or not any estoppel presumption is rebutted.

4. Please explain the relevance of Exhibit CX-487 (Random House Dictionary definition of "replace") on the claim construction of the term "replacing the native promoter" in the '655 patent claims and include a copy of the CX-487 exhibit.

In addition, in connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue one or more cease and desist orders that could result in the respondent(s) being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, *see Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843 (Dec. 1994) (Comm'n Op.).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

WRITTEN SUBMISSIONS: The parties to the investigation are requested to file written submissions on the questions identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy and bonding. Complainants are also requested to submit proposed remedial orders for the Commission's consideration. Complainants are also requested to state the date that the asserted patents expire and the HTSUS numbers under which the accused products are imported. Complainants are further requested to supply the names of known importers of the products at issue in this investigation.

Written submissions and proposed remedial orders must be filed no later than close of business on October 27, 2017. Reply submissions must be filed no later than the close of business on November 3, 2017. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit eight (8) true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of

Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the investigation number ("Inv. No. 337-TA-1005") in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, https://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf). Persons with questions regarding filing should contact the Secretary (202-205-2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel[1], solely for cybersecurity purposes. All non-confidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: October 12, 2017

[1] All contract personnel will sign appropriate nondisclosure agreements.

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 **NOTICE** has been served on the following parties, as indicated, on **October 12, 2017**.

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainants Ajinomoto Co., Inc. and Ajinomoto Heartland, Inc.:

Mareesa A. Frederick, Esq.
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001

☐ Via Hand Delivery
☐ Via Express Delivery
☒ Via First Class Mail
☐ Other:_____

On Behalf of Respondents CJ CheilJedang Corp., CJ America, Inc., and PT CheilJedang Indonesia:

Matthew J. Rizzolo, Esq.
ROPES & GRAY LLP
2099 Pennsylvania Ave., NW
Washington, DC 20006

☐ Via Hand Delivery
☐ Via Express Delivery
☒ Via First Class Mail
☐ Other:_____

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of **CERTAIN L-TRYPTOPHAN, L-TRYPTOPHAN PRODUCTS, AND THEIR METHODS OF PRODUCTION**	**Inv. 337-TA-1005**

NOTICE REGARDING ISSUANCE OF PUBLIC VERSION OF FINAL INITIAL DETERMINATION AND RECOMMENDED DETERMINATION ON REMEDY AND BOND

(September 1, 2017)

Administrative Law Judge Essex's final initial determination ("ID") in this investigation issued on August 11, 2017. Thereafter, the parties submitted proposed redactions of confidential business information for the public version of the ID. Neither party challenged the other's proposed redactions.

The undersigned has reviewed each party's proposed redactions, and has prepared a public version of the ID consistent with those redactions. The complete public version of the Initial Determination on Violation of Section 337 and Recommended Determination on Remedy and Bond is attached hereto.

SO ORDERED.

Charles E. Bullock
Chief Administrative Law Judge

ATTACHMENT A

PUBLIC VERSION

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**

INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND RECOMMENDED DETERMINATION ON REMEDY AND BOND

Administrative Law Judge Theodore R. Essex

(August 11, 2017)

Appearances:

For the Complainants Ajinomoto Co., Inc. and Ajinomoto Heartland, Inc.:

Mareesa A. Frederick, Esq., Thomas H. Jenkins, Esq., Barbara R. Rudolph, Esq., Hala S. Mourad, Esq., and Cora R. Holt, Esq. of Finnegan, Henderson, Farabow, Garrett & Dunner, LLP of Washington, D.C.

Charles E. Lipsey, Esq., and Alex K. Chung, Esq. of Finnegan, Henderson, Farabow, Garrett & Dunner, LLP of Reston, VA.

John D. Livingstone, Esq., M. David Weingarten, Esq., D. Alan White, Esq., Rachel Erdman, Esq., and Ashley M. Winkler, Esq. of Finnegan, Henderson, Farabow, Garrett & Dunner, LLP of Atlanta, GA.

For the Respondents CJ CheilJedang Corp., CJ America, Inc., and PT. CheilJedang Indonesia:

Matthew J. Rizzolo, Esq. of Ropes & Gray LLP of Washington, D.C.

Jesse J. Jenner, Esq. and Steven Pepe, Esq. of Ropes & Gray of New York, NY.

James F. Haley, Jr., Esq., Brian M. Gummow, Esq., of Haley Guiliano LLP of New York, NY.

For the Commission Investigative Staff:

(The Commission Investigative Staff did not participate in this investigation)

NOTICE OF INITIAL DETERMINATION

Pursuant to the Notice of Investigation, 81 Fed. Reg. 38736 (June 14, 2016), this is the Initial Determination in the matter of *Certain L-Tryptophan, L-Tryptophan Products, and their Methods of Production*, United States International Trade Commission Investigation No. 337-TA-1005. *See* 19 C.F.R. § 210.42(a).

It is held that no violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, has occurred in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain L-Tryptophan or L-Tryptophan products by reason of infringement of certain claims of U.S. Patent Nos. 6,180,373; and 7,666,655.

TABLE OF CONTENTS

TABLE OF ABBREVIATIONS

CDX	Complainant's demonstrative exhibit
CIB	Complainant's initial post-hearing brief
CPB	Complainant's pre-hearing brief
CPX	Complainant's physical exhibit
CRB	Complainant's reply post-hearing brief
CX	Complainant's exhibit
Dep.	Deposition
JX	Joint Exhibit
RDX	Respondent's demonstrative exhibit
RIB	Respondent's initial post-hearing brief
RPX	Respondent's physical exhibit
RPB	Respondent's Pre-hearing brief
RRB	Respondent's reply post-hearing brief
RRX	Respondent's rebuttal exhibit
RX	Respondent's exhibit
SIB	Staff's initial post-hearing brief
SRB	Staff's reply post-hearing brief
Tr.	Transcript

INITIAL DETERMINATION & RECOMMENDED DETERMINATION

I. BACKGROUND

A. Procedural History

By publication of a notice in the *Federal Register* on June 14, 2016, pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, the Commission instituted this investigation to determine:

> whether there is a violation of subsection (a)(1)(B)(ii) of section 337 in the importation into the United States, the sale for importation, or 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 one or more of claims 4, 7, 8 and 20 of the '655 patent and claim 10 of the '373 patent, and whether an industry in the United States exists or is in the process of being established as required by subsection (a)(2) of section 337.

81 Fed. Reg. 38736 ("NOI") (June 14, 2016). On July 14, 2016, the Administrative Law Judge ("ALJ") set a 16-month target date of October 16, 2017, and indicated that an evidentiary hearing would commence at 9:00AM on Monday, March 6, 2017, and conclude no later than Friday March 10, 2017. Order 4 (July 14, 2016). On December 1, 2016, the ALJ issued an initial determination extending the target date to December 18, 2017, and moved the evidentiary hearing to May 15–19, 2017. Order 8 (Dec. 1, 2016). There have been no additional changes to the target date or the scheduling of the evidentiary hearing in this matter.

On January 13, 2017, Respondents CJ CheilJedang Corp., CJ America, Inc., and PT. CheilJedang Indonesia (collectively, "CJ" or "Respondents"), moved for partial termination of this investigation with respect to U.S. Patent No. 6,180,373 ("the '373 Patent").[1] Mot. Dkt. No. 1005-008. On February 6, 2017, the ALJ denied CJ's motion. Order No. 11.

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[1] The '373 Patent is provided as JX-0001.

On March 10, 2017, Complainants Ajinomoto Co., Inc. and Ajinomoto Heartland, Inc. (collectively, "Ajinomoto" or "Complainants") moved for summary determination that they have satisfied the "economic prong" of the domestic industry requirement of 19 U.S.C. 1337(a)(2) and (3). Motion Dkt. No. 1005-016. On April 17, 2017, the ALJ issued an Initial Determination granting Ajinomoto's unopposed motion. Order No. 18. On May 17, 2017, the Commission issued a Notice of its determination not to review the Initial Determination granting summary determination to Ajinomoto that it had satisfied the economic prong of the domestic industry requirement. *See* EDIS Doc. ID 612005.

On March 10, 2017, Respondents moved for summary determination that the single asserted claim (claim 10) of the '373 Patent is invalid for failure to comply with the definiteness requirement of 35 U.S.C. § 112, second paragraph. Mot. Dkt. No. 1005-017. On April 21, 2017, the ALJ denied Respondents' motion due to the presence of genuine issues of material fact. Order No. 20 at 14.

On March 10, 2017 Respondents also moved for summary determination that claims 4, 7, 8, and 20 of U.S. Patent 7,666,655 ("the '655 patent")[2] are invalid for failure to comply with the definiteness requirement of 35 U.S.C. § 112, second paragraph. Mot. Dkt. No. 1005-018. On April 26, 2017, the ALJ denied Respondents' motion due to the presence of genuine issues of material fact. Order No. 22 at 13.

On March 10, 2017, Respondents also moved for summary determination that neither CJ's BestAmino™ brand L-tryptophan products made using production strains [redacted] (collectively, CJ's "Later Production Strains") nor the production of those products outside of the United States and their importation infringe any of the asserted claims of U.S.

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2 The '655 Patent is provided as JX-0003.

Patent 7,666,655 ("the '655 Patent"). Mot. Dkt. No. 1005-019. On April 28, 2017, the ALJ denied Respondents' motion due to the presence of genuine issues of material fact. Order No. 23 at 11.

On March 10, 2017, Respondents also moved for summary determination that neither CJ's BestAmino™ brand L-tryptophan products made using production strains [redacted] (collectively, CJ's "Earlier Production Strains") nor the production of these products outside of the United States and their importation infringe any of the asserted claims of the '655 Patent." Mot. Dkt. No. 1005-020. On April 28, 2017, the ALJ denied Respondents' motion due to the presence of genuine issues of material fact. Order No. 24 at 11.

On May 15, 2017, Complainants moved for partial termination of the investigation with respect to claims 1, 4, 7, and 8 of the '655 patent. Mot. Dkt. No. 1005-036. On May 16, 2017, the ALJ issued an Initial Determination granting Complainants unopposed motion and terminating the investigation as to claims 1, 4, 7, and 8 of the '655 patent. On June 2, 2017, the Commission issued a Notice of its determination not to review the Initial Determination granting termination of the investigation with respect to claims 1, 4, 7, and 8 of the '655 patent. *See* EDIS Doc. ID 613314.

The ALJ conducted an evidentiary hearing in this investigation beginning on Monday, May 15, 2017, and continuing through Thursday, May 18, 2017. Following the conclusion of the evidentiary hearing, the parties filed Initial Post-Hearing Briefs, and Reply Post-Hearing Briefs. Additionally, on June 9, 2017, Respondents moved to strike portions of Complainants' Initial Post-Hearing Brief and Proposed Findings of Fact for non-compliance with the ALJ's Ground Rules. Mot. Dkt. No. 1005-038. That motion included a request for a shortened response time.

The ALJ denied the request for a shortened response time and indicated that he would consider the issues raised by the motion to strike contemporaneously with his consideration of the parties' post-hearing briefs. *See* Order No. 32 at 3 (June 13, 2017).

The Commission Investigative Staff did not participate in this investigation.

As of the date of this Initial Determination, no other briefing addressing violation or remedy with respect to this investigation has been received by the ALJ.

B. The Parties

1. Complainants

The Complainants in this investigation are Ajinomoto Co., Inc. and Ajinomoto Heartland, Inc. (collectively, "Ajinomoto" or "Complainants"). Ajinomoto Co., Inc. is a corporation organized under the laws of Japan, with its principal place of business in Tokyo, Japan. CX-1531C QA17. Ajinomoto Heartland, Inc. is a wholly owned subsidiary of Ajinomoto Co.'s Ajinomoto Animal Nutrition Group. CX-1531C QA32. Ajinomoto Heartland is organized under the laws of the state of Delaware and has its principal place of business in Chicago, Illinois. CX-1531C at QA33.

2. Respondents

The Respondents in this investigation are CJ CheilJedang Corp., CJ America, Inc., and PT. CheilJedang Indonesia (collectively "CJ" or "Respondents"). CJ CheilJedang Corp. is a corporation organized under the laws of the Republic of Korea, with its principal place of business in Seoul, Republic of Korea. CIB at 5. PT CheilJedang Indonesia is a wholly owned subsidiary of CJ CheilJedang Corp., organized as an Indonesian entity with its principal place of business in Jakarta, Indonesia. CIB at 6. CJ America, Inc. is a wholly owned subsidiary of CJ

CheilJedang Corp., and is incorporated under the laws of the state of New York, with a principal place of business in Los Angeles, California. CIB at 6.

C. Asserted Intellectual Property & Technology

1. Technology

The technology of the asserted patents in this investigation generally relates to the amino acid L-tryptophan, and to methods for the production of L-tryptophan. *See* CIB at 6. Specifically, the inventions relate to the production of tryptophan through the use of bacteria that have been modified such that the bacteria produce greater amounts of tryptophan than they would in their unmodified state. *See* '373 Patent at Abstract; '655 Patent at Abstract.

2. U.S. Patent No. 6,180,373

U.S. Patent No. 6,180,373 is titled "Microorganisms for the Production of Tryptophan and Process for the Preparation Thereof." '373 Patent at p.1. Günter Wich and Walfred Leinfelder of Müchen, Germany, and Keith Backman of Bedford, Massachusetts are the named inventors. *Id.* The '373 Patent is directed to a "tryptophan producing strain of microorganism . . . selected from *E. coli* and Corynebacteria and [which] is tryptophan feedback resistant and serine feedback resistant." '373 Patent at Abstract. "A process for preparing this microorganism and a process for using this microorganism are disclosed" in the patent. *Id.*

Claim 10 is the only asserted claim of the '373 Patent in this investigation. Claim 10 provides:

> **10.** In a method for producing tryptophan comprising
>
> culturing a tryptophan producing strain of microorganism in a culture medium; and recovering the produced tryptophan from the culture medium; the improvement which comprises
>
> utilizing a tryptophan producing strain of microorganism selected from the group consisting of *E. coli* and Corynebacteria which

is tryptophan feedback resistant and serine feedback resistant and wherein said serine feedback resistance is by a mutation in a serA allele, where the mutated serA allele codes for a protein which has a K_i value for serine between 0.1 mM and 50 mM to produce said tryptophan; and

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.

'373 Patent at Cl. 10.

3. U.S. Patent No. 7,666,655

U.S. Patent No. 7,666,655 is titled "Escherichia Bacteria Transformed with the yddG Gene to Enhance L-amino Acid Producing Activity." '655 Patent at p.1. Maria Viacheslavovna Vitushkina, Vitaliy Arkadyevich Livshits, Sergei Vladimirovich Mashko, Vera Georgievna Doroshenko, Irina Vladimirovna Biryukova, Zhanna Iosifovna Katashkina, Aleksandra Yurievna Skorokhodova, and Alla Valentinovna Belareva, all of Moscow, Russia, are the named inventors. *Id.* The '655 Patent is directed to a "method of producing L-amino acid, such as . . . L-tryptophan [by] 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*." *Id.* at Abstract.

Claim 20 is the only remaining asserted claim of the '655 Patent in this investigation. Claim 20 provides:

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**.

'655 Patent at Cl. 20. For context independent claims 9 and 15 provide:

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 5fluoro-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., 1×SSC, 0.1% SDS and said protein has the activity to make the bacterium resistant to L-phenylalanine, fluoro-phenylalanine or 5fluoro-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.

'655 Patent at Cls. 9, 15.

D. 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." CIB at 7. For its part, CJ distinguishes the accused products into two categories based on whether the tryptophan products were created with CJ's "earlier" or "later" productions strains of bacteria. *See, e.g.,* RIB at 10. CJ defines "earlier production strains" to

mean [redacted]. *Id.*

II. MOTION TO STRIKE

On June 9, 2017, Respondents filed a motion to strike portions of Complainants' initial post-hearing brief and findings of facts. Mot. Dkt. No. 1005-038. With respect to the post-hearing brief, Respondents argue that various portions of the brief include new contentions that were not set forth in Complainants' pre-hearing brief, and thus should be deemed abandoned in accordance with Ground Rule 8.1(f). Mot. at 2. With respect to the findings of fact, Respondents argue that all of the proposed findings are improper because they are not adequately discussed in Complainants' post-hearing brief, as required by Ground Rule 11.4. *Id.*

Complainants address each category of allegedly new post-hearing argument in turn in its response to Respondents' motion. *See* Compls.' Opp. (June 21, 2017). The basic arguments in defense of each category are largely the same: the arguments were disclosed in the pre-hearing briefing, and to the extent they contain any new information, that information came out during the hearing because Respondents opened the door to it during cross-examination. *See, e.g., id.* at 1.

On July 6, 2017, Respondents filed a motion for leave to file a reply in support of its motion to strike. Mot. Dkt. No. 1005-040. Complainants filed a response opposing that request on July 17, 2017. Upon reviewing Respondents motion for leave to file a reply, the ALJ finds that Respondents have failed to establish good cause for such leave. Accordingly, Motion No. 1005-040 is **DENIED.**

After reviewing the allegedly improper arguments addressed in Respondents' primary motion, Motion No. 1005-038 is **DENIED-IN-PART**. Respondents' motion has several flaws.

First, much of the content Respondents complain of was developed, at least in part, during the hearing on re-direct in response to Respondents' cross-examination of Ajinomoto's witnesses—particularly Ajinomoto's experts. Ajinomoto cannot complain of unfair prejudice when it first opened the door to that testimony on cross-examination. This is particularly true in the case of the "corrections theory" that underlies a significant portion of Respondents' motion.

During cross-examination, Respondents questioned Dr. Stephanopoulos extensively on the effects that variations in assay conditions would have on the determination of K_i value. *See, e.g.,* Tr. 396:11–399:24. In response to that line of questioning, Dr. Stephanopoulos maintained a consistent position that, while varying assay conditions would affect the measured K_i value, they would not inhibit a person of ordinary skill in the art from comprehending the invention of the '373 Patent. In attempting to support that position, Dr. Stephanopoulos testified that variations in pH would alter the K_i values in predictable ways such that a person of ordinary skill could account for those variations. *See, e.g.,* Tr. At 480:4–484:10. This "corrections theory" is not an entirely new theory as Respondents contend, but rather is consistent with the point Dr. Stephanopoulos has always maintained: that the assay-dependent nature of K_i values does not render the invention incomprehensible to a person of ordinary skill in the art.[3] Of Ajinomoto's arguments related to the '373 patent that CJ seeks to strike, every single objection is based on the allegation that this "correction theory" is untimely and new. Consistent with the reasoning above, the ALJ finds that the "corrections theory" is not untimely, and, is admissible by virtue of the fact that CJ itself opened the door to Dr. Stephanopoulos's testimony during cross-examination. Ground Rule 8.1(f) precludes a party from raising a completely new argument in post-hearing

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[3] Whether this so-called "corrections theory" is probative with respect to the particular invalidity and infringement issues in this investigation is a separate matter from whether the argument should be stricken altogether.

briefing. It does not, however, provide a means to bury potentially unfavorable testimony elicited on cross-examination and re-direct during the evidentiary hearing.

Second, with respect to Ajinomoto's arguments related to the '655 patent, the ALJ finds that they are supported by the contentions in Ajinomoto's pre-hearing brief. CJ's arguments to the contrary appear to elevate form above substance, and seek to require verbatim identity between the arguments in the pre-hearing and post-hearing briefs. The ALJ declines to adopt such a strict rule. The purpose of ground rule 8.1(f), and all of the rules that require timely disclosure of contentions is to avoid gamesmanship and litigation-by-surprise. Here, the ALJ finds that Ajinomoto has not raised new arguments, but rather maintained its pre-hearing positions with additional support from the evidence presented at trial. Accordingly, CJ's motion to strike is **DENIED** insomuch as the arguments in Ajinomoto's post-hearing brief are concerned.

With respect to its proposed findings of fact, Ajinomoto points to a single page in its post-hearing brief where those findings are discussed. Opp. at 17 (citing RPB at 23). However, in reviewing that page from its brief, the only reference to the findings of fact appears in a single sentence, which cited all thirty-five of Ajinomoto's proposed findings of fact without any additional explanation. CIB at 23. Ground Rule 11.4 prohibits a party from presenting findings of fact without addressing them in its post-hearing briefing, yet that is exactly what Ajinomoto has done here.[4] Accordingly, Ajinomoto's proposed findings of fact are **STRICKEN**.

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[4] The ALJ notes that the findings of fact appear to re-hash a pre-trial evidentiary ruling in Ajinomoto's favor. While the ALJ instructed Ajinomoto that it could, in its post-hearing brief, note that certain testimony had been stricken, that could have been accomplished in as little as a sentence with a citation to the appropriate order or portion of the transcript. The submission of thirty-five proposed findings of fact is excessive, and looks very much like Ajinomoto is spiking the football on an evidentiary argument the ALJ has already disposed of.

III. IMPORTATION

Section 337 of the Tariff Act prohibits the importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignees of articles that infringe a valid and enforceable United States patent. *See* 19 U.S.C. § 1337(a)(1)(B). A complainant "need only prove importation of a single accused product to satisfy the importation element." *Certain Purple Protective Gloves*, 337-TA-500, Order No. 17 (September 23, 2004).

The parties have stipulated to the importation, sale for importation, and/or sale after importation of the accused products. CX-1454C. Further, there appears to be no dispute among the parties that CJ's activities with respect to both its earlier production strains and its later productions strains satisfy the importation requirement of Section 337. *See* CIB at 7; RIB at 4–5. As such, the ALJ finds that the importation requirement for purposes of Section 337 has been satisfied based on the parties' stipulation.

IV. JURISDICTION

In order to have the power to decide a case, a court or agency must have both subject matter jurisdiction and jurisdiction over either the parties or the property involved. *See Certain Steel Rod Treating Apparatus and Components Thereof*, Inv. No. 337-TA-97, Commission Memorandum Opinion, 215 U.S.P.Q. 229, 231 (1981). For the reasons discussed below, the ALJ finds the Commission has jurisdiction over this investigation.

Section 337 declares unlawful the importation, the sale for importation, or the sale after importation into the United States of articles that infringe a valid and enforceable United States patent by the owner, importer, or consignee of the articles, if an industry relating to the articles protected by the patent exists or is in the process of being established in the United States. *See* 19

U.S.C. §§ 1337(a)(1)(B)(i) and (a)(2). Pursuant to Section 337, the Commission shall investigate alleged violations of the Section and hear and decide actions involving those alleged violations.

As set forth *supra* in Section III, the importation requirement has been satisfied. Furthermore, Respondents have appeared and participated fully in this investigation and do not dispute the Commission's jurisdiction. *See* RIB at 4–5. Accordingly, the ALJ finds that Respondents have submitted to the jurisdiction of the Commission. *See Certain Miniature Hacksaws*, Inv. No. 337-TA-237, Pub. No. 1948, Initial Determination at 4, 1986 WL 379287 (U.S.I.T.C. Oct. 15, 1986) (unreviewed by Commission in relevant part). Thus, the ALJ finds that the Commission has jurisdiction under Section 337 to hear this investigation and has *in personam* jurisdiction over Respondents.

The ALJ also finds that the Commission has *in rem* jurisdiction over the products at issue by virtue of the fact that accused products and components have been imported into the United States. *See Enercon*, 151 F.3d at 1380; *Sealed Air Corp. v. International Trade Comm'n*, 645 F.2d 976, 985 (C.C.P.A. 1981) ("An exclusion order operates against goods, not parties, and therefore is not contingent upon a determination of personal jurisdiction over a foreign manufacturer.").

V. CLAIM CONSTRUCTION

A. Legal Standard

Pursuant to the Commission's Notice of Investigation, this investigation is a patent-based investigation. *See* 81 Fed. Reg. 38736 (July 20, 2015). Accordingly, all of the unfair acts alleged by Ajinomoto relate to the infringement of the '337 or the '655 patents. Consistent with established precedent, the consideration of a patent infringement claim necessarily involves the interpretation of one or more asserted patent claims, which define the scope of the exclusionary

right possessed by the patent holder. *See Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1476 (Fed. Cir. 1998) ("The claims are concise statements of the subject matter for which the statutory right to exclude is secured by the grant of the patent."). This interpretive action is commonly referred to as claim construction.

The ultimate construction of a patent claim is a question of law. However, that legal determination may be based upon subsidiary findings of fact. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1337 (Fed. Cir. 2015) (explaining that "the Supreme Court held that the ultimate construction of a claim term is a question of law, subject to de novo review, and that underlying subsidiary fact findings are subject to clear error review."). Claim construction is a required first step in determining whether a respondent has infringed an asserted patent claim, *see Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1376 (Fed. Cir. 2005) ("Courts determine patent infringement by construing the patent's claims and then applying that construction to the accused process or product."), and may also be a necessary preliminary step in considering certain types of invalidity challenges, *see, e.g., TI Grp. Auto. Sys. (N. Am.), Inc. v. VDO N. Am., L.L.C.*, 375 F.3d 1126, 1139 (Fed. Cir. 2004) ("Our validity analysis is a two-step procedure: The first step involves the proper interpretation of the claims. The second step involves determining whether the limitations of the claims as properly interpreted are met by the prior art." (internal quotation marks omitted)).

"The words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history." *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365–67 (Fed. Cir. 2012) (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc)). In construing claims, the ALJ should first look to intrinsic evidence, which consists of the

language of the claims, the patent's specification, and the prosecution history, as such evidence "is the most significant source of the legally operative meaning of disputed claim language." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996); *see also Bell Atl. Network Servs., Inc. v. Covad Comm'n. Group, Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001). The words of the claims "define the scope of the patented invention." *Covad Comm'n.*, 262 F.3d at 1582. And, the claims themselves "provide substantial guidance as to the meaning of particular claim terms." *Phillips*, 415 F.3d at 1314. It is essential to consider a claim as a whole when construing each term, because the context in which a term is used in a claim "can be highly instructive." *Id.* "[C]laim terms are presumed to be used consistently throughout the patent, such that the usage of the term in one claim can often illuminate the meaning of the same term in other claims." *Research Plastics, Inc. v. Federal Pkg. Corp.*, 421 F.3d 1290, 1295 (Fed. Cir. 2005). In addition:

> in clarifying the meaning of claim terms, courts are free to use words that do not appear in the claim so long as the resulting claim interpretation . . . accord[s] with the words chosen by the patentee to stake out the boundary of the claimed property.

Pause Tech., Inc. v. TIVO, Inc., 419 F.3d 1326, 1333 (Fed. Cir. 2005).

"Idiosyncratic language, highly technical terms, or terms coined by the inventor are best understood by reference to the specification." *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1287 (Fed. Cir. 2010). While the ALJ construes the claims in light of the specification, limitations discussed in the specification may not be read into the claims. *See id.*; *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1288 (Fed. Cir. 2009). Some claim terms do not have particular meaning in a field of art, in which case claim construction involves little more than applying the widely accepted meaning of commonly understood words. *Phillips*, 415 F.3d at 1314. Under such

circumstances, a general purpose dictionary may be of use.[5] *Id.; see also Advanced Fiber Tech. (AFT) Trust v. J & L Fiber Servs., Inc.*, 674 F.3d 1365, 3 (Fed. Cir. 2012).

Claim terms should generally be given their ordinary and customary meaning except "1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Thorner*, 669 F.3d at 1365. "To act as its own lexicographer, a patentee must 'clearly set forth a definition of the disputed claim term . . . .'"[6] *Id.* (quoting *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). And "[w]here the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside . . . the patent," even if the terms might otherwise be broad enough to cover that feature. *Id.* at 1366 (internal citation omitted). In other words, the intrinsic evidence must "clearly set forth" or "clearly redefine" a claim term so as to put one reasonably skilled in the art on notice that the patentee intended to so redefine the claim term. *Bell Atl.*, 262 F.3d at 1268. For example,

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5 Use of a dictionary, however, may extend patent protection beyond that to which a patent should properly be afforded. There is also no guarantee that a term is used the same way in a treatise as it would be by a patentee. *Phillips*, 415 F.3d at 1322.

6 Notwithstanding the requirement that a patentee must act *clearly* to set forth her own definition for a given claim term, there need not be an *in hac verba* expression of intent to act as lexicographer. *Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1330 (Fed. Cir. 2012). Intent to act as lexicographer "may be inferred from clear limiting descriptions of the invention in the specification or prosecution history." *Id.* The Federal Circuit has rejected any reading of *Thorner* that would require *explicit* redefinition to avoid the application of a claim term's ordinary meaning. *Trustees of Columbia Univ. in City of N.Y. v. Symantec Corp.*, 811 F.3d 1359, 1363 (Fed. Cir. 2016) ("Our case law does not require explicit redefinition or disavowal."). The same holds true for the disavowal of claim scope. *Id.*

disclaiming the ordinary meaning of a claim term—and thus, in effect, redefining it—can be affected through "repeated and definitive remarks in the written description." *Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1374 (Fed. Cir. 2008) (citing *Watts v. XL Sys.*, 232 F.3d 877, 882 (Fed. Cir. 2000)); *see, e.g., SafeTCare Mfg., Inc. v. Tele–Made, Inc.*, 497 F.3d 1262, 1270 (Fed. Cir. 2007) (finding disclaimer of "pulling force" where "the written description repeatedly emphasized that the motor of the patented invention applied a pushing force").

When the meaning of a claim term is uncertain, the specification is usually the first and best place to look, aside from the claim itself, in order to find that meaning. *Phillips*, 415 F.3d at 1315. The specification of a patent "acts as a dictionary" both "when it expressly defines terms used in the claims" and "when it defines terms by implication." *Vitronics*, 90 F.3d at 1582. For example, the specification "may define claim terms by implication such that the meaning may be found in or ascertained by a reading of the patent documents." *Phillips*, 415 F.3d at 1323. "The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Id.* at 1316. However, as a general rule, particular examples or embodiments discussed in the specification are not to be read into the claims as limitations. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 Fed. Cir. 1995).

The prosecution history "provides evidence of how the inventor and the PTO understood the patent." *Phillips*, 415 F.3d at 1317; *see also Pass & Seymour, Inc. v. Int'l Trade Comm'n*, 617 F.3d 1319, 1327 (Fed. Cir. 2010) (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1478 (Fed. Cir. 1998)). The ALJ may not rely on the prosecution history to construe the meaning of the claim to be narrower than it would otherwise be unless a patentee limited or surrendered claim scope through a clear and unmistakable disavowal. *Trading Tech. Int'l, Inc. v.*

eSpeed, Inc., 595 F.3d 1340, 1352 (Fed. Cir. 2010) (internal citations omitted); *Vitronics*, 90 F.3d at 1582–83.) For example, the prosecution history may inform the meaning of the claim language by demonstrating how an inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it otherwise would be. *Vitronics*, 90 F.3d at 1582-83; *see also Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005) ("The purpose of consulting the prosecution history in construing a claim is to exclude any interpretation that was disclaimed during prosecution."); *Microsoft Corp. v. Multi-tech Sys., Inc.*, 357 F.3d 1340, 1350 (Fed. Cir. 2004) ("We have held that a statement made by the patentee during prosecution history of a patent in the same family as the patent-in-suit can operate as a disclaimer."). The prosecution history includes the prior art cited, *Phillips*, 415 F.3d at 1317, as well as any reexamination of the patent, *Intermatic Inc. v. Lamson & Sessions Co.*, 273 F.3d 1355, 1367 (Fed. Cir. 2001).

Differences between claims may be helpful in understanding the meaning of claim terms. *Phillips*, 415 F.3d at 1314. "A claim construction that gives meaning to all the terms of a claim is preferred over one that does not do so." *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005). In addition, the presence of a specific limitation in a dependent claim raises a presumption that the limitation is not present in the independent claim. *Phillips*, 415 F.3d at 1315. This presumption of claim differentiation is especially strong when the only difference between the independent and dependent claim is the limitation in dispute. *SunRace Roots Enter. Co., v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

Finally, when the intrinsic evidence does not establish the meaning of a claim, the ALJ may consider extrinsic evidence, *i.e.*, all evidence external to the patent and the prosecution history, including inventor testimony, expert testimony, and learned treatises. *Phillips*, 415 F.3d

at 1317. Extrinsic evidence may be helpful in explaining scientific principles, the meaning of technical terms, and terms of art. *Vitronics*, 90 F.3d at 1583; *Markman*, 52 F.3d at 980. However, the Federal Circuit has generally viewed extrinsic evidence as less reliable than the patent itself and its prosecution history in determining how to define claim terms. *Phillips*, 415 F.3d at 1318. With respect to expert witnesses, any testimony that is clearly at odds with the claim construction mandated by the claims themselves, the patent specification, and the prosecution history should be discounted. *Id.*

B. Level of Skill in the Art

Because patents are interpreted from the position of a person of ordinary skill in the art, the ALJ must necessarily establish what the ordinary level of skill in the art is. With respect to the '373 patent, Respondents assert that the level of skill of a person of ordinary skill in the art is not in dispute. RIB at 6. Respondents submit that the ordinary level of skill relevant to the art of the '373 Patent is:

> a Ph.D. in biochemistry, microbiology, bacteriology, or an equivalent field, along with at least five years of experience in engineering bacteria for the biosynthesis of compounds, including amino acids. This experience would include mutagenesis of bacteria, recombinant DNA technology, enzymology (including enzyme isolation and activity measurements), and bacterial culture analysis. A POSITA would also have had access to and the ability to consult with other scientists having related and/or complementary knowledge and experience in the areas of biochemistry, microbiology, bacteriology, enzymology, enzyme kinetics, and process engineering of microorganisms.

RIB at 6 (internal citation omitted).

For their part, Complainants submit that the parties positions on the level of ordinary skill in the art of the '373 patent "differ slightly." CIB at 60–61. However, Complainants fail to

elaborate on what those differences are, and instead refer back to their pre-hearing brief.[7] Nonetheless, Complainants assert that their positions, as well as those of its expert, Dr. Stephanopoulos, are the same under either party's definition of ordinary skill in the art. CIB at 60–61. Respondents' expert, Dr. Grant, essentially echoes the same sentiment with respect to the level of skill in the art proposed by Dr. Stephanopoulos. RX-0221C at QA24–27. Accordingly, the ALJ adopts the level of skill proposed by Respondents and duplicated above for the '337 patent. This definition of the level of ordinary skill in the art of the '337 patent is supported by the evidence submitted by Respondents, and not subject to any meaningful dispute by the Complainants. *See* RX-0221C (Grant WS) at QA21, QA23.

With respect to the '655 patent, Respondents again assert that there is no meaningful dispute among the parties as to the level of ordinary skill in the art. RIB at 42. And again, Complainants demur to their prehearing brief without any additional elaboration. CIB at 8. As with the '373 patent, Complainants take the position that their arguments are valid irrespective of whether the Respondents' or their own definition of the level of ordinary skill in the art is adopted. *Id.* Given that neither party has identified a particular dispute with respect to the level of ordinary skill in the art of the '655 patent, the ALJ adopts that definition proposed by Respondents, which has evidentiary support in the record. *See* RX0223C (Roepe WS) at QA22. That definition is:

> a person of ordinary skill in the art to which the '655 Patent pertains would have a Ph.D degree in biochemistry, biochemical engineering, microbiology, chemical engineering, or an equivalent field along with at least five years of experience in metabolic engineering of microorganisms.

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[7] Incorporating elements of a pre-hearing brief by reference into a post-hearing brief is strongly disfavored. Referring to a page of briefing with a single sentence simply amounts to an end-run around the page limits set by the ALJ. While not explicitly forbidden in the ALJ's Ground Rules at the time of this investigation, litigants would be well-advised not to adopt incorporation by reference as a regular approach to briefing before the ALJ.

Id.

C. U.S. Patent No. 6,180,373

With respect to the '373 patent, the parties dispute the construction of the term "K_i value." The parties' constructions are as follows:

CJ's Construction	Ajinomoto's Construction
"the concentration of an inhibiting substance for an enzyme which reduces the activity of the enzyme to 50%, which may also be called IC_{50}."	"the concentration of inhibitor that inhibits the activity of the enzyme by 50%."

CIB at 61; RIB at 7. The only apparent dispute here is whether the definition of "K_i value" should include a statement that the term is synonymous with "IC_{50}."[8] Respondents submit that "K_i value" and "IC_{50}" are interchangeable, and rely on the testimony of their expert, Dr. Grant, and the testimony of Complainants' expert, Dr. Stephanopoulos. RIB at 7; *see also* RX-0221C (Grant WS) at QA96; CX-1529C (Steph. WS) QA218–19, 281; Tr. 477–481. Complainants agree that "K_i value" may be called "IC_{50}" in some instances, but argue that in other instances the two may differ. CIB at 61 (citing RX-221C QA96).

After reviewing the evidence cited by the parties, the ALJ declines to include a statement that "K_i value" and "IC_{50}" are synonymous in the construction of "K_i value." Respondents' own expert, Dr. Grant, indicates in his witness statement that the two terms are not always equivalent, *see* RX-221C QA96, and to the extent Dr. Stephanopoulos used the terms interchangeably, it was in response to specific questions about Dr. Grant's use of IC_{50}, CX-1529C (Steph. WS) QA218–

[8] Complainants' brief suggests that this dispute is an issue of giving the term its plain and ordinary meaning versus giving it some other meaning. *See* CIB at 61 ("the plain and ordinary meaning is sufficient to define the claim term "K_i value."). That suggestion misses the mark. No party has suggested that "K_i value" should be construed according to anything other than its plain and ordinary meaning. The dispute here is what that plain and ordinary meaning actually is, and specifically whether it includes recognition of "K_i value" and "IC_{50}" as synonyms.

19, or in response to questions from counsel during cross-examination that used "IC_{50}," Tr. 477–481. Moreover, Respondents have not identified any intrinsic evidence that supports including blanket equivalence to "IC_{50}" in the construction of "K_i value." Accordingly, the evidence presented does not support CJ's proposed construction. Thus, the ALJ construes "K_i value" to mean: "the concentration of an inhibiting substance for an enzyme which reduces the activity of the enzyme to 50%."

D. U.S. Patent No. 7,666,655

With respect to the '655 patent, the parties dispute the construction of two terms: 1) "recombinant *Escherichia coli* bacterium" and 2) "replacing the native promoter."

1. "recombinant *Escherichia coli* bacterium"

The parties present the following competing constructions for recombinant *Escherichia coli* bacterium:

Respondents' Construction	Complainants' Construction
"an *Escherichia coli* bacterium modified by recombinant DNA techniques (i.e. transforming the bacterium with DNA encoding a protein, replacing the native promoter that precedes the DNA encoding a protein on the chromosome of the bacterium with a more potent promoter, or introducing multiple copies of DNA encoding a protein) to enhance YddG activity"	"an *Escherichia coli* bacterium that is man-made, and not a product of nature"

RIB at 46; CIB at 9. The crux of the dispute is whether "recombinant" should be construed to exclude *E. coli* bacteria produced by chemical mutagenesis from the scope of claim 20 in the '655 patent. Complainants argue that "recombinant" should be construed simply to mean man-made, largely because the claim term was added during prosecution to overcome a subject-matter eligibility issue raised by the examiner. CIB at 10–11. Respondents, on the other hand, argue that the plain and ordinary meaning of "recombinant" covers only those techniques of genetic

modification that are based on the combination of DNA molecules of different origins. RIB at 46.

The ALJ finds that Respondents' construction is not supported by the intrinsic evidence, and that the extrinsic evidence is largely unhelpful as it both supports and refutes Respondents' construction. Specifically, claims 9 and 15, upon which asserted claim 20 relies for the description of the claimed bacterium, include additional terms that cover the limitations CJ submits are included within "recombinant." *See, e.g.,* '655 Patent at Cl. 15. For example, claim 15 recites:

> 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.

Id. (emphasis added); *see also* '655 Patent at Cl. 9 (reciting similar limitations). Construing "recombinant" to incorporate these other limitations would result in internal redundancy.

The specification also indicates that site-directed mutagenesis can be used to achieve deletion, insertion, substitution, or addition of an amino acid residue in the DNA of the invention. '655 Patent at 5:18–23. Thus, the specification supports a construction of recombinant that includes site-directed mutagenesis as a technique for effecting those DNA modifications. The ALJ agrees with Respondents that, as a matter of law, a patentee need not claim all that is disclosed in the specification. *See* RIB at 48 (citing *TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.*, 529 F.3d 1364, 1373 (Fed. Cir. 2008)). Thus, the fact that site-directed mutagenesis is disclosed in the specification is not itself dispositive of the meaning of "recombinant" in claim 20. Nonetheless, not just claim 20, but *every* independent claim of the '655 patent is directed to a recombinant bacterium. Thus, the practical effect of Respondents' construction, if accepted,

would be disavowal of bacteria created via mutagenesis throughout the entire patent. This interpretation is undercut by the specification's clear statement that the invention includes DNA modified by site-directed mutagenesis.[9]

In addition to the language of claim 20 and the specification, the prosecution history also does not support such a construction. As Complainants note, the addition of the phrase "recombinant" during prosecution appears to have been motivated by the need to distinguish the bacteria of the '655 patent from patent-ineligible naturally occurring bacteria. CIB at 10–11. There is no indication that the amendment was intended to do more than that, and certainly not the clear indication needed to effect a disavowal of bacteria created through site-directed mutagenesis.

With respect to the extrinsic evidence presented by Respondents, the ALJ acknowledges that these sources do tend to distinguish recombinant DNA techniques from chemical mutagenesis. *See* RIB at 46–47 (citing RX-0183 (Cell and Molecular Biology Chapter 17 (1996)) at 758, left col.; RX-0250; RX-0182 (Adrio *et al.*) at 116, left col.). However, as Complainants point out, other extrinsic evidence of record uses recombinant in a way that includes site-directed mutagenesis. CIB at 11–12 (citing JX-98C at 158:13-17; CX-1894 at 7:1-12). At best, these extrinsic references raise the possibility that a person of ordinary skill in the art, *without the context of the intrinsic evidence*, might define recombinant to exclude bacteria modified by site-directed mutagenesis. However, the relevant inquiry is not what a person of ordinary skill in the art would understand "recombinant" to mean in a vacuum, but rather what his understanding would be in the context of the patent and its prosecution history. Here, in the absence of any

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[9] This is not to suggest that it is never correct to construe a claim term in a way that excludes a disclosed embodiment. Rather, here, construing "recombinant" to exclude bacteria modified through mutagenesis is not supported by the whole of the evidence in the record.

intrinsic evidence supporting the exclusion of bacteria modified by site-directed mutagenesis from the definition "recombinant *E. coli* bacterium," equivocal extrinsic evidence alone is not sufficient to support such a construction. Accordingly, the ALJ construes "recombinant *Escherichia coli* bacterium" to mean: "an *Escherichia coli* bacterium that is man-made, and not a product of nature."

For completeness, the ALJ notes that CJ's proposed construction for this term also included a limitation restricting "recombinant *E. coli* bacteria" to those that have been modified to enhance YddG activity. The parties' briefing treats this limitation as secondary to the dispute about mutagenesis, and in fact, the YddG enhancement limitation is not addressed at all in CJ's initial post-hearing brief. The only support CJ provides for this limitation is in the form of extrinsic evidence, which upon review the ALJ finds does not support CJ's proposed limitation. *See* RRB at 6 (citing RX-0186C (AJ's February 7, 2017 Interrogatory Responses) at 74 and 150; Tr. at 352–355). Both claims 9 and 15, which are incorporated into claim 20 by reference, include terms that explicitly define a requirement to enhance protein activity. *See* '655 Patent at Cls. 9, 15. The ALJ declines to render those limitations superfluous by incorporating them into the definition of "recombinant *E. coli* bacterium," particularly in the absence of any intrinsic evidence supporting such incorporation.

2. "replacing the native promoter"

The parties present the following competing constructions for "replacing the native promoter:

Respondents	Complainants[10]
"removing the native upstream region of the *yddG* gene and inserting one of a class of promoters that controls expression of a different gene."	plain and ordinary meaning, i.e., altering the native promoter upstream of the *yddG* gene to create a more potent promoter, which includes but is not limited to various alteration methods well known in the art and also those described in the '655 patent, including complete replacement of the Escherichia chromosomal sequences upstream of the *yddG* gene, as well as changes to a portion or portions of such sequences made by, for example, mutagenesis.

RIB at 42. Here again, the practical consequence of this dispute is whether mutagenesis falls within the scope of this claim term. Respondents argue that "replacing the native promoter" refers to a specific recombinant technique that involves first removing a portion of the *yddG* gene and then inserting a new promoter in its place. *See* RIB at 42–43. By contrast, Complainants seek a much broader definition, which would encompass, without limitation, mutagenesis, as well as "many methods known in the art." CIB at 12.

The primary thrust of Respondents' argument is that Ajinomoto disclaimed the broad definition it seeks for "replacing the native promoter" by amending its claims during prosecution to overcome an enablement rejection. *See* RIB at 43–45. Respondents' other arguments include reliance on a general purpose dictionary, and assertions that Ajinomoto has changed its position on the construction of this term multiple times throughout this investigation. *See id.* at 43.

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[10] Complainants did not provide a clear definition for this term in their briefing. Rather, Complainants proposed the term be given its plain and ordinary meaning, and then gave non-limiting examples of what would be included in the plain and ordinary meaning. *See* CIB at 12–13. As noted *supra*, stating that a term is to be given its plain and ordinary meaning does little to illuminate the more pertinent question of what that meaning actually is. For the sake of framing the argument, the ALJ has reproduced the description of Complainants' position provided in Respondents' brief, which the ALJ finds to be a fair representation of Ajinomoto's position.

Complainants dispute Respondents' reading of the prosecution history, and argue that, while it did amend the relevant claim language by substituting the word "altering" for "replacing," that change should not now restrict the breadth of "replacing the native promoter." *See* CIB at 14–16. To summarize, Complainants assert that the purpose of the amendment was to narrow the phrase "expression regulation sequence," and that the change from "altering" to "replacing" carried no significant purpose. *See id.*. Complainants also argue that a broad definition for "replacing the native promoter" is appropriate because the plain claim language and the specification support a broad definition of "replacing," *see id.* at 13, and because a skilled artisan would have recognized that there were many ways to replace a native promoter with a more potent promoter, including by mutagenesis, *see id.* at 13–14.

While much of the parties' arguments revolve around prosecution history disclaimer and the disavowal of claim scope, those arguments presuppose that the plain and ordinary meaning of "replacing the native promoter" to a person of ordinary skill in the art in the context of the intrinsic evidence is broad enough to cover any method of changing the native promoter to a more potent promoter. If the plain and ordinary meaning is not that broad in the first place, whether the standard for disavowal has been met is irrelevant. Consistent with the guidelines laid out in *Phillips*, construction of "replacing the native promoter" must begin with the claim language itself. *See Phillips*, 415 F.3d at 1314.

Like the previous term, the relevant claim language actually appears in independent claims 9 and 15, which claim 20 refers to as a means of defining the structure of the bacterium to be created by its claimed method. *Compare* '655 Patent at Cl. 20 *with* Cls. 9, 15. The usage of the term is substantially similar between claims 9 and 15, and the ALJ will use claim 15 as an exemplar for this portion of the analysis. Claim 15 provides:

> **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, . . . 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.

'655 Patent at Cl. 15 (emphasis added). "Replacing the native promoter" does not appear in isolation, but rather as one of three options for enhancing the activity of the protein in a cell of the bacterium. Where, as here, the patentee has used different terms in the same claim, the ALJ presumes that those terms have distinct meanings. Accordingly, the ALJ finds that it would be inappropriate to give "replacing" a construction so broad that it would encompass either "transform[ing]" or "introduc[ing]," both of which have distinct meanings in the claim.

With respect to the specification, the phrase "replacing the native promoter" does not appear. *See generally* '655 Patent at Spec. This is unsurprising given that this claim language came about through amendment, and was not submitted contemporaneously with the original specification. JX-0004.0610–11. Instead, in describing the inventions disclosed in the '655 Patent, the specification describes a bacterium:

> . . . wherein the activity of the protein as defined in (A) or (B) is enhanced by transformation of the bacterium with a DNA coding for the protein as defined in (A) or (B), or by **alteration of expression regulation sequence of said DNA on the chromosome of the bacterium**.

'655 Patent at 3:11–15 (emphasis added). The emphasized portion of this passage corresponds to the original claim language that was amended to recite "replacing the native promoter which precedes the DNA on the chromosome of the bacterium with a more potent promoter." '655

Patent at Cl. 15. The closest analog to the "replacing the native promoter" claim language in the specification appears to be:

> 4) The bacterium according to the above bacterium, wherein native promoter of said DNA is substituted with more potent promoter.

'655 Patent at 3:19–21. Here, rather than use the term "replacing," the specification uses the term "substituted." This is one of only two instances in the specification where enhancement of protein activity via the replacement of a native promoter with a more potent promoter is discussed. The other instance introduces a discussion of the state of the art with respect to methods for determining promoter strength, and provides as follows:

> On the other hand, the enhancement of gene expression can be achieved by locating the DNA of the present invention under control of more potent promoter instead of the native promoter.

'655 Patent at 6:12–15. Taken together, these passages tend to suggest that, at a minimum, "replacing the native promoter" should be construed to include replacement by substitution, but they fail to give any clear indication that the scope of the term goes no further. Indeed, it is inappropriate to read the substitution language of the specification into claim 15 as an explicit limitation, and the second passage suggests that the patentee contemplated a broad scope of methods for "locating the DNA of the present invention under control of more potent promoter instead of the native promoter." '655 Patent at 13–15.

Considering the prosecution history of the '655 patent, several passages are relevant to the construction of "replacing the native promoter:" First is a non-final office action from the patent examiner rejecting certain pending claims for lack of enablement:

> Claims 2 and 3 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement. The specification, while being enabling for *Escherichia* strains wherein the native promoter for the DNA encoding SEQ ID NO: 2 has been changed by substitution with a more potent promoter, does not reasonably provide enablement for the genus of L-amino acid producing bacterium wherein the activity of proteins described by SEQ ID NO: 2 and related sequences is increased

due to specific alterations within the chromosomal expression regulation sequence for DNA encoding said proteins. The specification does not enable a person skilled in the art to which the invention pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The ability to make all *Escherichia* bacteria included in the scope of these claims would require undue experimentation.

* * *

The instant specification teaches how to select *Escherichia* bacteria that have an increased production of L-amino acids, and the art teaches how to mutagenize chromosomal DNA and how to characterize the mutations in the DNA. However, neither the specification nor the art contain any examples of how to specifically change endogenous *Escherichia* chromosomal expression regulation sequences for the DNA encoding proteins described by SEQ ID NO: 2, or related sequences, such that the activity of said proteins in the bacteria is increased. The art and the specification provide enablement for inserting a known promoter in the chromosomal DNA to upregulate the expression of the DNA encoding SEQ ID No: 2; however, neither the specification nor the art enable making specific changes to expression regulation sequences for DNA encoding SEQ ID No: 2 and related sequences on the chromosome of *Escherichia* bacteria. The art and specification lack a detailed description of the structure of the instant endogenous expression regulation sequences, and they lack any guidance on how to alter such sequences such that DNA expression is increased; therefore, to make the instant bacteria with altered expression regulation sequences would be unpredictable.

While the prior art combined with the instant specification describe means for identifying *Escherichia* bacteria that have increased L-amino acid production due to alteration in the expression regulation sequence for SEQ ID NO:2 and related sequences, these methods do not enable one of skill in the art to make all, or a relevant portion of, the *Escherichia* bacteria within the scope of the claims. The ability to find an *Escherichia* bacteria with an altered expression regulation sequence for the aforementioned DNA that increases L-amino acid production, is not equivalent to the ability to make an *Escherichia* bacteria with an altered expression regulation sequence as required by the statute (i.e., "make and use"). No description in the specification or the art provides the structure of the expression regulation sequence and the particular nucleic acid residues that are important within the sequence such that the activity of said proteins, and L-amino acid production, are enhanced. Thus, one of skill in the art would be unable to predict the structure of the other members of the genus in order to make such members. Therefore, the instant claims are not enabled to the full extent of their scope.

JX-0004.0375–77. In response to this rejection, the patentee made the following amendment:

The bacterium according to claim 1, wherein ~~said activities of proteins as defined as~~ the activity of said protein defined in (A) or (B) is enhanced by:

> a) transformation of said bacterium with DNA ~~coding for the protein as defined in (A) or (B)~~ encoding said protein and expressing the protein in said bacterium, or
>
> b) ~~by alteration of expression regulation sequence of said~~ replacing the native promoter that precedes a DNA encoding said protein on the chromosome of the bacterium with a more potent promoter.

JX-0004.0610–11. The patentee explained this amendment as follows:

> Applicants have amended Claim 2 consistent with the Examiner's recognition that the specification enables *Escherichia* strains wherein the native promoter for the DNA encoding SEQ ID NO: 2 has been changed by substitution with a more potent promoter. Specifically, the phrase "by alteration of expression regulation sequence of said DNA on the chromosome of the bacterium" has been replaced with the phrase "replacing the native promoter that precedes a DNA encoding said protein on the chromosome of the bacterium with a more potent promoter."

JX-0004.0623. Taken as a whole, the ALJ finds that the prosecution history supports the conclusion that the word "replacing" in "replacing the native promoter" was understood by the patentee and the examiner to be synonymous with substituting or inserting. Ajinomoto's proposed construction, which encompasses any method of altering the native promoter that results in a more potent promoter, not only lacks support, but is flatly contradicted by the patentee's statement that the purpose of its amendment was to obviate the enablement rejection by aligning the claim language with the examiner's recognition that substitution of a native promoter with a more potent promoter was enabled.

Further, Ajinomoto's suggestion that the ALJ should disregard the fact that its amendment includes changing the word "alteration" to "replacing" is unpersuasive. Ajinomoto has offered no support for the proposition that the ALJ can or should arbitrarily ignore one portion of a claim amendment in favor of another. Rather, Ajinomoto attempts to on rely on cases where the prosecution history was devoid of any connection to the limitation at issue. *See Cadence Pharms. Inc. v. Excel Pharm Sci. Inc.*, 780 F.3d 1364, 1369 (Fed. Cir. 2015); *Aria Diagnostics, Inc. v. Sequenom, Inc.*, 726 F.3d 1296, 1302 (Fed. Cir. 2013). But here, the

examiner's rejection clearly articulated two enablement flaws in the claim: "The art and specification lack a detailed description of the structure of the instant endogenous expression regulation sequences, **and** they lack any guidance on how to alter such sequences such that DNA expression is increased." JX-0004.0375–77 (emphasis added). The examiner also explicitly indicated that both substitution of a native promoter for a more potent promoter, or insertion of a more potent promoter was enabled. *Id.*

In sum, the examiner articulated two flaws with the claim as originally filed—the first being the broad reference to all expression regulation sequences, and the second being the nonspecific reference to any method of alteration. In order to overcome the examiner's enablement rejection, the patentee amended the claim to recite "replacing" and not "alteration," and explicitly stated that the purpose of the amendment was to bring it into line with the "Examiner's recognition that the specification enables *Escherichia* strains wherein the native promoter for the DNA encoding SEQ ID NO: 2 has been changed by substitution with a more potent promoter." JX-0004.0623. Ajinomoto cannot simply sweep its prior explanation of the purpose for its amendment under the rug.

As noted above, construing "replacing" such that it is synonymous with "substituting" or "inserting" also finds support in the specification itself, wherein one of only two discussions of native and more potent promoters is in the context of substituting one for the other. The other discussion of native and more potent promoters in the specification does not conflict with this reading.

Finally, the ALJ does not agree that this is necessarily a case of prosecution disclaimer. Indeed, the ALJ finds that the plain and ordinary meaning of "replacing the native promoter" to a person of ordinary skill in the art and in the context of the intrinsic evidence is "removing the

native upstream region of the *yddG* gene and inserting one of a class of promoters that controls expression of a different gene." However, even if the plain and ordinary meaning were broader and encompassed any known method altering the native promoter, as Ajinomoto suggests, the ALJ finds that the evidence in the prosecution history shows the type of clear and express intent to narrow that broad meaning for the purpose of overcoming the examiner's enablement rejection.

VI. U.S. PATENT NO. 6,180,373

A. Standing

As an initial matter, CJ asserts that Ajinomoto lacks standing to assert the '373 patent in this investigation. *See* RIB at 39. Specifically, CJ argues that Dr. Backman—one of the co-inventors of the '373 patent—lacked the right to assign his work to Consortium Für Elektrochemische Industrie GMBH ("the Consortium"), which in turn assigned its rights in the '373 patent to its parent Wacker, which ultimately assigned its rights in the '373 patent to Ajinomoto. *Id.* CJ presents its argument primarily as a failure of proof on the part of Ajinomoto. *See id.* It does, however, point to a handful of exhibits that it argues call into question Dr. Backman's legal ability to assign his rights to the Consortium. *See id.* [redacted].

Ajinomoto counters that Ajinomoto "owns all right, title and interest in the '373 patent," which was the result of a collaboration between the companies Biotechnica and Wacker. Ajinomoto indicates that Wacker purchased the rights to the development work from

Biotechnica, thus clearing the way for Wacker and the Consortium to grant Ajinomoto an exclusive license. CIB at 97 (citing JX-91C 35:3–21).

For the reasons stated below, the ALJ finds that Ajinomoto has standing to assert the '373 patent.

The heart of this dispute is whether Dr. Backman was obligated to assign his rights in the '373 patent to his former employer, and was thus unable to assign his rights to the Consortium, as he and his other co-inventors actually did. *See* RIB at 39. Upon reviewing the evidence cited by CJ, the ALJ does not find any indication that Dr. Backman lacked the ability to sell his rights in the '373 patent to the Consortium. To the contrary, the evidence tends to show that Wacker purchased Biotechnica's rights in the '373 patent, which placed the complete ownership interest for the '373 patent with Wacker and its subsidiary, the Consortium. *See* JX-91C 35:3–21. Moreover, the evidence of record includes an assignment of rights in the '373 patent, recorded at the United States Patent and Trademark Office, from all three co-inventors to the Consortium. *See* JX-10.3. The evidence of record also includes recorded assignments from the Consortium to Wacker, JX-10.10, and from Wacker to Ajinomoto, KX-10.14.

While CJ is correct that it is Ajinomoto's burden to establish standing, here Ajinomoto has made a suitable showing through the testimony of Dr. Backman and through the assignments recorded at the PTO that is does have standing to maintain suit on the '373 patent. "The recording of an assignment with the PTO is not a determination as to the validity of the assignment." *SiRF Tech., Inc. v. Int'l Trade Comm'n*, 601 F.3d 1319, 1327–28 (Fed. Cir. 2010) (citing 37 C.F.R. § 3.54). However, it does create a presumption that the assignment is valid, and places a burden to rebut that presumption on the party challenging the assignment. *Id.* Here, the ALJ finds that the evidence presented by CJ fails to rebut that presumption.

Accordingly, the ALJ finds that Ajinomoto has established that it has standing to bring suit on the '373 patent.

B. Priority Date

Ajinomoto and CJ include in the joint outline of issues to be decided a section directed to the priority date of the '373 Patent. However, the priority issues identified rise and fall with CJ's written description and enablement challenges to the validity of claim 10 of the '373 patent. Specifically, CJ asserts that the German Application DE 42 32 468 ("DE468 application") to which the '373 patent claims priority does not satisfy the written description or enablement requirements for the same reasons that claim 10 of the '373 patent fails those requirements. *See* RIB at 20, 22, 24–25. Accordingly, CJ asserts that claim 10 of the '373 patent is not entitled to claim priority to the DE468 application. RIB at 20 (citing *In re Chu*, 66 F.3d 292, 297 (Fed. Cir. 1995)).

For the reasons identified *infra*, the ALJ has found that claim 10 of the '373 patent does not satisfy the written description requirement of § 112, first paragraph. Accordingly, claim 10 of the '373 patent is not entitled to claim priority to the DE468 application. *See In re Chu*, 66 F.3d at 297.

C. Infringement

1. Legal Standard

In a Section 337 investigation, the complainant bears the burden of proving infringement of the asserted patent claims by a preponderance of the evidence. *Certain Flooring Products*, Inv. No. 337-TA-443, Commission Notice of Final Determination of No Violation of Section 337, 2002 WL 448690 at 59, (March 22, 2002); *Enercon GmbH v. Int'l Trade Comm'n,* 151 F.3d 1376 (Fed. Cir. 1998).

Each patent claim element or limitation is considered material and essential. *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed. Cir. 1991). Literal infringement of a claim occurs when every limitation recited in the claim appears in the accused device, *i.e.,* when the properly construed claim reads on the accused device exactly. *Amhil Enters., Ltd. v. Wawa, Inc.*, 81 F.3d 1554, 1562 (Fed. Cir. 1996); *Southwall Tech. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed Cir. 1995).

If the accused product does not literally infringe the patent claim, infringement might be found under the doctrine of equivalents. The Supreme Court has described the essential inquiry of the doctrine of equivalents analysis in terms of whether the accused product or process contains elements identical or equivalent to each claimed element of the patented invention. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 40 (1997).

Under the doctrine of equivalents, infringement may be found if the accused product or process performs substantially the same function in substantially the same way to obtain substantially the same result. *Valmont Indus., Inc. v. Reinke Mfg. Co.,* 983 F.2d 1039, 1043 (Fed. Cir. 1993). The doctrine of equivalents does not allow claim limitations to be ignored. Evidence must be presented on a limitation-by-limitation basis, and not for the invention as a whole. *Warner-Jenkinson*, 520 U.S. at 29; *Hughes Aircraft Co. v. U.S.*, 86 F.3d 1566 (Fed. Cir. 1996). Thus, if an element is missing or not satisfied, infringement cannot be found under the doctrine of equivalents as a matter of law. *See, e.g., Wright Medical*, 122 F.3d 1440, 1444 (Fed. Cir. 1997); *Dolly, Inc. v. Spalding & Evenflo Cos., Inc.*, 16 F.3d 394, 398 (Fed. Cir. 1994); *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538-39 (Fed. Cir. 1991); *Becton Dickinson and Co. v. C.R. Bard, Inc.*, 922 F.2d 792, 798 (Fed. Cir. 1990).

The concept of equivalency cannot embrace a structure that is specifically excluded from the scope of the claims. *Athletic Alternatives v. Prince Mfg., Inc.*, 73 F.3d 1573, 1581 (Fed. Cir. 1996). In applying the doctrine of equivalents, the Commission must be informed by the fundamental principle that a patent's claims define the limits of its protection. *See Charles Greiner & Co. v. Mari-Med. Mfg., Inc.*, 92 F.2d 1031, 1036 (Fed. Cir. 1992). As the Supreme Court has affirmed:

> Each element contained in a patent claim is deemed material to defining the scope of the patented invention, and thus the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole. It is important to ensure that the application of the doctrine, even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety.

Warner-Jenkinson, 520 U.S. at 29. Finally, when a patentee discloses but does not claim subject matter, the unclaimed matter is dedicated to the public and cannot be reclaimed under the doctrine of equivalents. *PSC Computer Products. v. Foxconn Int'l*, 355 F.3d 1353, 1355-6 (Fed. Cir. 2004).

To prove direct infringement, Ajinomoto must prove by a preponderance of the evidence that each of the accused products either literally infringe or infringe under the doctrine of equivalents the asserted claims of the asserted patents. *Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc.*, 261 F.3d 1329, 1336 (Fed. Cir. 2001).

2. Claim 10 of the '373 Patent

As an initial matter, the ALJ finds that CJ has not infringed claim 10 of the '373 patent because claim 10 is invalid as indefinite, and for lack of written description support. *See* infra, § VI(D)(1)–(2). Nonetheless, should the Commission determine that claim 10 is valid, the ALJ finds that Ajinomoto has failed to establish that CJ has infringed claim 10 through production of Tryptophan with either its earlier or later strains. For the purposes of this infringement analysis,

the ALJ assumes that Ajinomoto's argument regarding the required assays for the measurement of K_i values was persuasive. In other words, though contrary to the ALJ's findings *infra*, for the purposes of this infringement analysis, it is assumed that claim 10 includes a requirement that the K_i values for the *serA* and *trpE* alleles must be measured with the reverse McKitrick and Bauerle assays, respectively.

The parties appear to be in agreement that the dispute over infringement of claim 10 is limited to whether the proteins coded by the mutated *serA* and *trpE* alleles have K_i values that fall within ranges recited in claim 10. The relevant claim language is as follows:

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

'373 Patent at Cl. 10.

Ajinomoto has produced evidence that CJ produces or has produced tryptophan using each of the production strains at issue in this investigation. CIB at 62 (citing CX-73C.2-6; RX-302C QA28; RX-300C QA30-32, 51-53; RX-275C). Ajinomoto has produced evidence that CJ cultures its production strains, which are tryptophan producing, in a culture medium, and then recovers the produced tryptophan from the culture medium. *Id.* (citing CX-73C.2-6; JX-98C 156:19-157:16; CX-1529C QA148-53, 315-19). Accordingly, Ajinomoto has established that

CJ's tryptophan production methods include all of the elements of the first clause of claim 10—the "culturing" clause.

Ajinomoto has also presented evidence that "each of CJ's Production Strains was derived from [redacted]" and "therefore, meets the 'microorganism selected from the group consisting of *E. coli* and Corynebacteria'" limitation of claim 10. *Id.* at 63 (citing CX-73C.2-6, CX-1529C QA156, 322; CX-73C.2-6). Additionally, Ajinomoto has produced evidence that "each of CJ's Production Strains is 'tryptophan feedback resistant and serine feedback-resistant' due to modified *trpE* alleles and modified *serA* alleles, respectively." *Id.* (citing CX-1529C QA157-71, 176-77, 183-97, 201-28, 234-71, 323-28; CX-20C.19; CX-19C.131-72). CJ does not appear to dispute that the process it uses or has used to produce tryptophan meets at least these limitations. Thus, the only remaining limitations in claim 10 to dispute are the two "wherein" clauses describing the mechanisms by which serine and tryptophan feedback resistance is achieved.

The first wherein clause deals with serine feedback resistance, and requires that resistance to be achieved by a mutated *serA* allele that codes for a protein with a K_i value for serine between 0.1mM and 50mM. '373 Patent at Cl. 10. Ajinomoto submits that each of the CJ production strains includes at least one [redacted]." CIB at 63 (citing CX-1529C QA196; CPB at 89, 96; RX-300C QA54-57; RX-301 QA20-32; RX-302C QA38, 62; *see also* CX-19C.131-72; CX-20C.19-20; CX-73C.7-33). Ajinomoto further submits that this particular allele confers serine feedback resistance. *Id.* (citing CX-1529C QA201-20, 225-228; CX-464; CX-466; CX-765; JX-94C 82:15-21.).

In addition to the [redacted], which Ajinomoto contends is present in all of CJ's production strains, Ajinomoto also contends that "CJ's Production Strains [redacted] are serine feedback resistant for the additional reason that each strain harbors a [redacted]." CIB 63–64 (citing CX-1529C QA196, 273). CJ does not appear to dispute that these alleles are present in these particular production strains, but instead argues that the Ajinomoto has failed to meet its burden to establish that those alleles code for proteins with K_i values for serine between 0.1mM and 50mM. *See* RIB at 10.

More specifically, CJ argues that the evidence Ajinomoto relies on to establish the K_i values for the proteins coded by the [redacted] did not use the reverse McKitrick assay to determine those K_i values. *Id.* Instead, the evidence on which Ajinomoto relies—two articles by CJ's own expert, Dr. Grant—"used a different pH (7.5 versus 8.5) and a different substrate (α-ketogluterate versus hydroxyl pyruvic acid phosphate) than the reverse McKitrick assay." *Id.* CJ submits that Ajinomoto's failure to present infringement evidence based on the reverse McKitrick assay is fatal to its infringement case.

Ajinomoto concedes the point that the Grant articles upon which it relies "did not determine K_i using the identical conditions as the assay identified as exemplary in the '373 patent (a 1980 reference by McKitrick)." CIB at 64. Ajinomoto does not retreat from its position that a person of ordinary skill in the art would read claim 10 of the '373 patent as requiring the use of the reverse McKitrick assay to determine K_i for serine. Rather, Ajinomoto contends that its reliance on the Grant articles is sufficient because a person of ordinary skill in the art could correct for the differences between the conditions present in the Grant article assay and the reverse McKitrick assay. *See* CIB at 64–65. Specifically, Ajinomoto argues that it is known in

the art that a lower pH, such as the one used in the Grant articles as compared to the reverse McKitrick assay, will result in a correspondingly lower K_i determination. Thus, it argues that the K_i reported in the Grant article—.142mM—would actually be higher if measured according to the reverse McKitric assay. *Id.* From that observation, Ajinomoto concludes "if one skilled in the art had used pH 8.5 (as described by McKitrick), the K_i value would be higher and would be pushed further within the claimed range." *Id.*

CJ's chief position with respect to Ajinomoto's "corrections" argument is that it is untimely and should be stricken. RIB at 10. As explained *supra* in § II, the ALJ declines to strike the "corrections" argument. However, CJ also argues that Dr. Stephanopoulos's corrections theory is impermissibly speculative and cannot support a finding of infringement as a matter of law. RIB at 11. CJ also points out that Dr. Stephanopoulos's corrections testimony only addressed the effect of pH variances on K_i values and "did not address all of the other possible variables that can affect K_i measurement—temperature, substrate, enzyme or buffer concentration." *Id.*

The ALJ agrees that Ajinomoto's infringement case suffers from a failure of proof. Ajinomoto has adopted the position that claim 10 of the '373 patent should be interpreted such that the ranges for K_i disclosed therein require measurement by the reverse McKitrick assay described in the '373 specification. Ajinomoto has not, however, produced any evidence showing what the K_i value for serine of the protein coded by the [redacted] is if measured according to the conditions of the reverse McKitrick assay. Dr. Stephanopoulos's testimony about the relationship between pH and K_i is not sufficient to cure this evidentiary failing. As CJ correctly noted, Dr. Stephanopoulos's testimony addressed only one variable among the conditions under which K_i is measured. Dr. Stephanopoulos's testimony also does not address

the extent to which the higher pH of McKitrick would elevate the K_i of the [redacted] above the value measured by Dr. Grant. Thus, the record is silent on whether the higher pH of McKitrick would elevate the K_i beyond the upper limit of the K_i range for serine in claim 10. The record is also silent on how multiple changes to the conditions of the reverse McKitrick assay would interact to affect measured K_i values. Ajinomoto's brief suggests that each variable can be considered completely independent of each other, *see* CIB at 65, but the record does not support that suggestion with reliable evidence. This is particularly relevant here, where Ajinomoto submits that both the lower pH and the use of a phosphate buffer in Grant, would yield a lower K_i than the pH and substrate of McKitrick. *See id.*

Finally, the ALJ notes that Ajinomoto criticizes CJ for failing to rebut its infringement case with test results showing noninfringement. *See id.* at 64. That argument impermissibly attempts to shift Ajinomoto's burden of persuasion on infringement to CJ. It is not CJ's burden to prove noninfringement when Ajinomoto has failed to first lay out a prima facie case of infringement. The same is true for Ajinomoto's suggestion that the ALJ should discount the other variables underlying the measurement of K_i because CJ has not produced evidence that those variables are significant to the infringement analysis in this investigation. Ajinomoto made the choice to put forth an infringement case that did not include measuring the K_i value for the accused products according to the assay it says is required by the '373 patent. It cannot now shift its burden to prove infringement onto CJ to fill the evidentiary gaps in its own case.

Finally, the ALJ finds that much of Dr. Stephanopoulos's testimony regarding the K_i value for the [redacted] is speculative, and falls short of establishing infringement by a preponderance of the evidence. Most telling in this regard is Dr. Stephanopoulos's failure to ever indicate what the K_i value for the protein coded by [redacted] actually is. While Dr.

Stephanopoulos offers numerous qualitative comparisons between the K_i value reported in the Grant articles and the K_i value that would be achieved if the McKitrick assay had been used, *see, e.g.*, Tr. at 468:3–476:7, those comparisons were not sufficiently specific to allow Dr. Stephanopoulos to report an actual K_i value. In the absence of actual evidence showing that the K_i value falls within the range given by claim 10, the ALJ is unwilling to assume as much based only on the qualitative comparisons offered by Dr. Stephanopoulos.

Accordingly, the ALJ finds that Ajinomoto has not met its burden to show that proteins encoded by the [redacted] have a K_i for serine between 0.1mM and 50mM when measured according to the reverse McKitrick assay.

With respect to the [redacted], which is used in CJ's earlier production strains, Ajinomoto's reliance on the Grant articles to establish the K_i range fails for the same reason it failed in the context of the [redacted]. The Grant articles did not use the reverse McKitrick assay to determine K_i for serine, and Dr. Stephanopoulos's suggestion that one could "infer" what the K_i for serine would have been if measured according to the reverse McKitrick assay falls short of establishing infringement by a preponderance of the evidence. However, Ajinomoto also argues that the specification of the '373 patent discloses a K_i value for the [redacted] that is within the range claimed in claim 10. Specifically, Ajinomoto points to Table 1 of the '373 patent, which reports a [redacted] for the protein coded by the [redacted]. '373 patent at Table 1.

The '373 specification lacks intrinsic detail as to the conditions under which the K_i values were measured. The table follows a portion of the specification text that 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. *See* '373 Patent at 6:27–43. Ajinomoto argues

that "the paragraph immediately preceding Table 1 expressly states that K_i values were determined using the McKitrick 1980 assay." CRB at 31. This is true, but that paragraph of the specification also indicates that either the forward or the reverse McKitrick method may be used. *See* '373 Patent at 6:29–37. Ajinomoto does not argue that the differences between the forward and reverse reaction rate are immaterial to the measured K_i value for serine. Instead, relying on Dr. Stephanopoulos's testimony, Ajinomoto argues that a person of ordinary skill in the art would have selected the reverse reaction "because of its simplicity and lack of radioactivity," connected with the reverse reaction. CRB at 31–32 (citing Tr. 393:9-21; JX-99C at 31:21-32:11).

Dr. Stephanopoulos's testimony misses the mark, however. The relevant inquiry here is what conditions were actually employed to generate the K_i values in Table 1. This is a relatively straightforward question of fact. Dr. Stephanopoulos's opinion that a person of ordinary skill in the art would prefer the reverse reaction fails to address that factual inquiry, and tends to underscore the point that Dr. Stephanopoulos has no personal knowledge about the conditions under which the data in Table 1 was generated. Moreover, even assuming Dr. Stephanopoulos's opinion was probative, [redacted] calls into question Dr. Stephanopoulos's opinion that a person of ordinary skill in the art would definitely choose the reverse reaction. Here again, Ajinomoto has failed to put forth evidence showing what the K_i value for serine would be if measured with the assay it argues is required by claim 10. As noted above, the burden rests with Ajinomoto to show infringement by a preponderance of the evidence. The ALJ finds that Ajinomoto's reliance on inferences from a person of ordinary skill in the art is

insufficient to meet that burden. Accordingly, the ALJ finds that Ajinomoto has not established that CJ's production strains infringe claim 10 by their use of [redacted].

Consistent with the reasoning above, the ALJ finds that Ajinomoto has failed to establish by a preponderance of the evidence that CJ's production strains—both the earlier and later strains—practice the limitation in claim 10 that recites the use of a mutated *serA* allele that codes for a protein with a K_i for serine between 0.1mM and 50mM. Accordingly, and because a showing of infringement requires proof that the accused products or processes practice every limitation of the asserted claim, the ALJ finds that Ajinomoto has failed to establish that CJ infringes claim 10 of the '373 patent by use of any of its production strains. As such, the ALJ need not address whether CJ's tryptophan production methods practice the related *trpE* limitation in claim 10 of the '373 patent.

D. Validity

1. Indefiniteness

a) Legal Standard

The second paragraph of pre-AIA 35 U.S.C. § 112 provides:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

35 U.S.C. § 112 (2006).[11] Failure to comply with this paragraph of § 112 will cause a patent to be invalid as indefinite. This requirement is also known as the "definiteness" requirement. *See* 4 Annotated Patent Digest § 23:1 (Apr. 2017). The definiteness requirement of § 112 is distinct from the other requirements of that section, such as the written description and enablement

[11] The '373 patent is subject to the pre-AIA version of § 112 because it has an effective filing date prior to September 16, 2012. Accordingly, references in this determination to § 112 refer to the pre-AIA version of § 112 unless otherwise noted.

requirement found in the first paragraph. *See Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358 n.2 (Fed. Cir. 1999) ("definiteness and enablement are analytically distinct requirements, even though both concepts are contained in 35 U.S.C. § 112."); *Augme Techs., Inc. v. Yahoo! Inc.*, 755 F.3d 1326, 1340 (Fed. Cir. 2014) ("Appellants' arguments appear to be based on the wrong legal standard, i.e., written description or enablement as opposed to indefiniteness"). The underlying purpose of the definiteness requirement is to provide the public with clear notice of the scope of a patent's claims. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 730–31 (2002) ("The monopoly is a property right; and like any property right, its boundaries should be clear. This clarity is essential to promote progress, because it enables efficient investment in innovation. A patent holder should know what he owns, and the public should know what he does not.")

"The Supreme Court has instructed that '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.'" *SimpleAir, Inc. v. Sony Ericsson Mobile Commc'ns AB*, 820 F.3d 419, 432 (Fed. Cir. 2016) (quoting *Nautilus, Inc. v. Biosig Instruments, Inc.* 134 S. Ct. 2120 (2014)). This standard replaced the previously applicable standard for indefiniteness, which asked whether claim language was insolubly ambiguous, or rather was amenable to construction. *Dow Chem.*, 803 F.3d at 630 ("there can be no serious question that *Nautilus* changed the law of indefiniteness. This was indeed the very purpose of the *Nautilus* decision. . . . In *Nautilus,* the Supreme Court expressly rejected that "insolubly ambiguous" or "amenable to construction" standard.").

Whether a patent claim complies with the indefiniteness standard is a question of law that is subject to the determination of underlying facts. *Akzo Nobel Coatings, Inc. v. Dow Chem. Co.*,

811 F.3d 1334, 1343 (Fed. Cir. 2016). As is the case with all assertions of invalidity after issuance, the standard of proof that governs factual disputes is clear and convincing evidence.[12] *See id.*; 35 U.S.C. § 282. The burden of persuasion rests on the party asserting invalidity. *See* 35 U.S.C. § 282.

The Federal Circuit has had multiple opportunities to address the application of the definiteness requirement to patent claims that include limitations which may depend on a particular method of measurement. In *Takeda Pharm. Co. v. Zydus Pharm. USA, Inc.*, 743 F.3d 1359 (Fed. Cir. 2014), prior to the Supreme Court's decision in *Nautilus*, the Federal Circuit rejected the argument that the asserted patent was indefinite for failure to specify the method of

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12 The ALJ notes that standards of proof are typically applicable only to questions of fact and not to questions of law. As explained by Justice Breyer:

> [T]he evidentiary standard of proof applies to questions of fact and not to questions of law. *See, e.g., Addington v. Texas,* 441 U.S. 418, 423, 99 S. Ct. 1804, 60 L.Ed.2d 323 (1979). Thus a factfinder must use the "clear and convincing" standard where there are disputes about, say, when a product was first sold or whether a prior art reference had been published. Many claims of invalidity rest, however, not upon factual disputes, but upon how the law applies to facts as given. Do the given facts show that the product was previously "in public use"? 35 U.S.C. § 102(b). Do they show that the invention was "nove[l]" and that it was "non-obvious"? §§ 102, 103. Do they show that the patent applicant described his claims properly? § 112. Where the ultimate question of patent validity turns on the correct answer to legal questions—what these subsidiary legal standards mean or how they apply to the facts as given—today's strict standard of proof has no application.

Microsoft Corp. v. I4I Ltd. P'ship, 564 U.S. 91, 114 (2011) (Breyer, J. concurring). The Federal Circuit has echoed this sentiment on multiple occasions. *See Newell Companies, Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 767 (Fed. Cir. 1988) ("Our precedent holds that the disputed facts underlying the legal conclusion must be established by clear and convincing evidence, not the ultimate legal conclusion of obviousness itself."); *SSIH Equip. S.A. v. U.S. Int'l Trade Comm'n*, 718 F.2d 365, 375 (Fed. Cir. 1983) ("we find it inappropriate to speak in terms of a particular standard of proof being necessary to reach a legal conclusion. Standard of proof relates to specific factual questions. While undoubtedly certain facts in patent litigation must be proved by clear and convincing evidence, the formulation of a legal conclusion on validity from the established facts is a matter reserved for the court." (internal citation omitted)).

measurement for determining average particle diameter. *Id.* at 1366. Because the asserted claims included limitations directed to average particle sizes, and because some variation in results would occur depending on the measurement method used, Zydus argued that the same tested sample could be found to be both infringing and non-infringing depending on the measurement method used. *Id.* In rejecting that argument, the Federal Circuit characterized the "different results from different measurement techniques" as a "mere possibility" and explained that the evidence showed that both measurement methods at issue would provide accurate results. *Id.* at 1366–67. The Federal Circuit also emphasized that there was no evidence to show that the variations in the results were significant. *Id.* at 1367.

By contrast, in *Teva*, which expressly applied the "reasonable certainty" standard of *Nautilus*, the Federal Circuit concluded that the asserted claim was indefinite because "the claim on its face offers no guidance on which measure of 'molecular weight' the claims cover." 789 F.3d at 1341. The Federal Circuit noted that the parties agreed that molecular weight could refer to M_p, M_w, or M_n, that each of those measures is calculated differently, and that each would typically yield a different result for a given sample. *Id.* Additionally, the court noted that the patent specification did not provide an express definition of "molecular weight." *Id.* The court also considered evidence from prosecution showing that the patentee had in one instance defined molecular weight as M_w and in another instance as M_p. *Id.* at 1345. Ultimately, the Federal Circuit concluded that "claim 1 is invalid for indefiniteness by clear and convincing evidence because read in light of the specification and the prosecution history, the patentee has failed to inform with *reasonable certainty* those skilled in the art about the scope of the invention." *Id.* (emphasis in original).

Shortly thereafter, the Federal Circuit again considered the application of the reasonable certainty standard in *Dow Chemical*. In that case, the relevant claim term was "a slope of strain hardening coefficient greater than or equal to 1.3." 803 F.3d at 631. The asserted patent explained that "the 'slope of strain hardening coefficient' ("SHC") is calculated according to the following equation:

$$SHC = (\text{slope of strain hardening}) * (I_2)^{0.25}$$

where I_2=melt index in grams/10 minutes." *Id.* The accused infringer argued that the SHC term was "indefinite because the patent fail[ed] to teach with reasonable certainty where and how the 'slope of strain hardening' should be measured." *Id.* at 632. While the Federal Circuit credited the testimony of Dow's expert insomuch as he testified that the slope should be measured at the end of the curve by the maximum slope, it nonetheless noted that there were three different methods of determining slope at that one point. *Id.* at 633. The Federal Circuit explained that there was "no question that each of these four methods may produce different results, *i.e.*, a different slope." *Id.*

Describing its pre-*Nautilus* jurisprudence, the Federal Circuit explained that "a claim was not indefinite if someone skilled in the art could arrive at a method and practice that method." *Id.* at 634. Under that standard, because Dow's expert had been able to develop and use a method for measuring maximum slope, the claim was found not to be indefinite. *See id.* However, under the *Nautilus* standard, and analogizing to *Teva*, the court held that even though Dow's expert could determine which of several measurement methods was most appropriate, the lack of clear guidance in the patent rendered the claim indefinite. *Id.* at 635.

b) Claim 10 of the '373 Patent

The sole indefiniteness dispute with respect to claim 10 of the '373 patent revolves around the claimed ranges for K_i values that define the scope of the claim. CJ argues that K_i values depend on the parameters used to measure those values, *i.e.*, they are assay-dependent, and that claim 10 of the '373 patent fails to identify which parameters to use to in determining K_i values. RIB at 17. Without knowing which assay should be used to determine the K_i values, CJ argues that the scope of claim 10 is impermissibly uncertain, and thus is indefinite. *See id.*

For its part, Ajinomoto concedes that K_i values are assay-dependent. *See* CRB at 44 ("CJ argues that one skilled in the art would understand that assay conditions may affect the K_i value. Ajinomoto agrees." (internal citations omitted)). Instead, Ajinomoto argues that claim 10 should be construed to require the use of the exemplary methods McKitrick and Bauerle to determine K_i values for *serA* and *trpE* alleles, respectively. *See id.* at 42. Those exemplary methods are disclosed in the specification. '373 Patent at 6:27–43; 8:32–35. Ajinomoto advances several variations on its argument, including that a person of ordinary skill in the art would be motivated by the assay-dependent nature of the K_i values to import the use of McKitrick and Bauerle assays into claim 10 as additional limitations to alleviate the uncertainty CJ has identified. *See* CRB at 44. Ajinomoto also argues that its expert, Dr. Stephanopoulos, testified that the variation in some assay conditions skews the K_i value in a predictable way. CIB 89, 91. Dr. Stephanopoulos thus concluded that a person of ordinary skill in the art could "correct" the K_i values given by assays other than McKitrick and Bauerle to give the values that would have been measured if those assays had been used. *See id.*

For the reasons detailed below, the ALJ agrees with Respondents that claim 10 of the '373 Patent is indefinite, and thus invalid.

The present dispute about the indefiniteness of claim 10 is fundamentally similar to the disputes of *Teva* and *Dow Chemical.* The scope of claim 10 is defined in part by a range of measured K_i values. The parties do not dispute that K_i values do vary depending on the particular assay and conditions used to measure K_i. The ALJ finds that, as an underlying issue of fact, the evidence presented during the hearing also establishes that K_i values depend on the conditions under which measurements are taken. *See, e.g.,* RX-0221C (Grant WS) at QA150–83. Like the claim at issue in *Teva*, claim 10 offers no guidance on its face that as to which assay or conditions should be used to measure K_i. *See* '373 Patent at Cl. 10. Claim 10 does not mention, let alone require, that the assays described in McKitrick or Bauerle must be used to measure K_i. *Id.* The specification also fails to support such a limitation.

To the extent the specification of the '373 patent references McKitrick and Bauerle, it is in the context of an exemplary embodiment. *See* '373 Patent at 6:27–32. Ajinomoto has not identified, and the ALJ cannot find, any portion of the specification that demonstrates an express intent on the part of the patentee to define K_i such that it must be measured by these methods for serine and tryptophan, respectively. To the contrary when read in the context of the entire paragraph where McKitrick is discussed, the stronger interpretation of the specification is the opposite—the patentee did not understand the measurement of K_i values to be limited to any one method of measurement:

> The following assays were used to test the gene products of the serA alleles for PGD activity and serine sensitivity:
>
> The PGD activity was determined by detection of the forward or reverse reaction of the enzyme by the method of McKitrick, J. C. and Lewis J. P., 1980, J. Bact. 141:235—245. The enzyme activity is measured in this case without serine and with various concentrations of serene. The said assay is suitable for determining the serine sensitivity of any phosphoglycerate

> dehydrogenase. **It is likewise possible to employ any other method for measuring the PGD activity**.

'373 Patent at 6:27–37 (emphasis added). Ajinomoto attempts to downplay this portion of the specification by arguing that CJ and its expert, Dr. Grant, "selectively cite only the portions of the specification that describe 'enzymatic activity.'" CIB at 88. Accordingly, the ALJ has examined the entire specification for references to the McKitrick assay, and with the exception of the list of references cited in the introductory pages, the portion of the specification reproduced above is the *only* express reference to the McKitric assay in the specification. *See generally* '373 Patent. Indeed, Ajinomoto, and its expert, Dr. Stephanopoulos, rely on the very same passage to argue that the McKitrick assay is required to measure the K_i value for serine. *See* CIB at 88 (citing JX-1 at 6:34–35; CX-1977C at 204–05, 208–09). Ajinomoto cannot credibly argue that the method of McKitrick was intended to be the exclusive means of measuring the K_i value for serine when the only discussion of the McKitrick assay in the specification indicates the opposite. Further, even if the specification did not indicate that other methods besides McKitrick could be used to measure K_i values, the law governing claim construction would preclude the ALJ from importing a limitation from an exemplary embodiment in the specification into claim 10. *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014) ("While we read claims in view of the specification, of which they are a part, we do not read limitations from the embodiments in the specification into the claims.").

Ajinomoto's other arguments with respect to claim 10 are also unpersuasive. Many portions of Dr. Stephanopoulos's testimony on this point are unhelpful as they amount to conclusory statements that a person of ordinary skill in the art would interpret claim 10 to require the use of the McKitrick assay to measure K_i values for serine. Expert testimony that does not

apply the specialized knowledge and experience of the expert to technical or scientific questions of fact is generally not helpful to the ALJ. Moreover, much of Dr. Stephanopoulos's testimony on indefiniteness is based on the incorrect assumption that it is acceptable to treat the use of the McKitrick method described in the specification's exemplary embodiment as a required limitation on claim 10.

Ajinomoto and Dr. Stephanopoulos also conflate enablement with indefiniteness in at least one instance. Specifically, Ajinomoto argues that "Dr. Stephanopoulos has testified that inhibition activity and the methods used for determining inhibition activity were well-known in the art at the time of the invention. He also testified that a person of ordinary skill would have been able to use the McKitrick assay to determine the inhibition activity of the *serA* enzyme in a given mutated *serA* allele." CIB at 88. Dr. Stephanopoulos's testimony, if credited, only establishes that the content of the art and the guidance in the specification are sufficient to enable a person of ordinary skill in the art to practice the '373 invention.

Finally, the fact that a person of ordinary skill in the art may be able to practice claim 10 by choosing one of several possible measurement techniques does not establish that the claim satisfies the definiteness requirement. While that argument may have fared better under the now-defunct "amenable to construction" indefiniteness standard, it fails under the "reasonable certainty" standard of *Nautilus*. For example, in both *Teva* and *Dow*, a similar argument could have been made that a person of ordinary skill in the art could merely choose one of the methods for determining molecular weight, or measuring slope, and would thus have been able to practice the claim. Nonetheless, the Federal Circuit indicated in both of those cases that the absence of any clear guidance as to which of several methods of measurement rendered the asserted claims impermissibly indefinite. *See* supra, § VI(D)(1)(a).

Accordingly, the ALJ finds that CJ has met its burden of persuasion and established by clear and convincing evidence that claim 10 of the '373 Patent is invalid as indefinite.

2. Written Description

a) Legal Standard

The Federal Circuit has interpreted 35 U.S.C. § 112, ¶ 1, to include a written description requirement that requires a patent specification reasonably convey "to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). "Compliance with the written description requirement is a question of fact." *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1376 (Fed. Cir. 2009). Terms need not be used *in haec verba, Eiselstein v. Frank*, 52 F.3d 1035, 1038 (Fed. Cir. 1995), and the requirement can be satisfied by "words, structures, figures, diagrams, formulas, etc.," *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). A description that merely renders the claimed subject matter obvious, however, does not satisfy the requirement. *Id.* at 1571-72.

b) Claim 10 of the '373 Patent

CJ argues that the limitation, "recovering the produced tryptophan from the culture medium," in claim 10 of the '373 patent lacks support in the specification thus fails to satisfy the written description requirement of § 112, first paragraph. RIB at 20. CJ submits that "[t]here is nothing in the '373 Patent specification (or DE468) that describes the step of recovering the produced tryptophan from the culture media," and that "[t]he only reference to recovery, isolation, or purification is unrelated to the recovery of tryptophan." RIB at 21. CJ notes that the recovery step was added four years after the filing date of the '373 patent in response to an office

action. *Id.* (citing RX-0221C (Grant WS) at QA215-17; JX-0002 ('373 FH) at JX-0002.0384-85).

Ajinomoto counters that recovery of tryptophan from a culture medium was known in the art at the time of application. CIB at 93 (citing CX-1977C QA244-50; RX-221C QA221-24, 314, 346). It also points to the cited reference CA409 as further evidence that recovery of tryptophan from a culture medium was known in the art. CIB at 93 (citing RX-119 at 2:19-20; JX-1 at 5:17–25). Ajinomoto notes that the written description requirement does not require *in haec verba* disclosure in the specification. *Id.*; *see also Koito Mfg. Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1154 (Fed. Cir. 2004). Ajinomoto also argues that CJ's expert, Dr. Grant, opined that a reference with fewer disclosures about tryptophan recovery than the '373 patent, nonetheless disclosed tryptophan recovery based on its discussion of tryptophan production and methods of recovery that were known in the art. Ajinomoto reasons that Dr. Grant's opinions about Aiba necessarily imply that the '373 patent, which it contends exceeds the level of disclosure in Aiba, sufficiently discloses tryptophan recovery to satisfy the written description requirement. CIB at 93.

Apart from its reliance on the CA409 reference in the cited references list, the only portion of the specification Ajinomoto actually points to as support for the "tryptophan recovery" limitation is Example 5 from the specification. *See* CRB at 45. CJ counters that Example 5, which discloses using high-performance liquid chromatography ("HPLC") to evaluate the tryptophan content of the culture medium, does not include recovery of the tryptophan from the culture medium. Rather, CJ points to the testimony of its expert, Dr. Grant, who explained that HPLC involves placing the entire culture medium onto the HPLC column, and does not require

recovery of the tryptophan from the medium. RIB at 22 (citing RX-0221C (Grant WS) at QA218-20; *see, also, id.*, at 221-55).

Here, the parties appear to be in agreement on several basic points. First, the parties agree that recovery of tryptophan was known in the art as of the priority date of the '373 patent. The parties also appear to agree that there is no explicit disclosure of tryptophan recovery in the '373 specification, while also acknowledging that the written description inquiry does not rise and fall with the presence of the specific words "tryptophan recovery" in the specification. The ALJ finds that the evidence supports both of these points.

The ALJ disagrees with Ajinomoto's argument that the written description requirement is satisfied because tryptophan recovery was well-known in the art. That argument amounts to the type of backfilling that the Federal Circuit has rejected as a means of shoring up a specification otherwise devoid of support for a given claim limitation. *Adrian Rivera Maynez Enterprises v. ITC*, 2017 WL 2233501, at *6 (Fed. Cir. May 23, 2017). The knowledge of a person of ordinary skill in the art informs what is in the specification; it cannot substitute for actual disclosure in the specification, however. *See id.*

Ajinomoto's argument regarding Dr. Grant's analysis of Aiba also misses the mark. Not only does that argument stray beyond the four corners of the '373 patent, where written description support for the tryptophan recovery term must be found, it also fails to recognize that disclosures that would render a limitation obvious do not necessarily equate to written description support for the same limitations. *See id.*

Finally, the evidence of record indicates that Example 5 in the '373 patent does not discuss tryptophan recovery, but rather involves the measurement of tryptophan yield grown under the conditions specified in the example. As indicated by Dr. Grant's testimony, the

measurement of tryptophan yield described in Example 5 would have involved placing the entire culture medium on the HPLC column, and would not necessitate recovering the tryptophan from the medium. While Dr. Stephanopoulos indicated that he disagreed with Dr. Grant's opinion regarding written description, he did not disagree with the factual point that the entire culture medium would be placed on the HPLC column. Instead, like Ajinomoto, Dr. Stephanopoulos relies on the knowledge of those skilled in the art to provide support for the tryptophan recovery limitation. As noted above, that reasoning is legally insufficient.

In light of the evidence presented, including the specification of the '373 patent, and the testimony of Drs. Grant and Stephanopoulos, the ALJ finds that CJ has established by clear and convincing evidence that '373 patent specification does not provide support for the "recovering the produced tryptophan from the culture medium," limitation of claim 10. Accordingly, the ALJ finds that claim 10 is invalid for failure to comply with the written description requirement of § 112, first paragraph.

3. Enablement

CJ argues that claim 10 of the '373 Patent is invalid because it fails to comply with the enablement requirement of § 112, first paragraph. RIB at 22. Specifically, CJ focuses the portion of claim 10 dealing with *serA* and *trpE* alleles. *See id.* CJ submits that because claim 10 places no limits on the source or structure of the *serA* and *trpE* alleles, a person of ordinary skill in the art would necessarily have to engage in undue experimentation to practice claim 10. *See id.* at 24. CJ also argues that claim 10 runs afoul of the enablement requirement because the *serA* and *trpE* alleles are described according to their function in terms of K_i value, and also because the specification discloses obtaining the alleles through mutagenesis, which it equates with a random process.

Ajinomoto breaks CJ's enablement challenge into two arguments and addresses each individually. *See* CIB at 94. First, Ajinomoto argues that methods of making and using *serA* and *trpE* alleles were known in the art, are taught in the '373 patent, and that the nature of the invention in claim 10 is not that of a specific allele, but rather is a method of producing tryptophan with a modified microorganism. *See* CIB at 94–95. Ajinomoto also notes that the K_i value limitation in claim 10 reduces the breadth of claim such that not all *serA* and *trpE* alleles are covered by the claim. *Id.* at 95. Finally, Ajinomoto submits that, while the methods for generating appropriate *serA* and *trpE* alleles may be time intensive, they are nonetheless well-known and "simple" methods that would not require undue experimentation. *Id.* at 96 (citing Tr. 787:9–17). Ajinomoto's second set of arguments largely parallel the first, and rely on the breadth of claim 10, the state of the art, and the guidance in the '373 patent, to support its position that a person of ordinary skill in the art would not need to engage in undue experimentation to practice claim 10 of the '373 patent.[13] *See* CIB at 96–97.

For the reasons explained below, the ALJ finds that CJ has not shown by clear and convincing evidence that claim 10 is invalid for failure to comply with the enablement requirement of § 112, first paragraph.

First, CJ's reliance on *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002) for the proposition that claim limitations with functional elements lack enablement is misplaced. *Enzo Biochem* dealt with a written description challenge, and in fact specifically states that the enablement and written description requirements are distinct requirements in

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[13] The ALJ notes that, rather than present two truly distinct enablement challenges, CJ has presented a single enablement challenge, which it supports with arguments directed to several of the *Wands* factors that typically govern the undue experimentation analysis. Thus, to the extent CJ has argued that claim 10 is overly broad, and also that the '373 patent specification lacks guidance regarding the creation of *serA* and *trpE* alleles, those arguments address two different *Wands* factors in the context of a single enablement challenge.

§ 112, first paragraph. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 963 (Fed. Cir. 2002) ("We have interpreted [section 112] as requiring a 'written description' of an invention separate from enablement."). Moreover, *Enzo Biochem* further explained that "[i]t is not correct, however, that all functional descriptions of genetic material fail to meet the written description requirement." *Id.* at 964. While describing genetic material with functional language may raise the specter of an enablement problem, it is not a *per se* rule that the presence of a limitation described in functional language will cause a claim to fail for lack of enablement. In the absence of any additional detail or evidence in CJ's brief on this point, the ALJ finds that CJ's enablement challenge cannot be sustained on the basis of the fact that the *serA* and *trpE* alleles are described with some functional language in claim 10.

Further, the ALJ disagrees that claim 10 lacks enablement because it is overly broad, or because the specification lacks guidance directed to creating the *serA* and *trpE* alleles. As discussed above, claim 10 does not cover all *serA* or *trpE* alleles, but rather is limited to those that have specific K_i values. Moreover, breadth alone is not sufficient to establish a lack of enablement, particularly where there is actual guidance in the specification about how to create the claimed subject matter. Here, the specification provides guidance that the *serA* and *trp*E alleles can be obtained through mutagenesis, and the ALJ further credits Dr. Stephanopoulos's testimony that methods of obtaining those alleles were well-known in the art.

Accordingly, the ALJ finds that CJ has not established by clear and convincing evidence that claim 10 is invalid for lack of enablement.

4. Obviousness

Included within the presumption of validity is a presumption of non-obviousness. *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 714 (Fed. Cir. 1984). Obviousness is grounded in 35 U.S.C. § 103, which provide, *inter alia*, that:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

35 U.S.C. § 103. Under 35 U.S.C. § 103, a patent is valid unless "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103. The ultimate question of obviousness is a question of law, but "it is well understood that there are factual issues underlying the ultimate obviousness decision." *Richardson-Vicks Inc.*, 122 F.3d at 1479; *Wang Lab., Inc. v. Toshiba Corp.*, 993 F.2d 858, 863 (Fed. Cir. 1993).

Obviousness is a question of law based on underlying facts, as set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). "The Graham factors are (1) the scope and content of the prior art, (2) the difference between the prior art and the claimed invention, (3) the level of ordinary skill in the field of the invention, and (4) any relevant objective considerations." *Soverain Software LLC v. NewEgg, Inc.*, 705 F.3d 1333, 1336 (Fed. Cir. 2013). "The Graham Court explained that 'the ultimate question of patent validity is one of law.'" *Id.* (citing *Graham*, 383 U.S. at 17).

"Generally, a party seeking to invalidate a patent as obvious must demonstrate 'by clear and convincing evidence that a skilled artisan would have been motivated to combine the

teaching of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.'" *OSRAM Sylvania, Inc. v. Am. Induction Techs., Inc.*, 701 F.3d 698, 706-707 (Fed. Cir. 2012) (quoting *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007)); *see also Amgen, Inc. v. F. Hoffman–LA Roche Ltd.*, 580 F.3d 1340, 1362 (Fed. Cir. 2009) ("An obviousness determination requires that a skilled artisan would have perceived a reasonable expectation of success in making the invention in light of the prior art." (citations omitted)). "The Supreme Court has warned, however, that, while an analysis of any teaching, suggestion, or motivation to combine known elements is useful to an obviousness analysis, the overall obviousness inquiry must be expansive and flexible." *OSRAM*, 701 F.3d at 707.

Obviousness may be based on any of the alleged prior art references or a combination of the same, and what a person of ordinary skill in the art would understand based on his knowledge and said references. If all of the elements of an invention are found, then:

> a proper analysis under § 103 requires, inter alia, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. *Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure.*

Velander v. Garner, 348 F.3d 1359, 1363 (Fed. Cir. 2003) (emphasis added) (internal citations omitted).

The critical inquiry in determining the differences between the claimed invention and the prior art is whether there is a reason to combine the prior art references. *See C.R. Bard v. M3 Sys.*, 157 F.3d 1340, 1352 (Fed. Cir. 1998). For example:

> *[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the*

> *prior art*. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, *it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered*, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 418-19 (2007) (emphasis added). The Federal Circuit case law previously required that, in order to prove obviousness, the patent challenger must demonstrate, by clear and convincing evidence, that there is a "teaching, suggestion, or motivation to combine. The Supreme Court has rejected this "rigid approach" employed by the Federal Circuit in *KSR Int'l Co. v. Teleflex Inc.*, 500 U.S. 398, 415 (2007). The Supreme Court stated:

> When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. Sakraida and Anderson's-Black Rock are illustrative–a court must ask whether the improvement is more than the predictable use of prior art elements according to their established function.
>
> Following these principles may be more difficult in other cases than it is here because the claimed subject matter may involve more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement. Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicitly. See *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusions of obviousness"). As

> our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.
>
> [. . .]
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> The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way. In many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design trends. Granting patent protection to advance that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility.

KSR, 550 U.S. at 417-419. The Federal Circuit has harmonized the KSR opinion with many prior circuit court opinions by holding that when a patent challenger contends that a patent is invalid for obviousness based on a combination of prior art references, "the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so." *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007) (citing *Medichem S.A. v. Rolabo S.L.*, 437 F.3d 1175, 1164 (Fed. Cir. 2006)); *Noelle v. Lederman*, 355 F.3d 1343, 1351-52 (Fed. Cir. 2004); *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 229 F.3d 1120, 1121 (Fed. Cir. 2000) and *KSR*, 550 U.S. at 416 ("a combination of elements 'must do more than yield a predictable result'; combining elements that work together 'in an unexpected and fruitful manner' would not have been obvious"). Further, a suggestion to combine need not be express and may come from the prior art, as filtered through the knowledge of one skilled in the art. *See Certain Lens-Fitted Film Pkgs.*, Inv. No. 337-TA-406, Order No. 141 at 6 (May 24, 2005).

"Secondary considerations," also referred to as "objective evidence of non-obviousness," must be considered in evaluating the obviousness of a claimed invention, but the existence of such evidence does not control the obviousness determination. *Graham*, 383 U.S. at 17-18. A court must consider all of the evidence under the *Graham* factors before reaching a decision on obviousness. *Richardson-Vicks Inc.*, 122 F.3d at 1483-84. Objective evidence of non-obviousness may include evidence of the commercial success of the invention, long felt but unsolved needs, failure of others, copying by others, teaching away, and professional acclaim. *See Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 894 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 857 (1984); *Avia Group Int'l, Inc. v. L.A. Gear California*, 853 F.2d 1557, 1564 (Fed. Cir. 1988); *In re Hedges*, 783 F.2d 1038, 1041 (Fed. Cir. 1986); *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565 (Fed. Cir. 1986), *cert. denied*, 479 U.S. 1034 (1987). The burden of showing secondary considerations is on the patentee and, in order to accord objective evidence substantial weight, a patentee must establish a nexus between the evidence and the merits of the claimed invention; a *prima facie* case is generally set forth "when the patentee shows both that there is commercial success, and that the thing (product or method) that is commercially successful is the invention disclosed and claimed in the patent." *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995); *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988), *cert. denied*, 488 U.S. 956 (1988); *Certain Crystalline Cefadroxil Monohydrate*, Inv. No. 337-TA-293, Comm'n Op. (March 15, 1990). Once a patentee establishes nexus, the burden shifts back to the challenger to show that, *e.g.*, commercial success was caused by "extraneous factors other than the patented invention, such as advertising, superior workmanship, etc." *Id.* at 1393.

Generally, a prior art reference that teaches away from the claimed invention does not create *prima facie* case of obviousness. *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994); *Certain Rubber Antidegradants*, Inv. No. 337-TA-533 (Remand), Final ID (Dec. 3, 2008) (stating, "*KSR* reaffirms that obviousness is negated when the prior art teaches away from the invention.")). However, the nature of the teaching is highly relevant. *Id.* "A reference may be said to *teach away when* a person of ordinary skill, upon reading the reference, would be *discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant*." *Id.* (emphasis added). For example, "a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *Id.*

The Federal Circuit has recently explained, moreover, that the obviousness inquiry requires examination of all four Graham factors. *E.g.*, *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1375 (Fed. Cir. 2012). Indeed, courts must consider all of the Graham factors prior to reaching a conclusion with respect to obviousness. *In re Cyclobenzaprine Hydrochloride Extended–Release Capsule Patent Litig.*, 676 F.3d 1063, 1076–77 (Fed. Cir. 2012) (collecting cases). At all times, the burden is on the defendant to establish by clear and convincing evidence that the patent is obvious. *Id.* at 1077–78.

CJ submits four combinations of prior art that it contends render the '373 patent obvious: 1) Aiba (RX-0136) in view of Tosa (RX-0116); 2) Aiba in view of WO235 (RX-0124); 3) EP735 in view of Tosa; and 4) EP735 (RX-0121) in view of WO235. RIB at 31–39. CJ asserts that the primary dispute between Ajinomoto and CJ with respect to obviousness is whether there is any motivation to combine these references as CJ has done. RIB at 25; *see also* CRB at 36. Indeed, the parties appear to be in rough agreement that Aiba and EP735 disclose the use of a

recombinant, feedback resistant *trpE* allele for the production and collection of tryptophan in *E. coli*. *Compare* RIB at 31–32, CIB at 36 *with* CIB at 75–76. The parties also appear to agree that Tosa and WO235 disclose the feedback resistant *serA* alleles with K_i values within the range claimed by the '373 patent. *Compare* RIB at 32, 34 *with* CIB at 77–78. Moreover, there appears to be agreement that Aiba and EP735 do not disclose feedback resistant *serA* alleles, while Tosa and WO235 do not disclose feedback resistant *trpE* alleles. Accordingly, with the exception of a dispute about the priority date for the '373 patent, which affects only WO235, the parties are largely in agreement about the scope and content of the prior art, as well as the differences between the art and claim 10 of the '373 patent.

CJ argues a person of ordinary skill in the art would have been motivated to combine the *trpE* allele references with the *serA* allele references because it was well-known that a feedback resistant *serA* allele would increase the level of serine in a cell, and it was also known that serine was rate limiting in the production of tryptophan, and that the *serA* allele was inhibited by intracellular serine. Accordingly, CJ concludes that a person of ordinary skill in the art would have recognized that the combination of a feedback resistant *serA* allele with a feedback resistant *trpE* allele would have yielded greater tryptophan production. RIB at 26.

Ajinomoto counters that a person of ordinary skill in the art would not have been motivated to make such a combination because it was believed at the time of the invention that bacteria strains with deregulated tryptophan metabolism, which already contained serine levels too low to trigger *serA* feedback inhibition, would not benefit from further increasing the amount of serine that could be tolerated before feedback inhibition would kick in. CRB at 37. In short, Ajinomoto does not dispute that it was well-known that introducing a feedback resistant *serA*

allele to a cell would enhance serine in that cell generally; Ajinomoto more pointedly argues that there was no motivation to do that for the particular tryptophan producing bacteria at issues here.

The ALJ finds that CJ has not established that claim 10 of the '373 patent is obvious by clear and convincing evidence. Particularly, the ALJ agrees with Ajinomoto that CJ has not established a motivation to combine the *trpE* allele references with the *serA* allele references. First, much of the evidence from its expert, Dr. Grant, is conclusory in nature. Second, the portions of Dr. Stephanopoulos's testimony that Ajinomoto points to do not appear to support the conclusion that a person of ordinary skill in the art would have been motivated to combine *serA* alleles with *trpE* alleles to increase tryptophan production. Rather, they appear to support the uncontested point that introduction of a feedback resistant *serA* allele generally increases the level of intracellular serine in a cell. CJ's evidence fails to address the more salient point of whether a person of ordinary skill in the art would have been motivated to introduce a feedback resistant *serA* allele to a cell where it was thought that serine inhibition had yet to be triggered. In sum, the ALJ finds that CJ's obviousness argument appears to be based on the benefit of hindsight, having the advantage now of knowing that the combination of feedback resistant *serA* and *trpE* alleles does yield increased tryptophan production. This conclusion is supported by various objective indicia of nonobviousness.

For example, the prior art acknowledges that a rising demand for L-tryptophan had created a need for an improved process for producing L-tryptophan. RX-121 at 2:25-26. Though the art acknowledges the need for improved tryptophan producing processes, and the parties agree that feedback resistant *serA* alleles were known at the same time, feedback resistant *trpE* alleles and *serA* alleles had not been combined to produce a process to address that need. Additionally, as Ajinomoto explains in rebutting CJ's motivation to combine, the evidence tends

to show that the results of combining feedback resistant *serA* alleles with feedback resistant *trpE* alleles produced unexpected results insomuch as it was previously believed that the already low levels of serine in the bacteria would not trigger the feedback inhibition response, and thus feedback resistant *serA* alleles would not markedly improve tryptophan production. As such, the ALJ finds that at least long-felt but unmet need and unexpected results further support the conclusion that CJ has not established that claim 10 of the '373 patent is obvious.

In sum, the ALJ finds that the prior art does disclose the elements of claim 10 through various references. However, the ALJ finds that CJ has not established a motivation to combine those references, and that Ajinomoto has produced evidence of objective indicia of nonobviousness. Accordingly, the ALJ finds that CJ has failed to establish by clear and convincing evidence that claim 10 of the '373 patent is invalid as obvious.

VII. U.S. PATENT NO. 7,666,655

A. Infringement

Ajinomoto asserts infringement of claim 20 of the '655 patent by CJ's earlier production strains, as well as its later production strains. The parties address infringement of the earlier strains as a group. The parties address infringement of the later strains both together, and with arguments specific to either [redacted]. Accordingly, the ALJ will address each of these three groups of "accused products" in turn.

1. Earlier Strains

The primary infringement dispute regarding CJ's earlier strains revolves around the claim limitation that requires enhancement of the claimed protein by one of three methods. Specifically, Ajinomoto asserts that CJ's earlier strains meet the enhancement limitation because

the protein produced by these strains "is 'enhanced' by 'replacing the native promoter which precedes the DNA on the chromosome of the bacterium with a more potent promoter.'" CIB at 31. However, Ajinomoto does not provide evidence that a native promoter was "replaced" with a more potent promoter in the operative protein. Instead, Ajinomoto provides evidence that the [redacted]. Specifically, Ajinomoto submits that [redacted] CIB at 31. Nowhere in its brief does Ajinomoto indicate how the [redacted] occurred, nor does it point to any evidence on that point. In short, in making its infringement case for the earlier strains, Ajinomoto does not address the method of enhancement in the claim, which requires "replacing" the native promoter with a more potent promoter. Instead Ajinomoto focuses on the outcome, i.e., that the earlier strains, as a composition, include a [redacted]. This approach to infringement assumes a claim construction for the term "replacing" that would include any method of [redacted], without restriction, as long as the outcome is that the activity of the YddG protein is enhanced.

As noted *supra*, the ALJ declines to afford "replacing" the unrestricted construction Ajinomoto seeks. To the extent it was unclear based only on the portions of Ajinomoto's brief addressing claim construction, Ajinomoto's infringement arguments make it clear that under their construction, the term "replacing" would have no purpose at all in the claim, as any method of [redacted] would fall within the claim scope. As long as the YddG gene includes a *yddG* promoter that is more potent than the native p romoter, the enhancement

limitation would be satisfied. The enhancement limitation would focus only on the outcome of the enhancement, and not on the method.

Claim 20, however, does not merely recite an outcome of enhanced protein activity. It recites enhancement of protein activity through one of three methods. Here, the method of enhancement Ajinomoto relies on to show infringement requires replacement of a native promoter with a more potent promoter. Accordingly, Ajinomoto must show that CJ enhanced the activity of the *yddG* protein by replacing the native promoter with a more potent promoter. Because Ajinomoto has failed to address the manner of replacement at all, the ALJ finds that it has not shown by a preponderance of the evidence that CJ's earlier strains infringe claim 20 of the '655 patent. Moreover, and consistent with the claim construction discussion *supra*, the ALJ declines to construe "replacing" in such a way that would obviate Ajinomoto's evidentiary failing by rendering that particular claim limitation meaningless.

2. Later Strains

[redacted]

Ajinomoto alleges that CJ's later [redacted] infringes claim 20 of the '655 patent. In its brief, Ajinomoto addresses each element of claim 20 in turn with respect to [redacted]. *See* CIB at 18–34. CJ disputes Ajinomoto's infringement case with respect to the [redacted] on two grounds. First, CJ argues that its use of [redacted] does not meet the protein definitions laid out in claims 9 or 15, which are incorporated into claim 20 by reference. *See* RIB at 58–62. Second. CJ argues that its use of the [redacted] does not meet the "enhancement" and "resistance" limitations of claim 20 as incorporated from claims 9 and 15. *See* RIB at 62–64.

(1) Protein Definitions

Claims 9 and 15, which define how to produce the bacterium of asserted claim 20, are substantially similar. They differ primarily in their definition of the protein to be enhanced by one of three methods. Claim 9 defines the protein this way: "said protein consists of the amino acid sequence of SEQ ID NO: 2." *See* '655 Patent at Cl. 9. Claim 15 defines the protein this way: "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., I><SSC, 0.1% SDS." '655 Patent at Cl. 15. The remaining portions of the two claims are substantially similar.

Ajinomoto asserts that [redacted] falls within the scope of the protein definition both literally and under the doctrine of equivalents. CIB at 20, 24. Ajinomoto notes that [redacted]. CIB at 21. Ajinomoto submits that "[redacted] meets the protein limitation of claim 15." CIB at 21 (citing CX-1529C QA683). Ajinomoto also asserts that the "[redacted] meets the protein limitation of claim 15 as well." CIB at 21 (CX-1529C QA684-89). For this latter point, Ajinomoto relies on a computational analysis conducted by its expert, Dr. Rigoutsos, using a computer program called "mfold." *See* CIB at 20. Dr. Rigoutsos's analysis "predicted hybridization as recited in claim 15." CIB at 20.

CJ argues that Ajinomoto "has not met its burden of establishing that the use of [redacted] infringes claim 20." RIB at 58. CJ concedes that "[redacted] encodes the protein of claim 9." RIB at 59. However, CJ argues that this gene [redacted] and therefore does not meet the enhancement limitation discussed *infra*. RIB at 59.

As for the [redacted] in [redacted], CJ argues that it "encodes a protein that differs from SEQ ID NO: 2 by [redacted], so it does not encode the protein of claim 9." RIB at 59. With respect to claim 15, CJ argues that the mfold analysis evidence is insufficiently reliable to establish that [redacted] will meet the protein definition therein, i.e., to establish that the gene will hybridize with the complement of the nucleotide sequence of SEQ ID NO: 1 under stringent conditions comprising 60° C., l><SSC, 0.1% SDS. RIB at 59–62. *See* RIB at 59.

At a broad level CJ criticizes the mfold analysis as a "predictive" one that merely establishes that [redacted] is likely to hybridize to the complement of SEQ ID NO: 1. *See* RIB at 59. More specifically, CJ criticizes Dr. Rigoutsos's analysis because "mfold is designed to determine the structure of a ***single*** nucleic acid molecule, not to predict the hybridization of ***two separate*** nucleic acid molecules." *See* RIB at 59–60 (citing CX-1530C (Rig. WS)). CJ submits that a more appropriate program designed to evaluate the hybridization of two separate DNA molecules was available and could have been used. *See* RIB at 60. CJ also criticizes Dr. Rigoutsos for "alter[ing] the query sequences ([redacted] and the complement of SEQ ID NO: 1) by joining them together using a string of 4,000 nucleotides, which gives an improper ΔG value (which reflects the stability of the predicted structure), even though mfold includes a linker feature to address this problem." RIB at 60 (citing CX-1530C (Rig. WS)).

CJ also argues that the ΔG value that Dr. Rigoutsos calculated for his mfold analysis is significantly less negative than what the evidence he relied on suggests would be necessary to show that structure predicted by the mfold analysis exhibits stable hybridization. *See* RIB at 60. CJ submits that when Dr. Rigoutsos was confronted with the discrepancy between the ΔG value

he calculated and the value expected in the document he cited to, he indicated that CX-0780 was not relevant. Because Dr. Rigoutsos cited only to CX-0780 in support of his ΔG value calculation, but then backed away from that document, CJ submits that Dr. Rigoutsos has failed to present any evidence supporting the stability of the predicted hybridization from his mfold analysis. *See* RIB at 60.

Finally, CJ argues that Dr. Rigoutsos lacks the experience necessary to use "mfold to predict DNA-DNA hybridization using long DNA sequences (e.g., 1,764 nucleotides for his *yddG* analysis)." RIB at 60. Additionally, CJ submits that "while the accuracy for predicting structures for sequences fewer than 700 nucleotides is as high as 73%, for longer sequences the accuracy is much lower." RIB at 61 (Rigoutsos Tr. at 264-65; RX-0360 (Reuter) at 1-2).

Ajinomoto counters CJ's criticisms of Dr. Rigoutsos's analysis, first by noting that there is no requirement in the '655 patent to test hybridization using a "wet lab" experiment. CIB at 21. Second, in response to the reliability issues raised by CJ, Ajinomoto points to evidence that mfold is a well-known and frequently used program for studying folding and hybridization. *See* CIB at 21–22. With respect to Dr. Rigoutsos's use of a linker string and the length of the nucleotide string, Ajinomoto points to evidence where Dr. Rigoutsos "explained in detail the rationale behind using these parameters." CRB at 9 (CX-1530C QA8-17, 54-57, 63-67, 81-84). Ajinomoto also submits that Dr. Rigoutsos explained "that to the extent the linker caused any potential issues, those issues related to determinations of melting temperature and energy of the hairpin loop, neither of which are relevant to this case." Tr. 296:4-300:2. With respect to the discrepancy in ΔG values, Ajinomoto points to testimony from Dr. Rigoutsos explaining that the ΔG values cannot be compared because one involved the interaction of 9000 bases computed at

37 degrees Celsius, while the other involved the interaction of only 882 bases computed at 60 degrees Celsius. *See* CRB at 10 (Tr. 300:23-303:5, 306:3-307:11.).

The ALJ finds that Ajinomoto has shown that CJ's use of [redacted] meets the protein definition of claim 15 by a preponderance of the evidence. First, there is no requirement in the '655 patent that hybridization be shown by a wet lab experiment as opposed to other means. Moreover, the parties have not pointed to, and the ALJ is not aware of, any precedent that would *per se* foreclose the use of a computational tool, such as the mfold program, as a means of meeting Ajinomoto's burden of proof on infringement. Additionally, the evidence of record supports the conclusion that at a general level, mfold is a well-known and reliable tool for predicting hybridization. The more pertinent question in this case is whether Dr. Rigoutsos's specific use of the mfold program was reliable and probative. The ALJ finds that it was.

Ajinomoto has pointed to evidence addressing each of CJ's criticisms of the specific mfold analysis Dr. Rigoutsos conducted in this case. As Ajinomoto correctly notes, CJ was precluded from offering additional evidence regarding the hybridization of [redacted] in an earlier evidentiary ruling. Accordingly, CJ's only avenue forward is to cast sufficient doubt on Dr. Rigoutsos's mfold analysis to render it insufficiently reliable to establish the hybridization element of claim 20, even in the absence of any contradictory evidence. While the ALJ has considered CJ's arguments regarding the ΔG values, the linker string, and the length of the nucleotides analyzed, the ALJ does not find those criticisms to be sufficiently supported to overcome Ajinomoto's evidence. Accordingly, the ALJ finds that Ajinomoto has established, by a preponderance of the evidence, that the use of [redacted] meets the protein definition of claim 15, which is incorporated by reference into claim 20.

(2) Enhanced Activity & Resistance

Claim 20, via claims 9 and 15, also requires that the subject protein have enhanced activity related to resistance to L-phenylalanine, fluoro-phenylalanine, or 5-fluoro-DL-tryptophan. CJ submits that Ajinomoto has failed to prove "any of the genetic alterations in [redacted] or CJ's Earlier Production Strains has enhanced resistance to L-phenylalanine, fluoro-phenylalanine, or 5-fluoro-DL-tryptophan beyond the levels observed in a wild-type of said bacterium." RIB at 62. Instead, CJ argues that Ajinomoto has relied on inferences about enhanced resistance based on the fact that the strain is a commercial production strain. *See id.* at 62–63. CJ submits that "Dr. Stephanopoulos's generalized inference based on his conclusory opinion about commercial strains does not address the strains at issue, which are highly engineered and, therefore, may be commercially viable due to any number of other genetic changes." *Id.*

Additionally, CJ argues that Ajinomoto cannot rely on the presence of the strains tested in Table 1 of the '655 patent to show enhancement because those strains "expressed the *yddG* gene from a high copy-number plasmid and a moderate copy-number plasmid." RIB at 63. As CJ explains, "[t]hose plasmids typically provide more than 100 copies or 20-50 copies, respectively, of the *yddG* gene per host cell," which in turn "means there is a far greater amount of YddG protein in those plasmid-based cells." RIB at 63. By contrast, CJ argues that [redacted] RIB at 63. In sum, CJ submits that Table 1 of the '655 patent stands for the proposition that "resistance is dependent on *yddG* copy number." RIB at 63 (RX-303C (Roepe RWS) at QA55, 61, 113, 290). [redacted] CJ submits that Ajinomoto cannot rely on Table 1 to establish the enhancement limitation.

In response, Ajinomoto argues that "commercial production strains such as CJ's must *necessarily* be resistant to aromatic amino acids and their analogs in order to overproduce and accumulate those amino acids," and that its expert, Dr. Stephanopoulos testified that such an inference is consistent with his own commercial experience, and various scientific publications. CRB at 14. Ajinomoto takes a similar approach to rebutting CJ's plasmid-based versus chromosomal-based argument distinguishing Table 1 of the '655 patent as a means of showing resistance. Specifically, Ajinomoto argues that "if CJ's strains were not resistant, they would not be commercially viable producers of tryptophan—they would not 'work.'" CRB at 14 (Tr. 452:18-454:7; *see also* CX-1529C QA563-64).

The ALJ finds that Ajinomoto has failed to establish by a preponderance of the evidence that [redacted] meets the resistance limitation of claim 20. Specifically, Ajinomoto's evidence of infringement with respect to this element is not evidence at all, but is an inference, or assumption, based on the fact that [redacted] was at one time a [redacted]. As CJ points out, the causality between the commercial viability of strain 4127 and the specific resistance required by claim has not been established, *i.e.*, it is not clear based on the evidence of record that [redacted] was commercially viable due to its resistance, and not due to some other feature of the strain. The ALJ finds that the inference upon which Ajinomoto relies to establish the resistance element of claim 20 with respect to [redacted] is insufficient to meet its burden to establish infringement by a preponderance of the evidence. Because a showing of infringement requires that the each and every element of the patent claim be present in the accused product, the ALJ also finds that Ajinomoto has failed to establish infringement of strain 4127 by a preponderance of the evidence.

[redacted]

Ajinomoto asserts infringement by CJ's use of [redacted] via the doctrine of equivalents. Specifically, Ajinomoto asserts that [redacted] infringes "the protein limitation of claim 9 under the doctrine of equivalents." CIB at 24 (citing CX-1529C QA667-81). The central question is whether the [redacted], which does not literally meet the protein definition of claim 9, is nonetheless equivalent to that protein for the purposes of establishing infringement.[14] In support of its equivalence argument, Ajinomoto submits that "it is undisputed that *E. coli* and [redacted]." CIB at 26 (citing RX-180 at CJ-ITC1005_0005164 [redacted]). Also, Ajinomoto argues that "it is likewise undisputed that [redacted] and *E. coli* [redacted] are in the same family, are [redacted]." CIB at 26 (citing JX-98C 129:9-12; CX-89.1 (stating that the [redacted] is "95% identical" to the *E. coli* [redacted]); CX-1529C QA671-72).

Ajinomoto argues that "both [redacted] and *E. coli* [redacted] act by increasing resistance to, and exporting, a target product." CIB at 26 (citing CX-1529C QA 670-72). Among other references in support of this point, Ajinomoto notes that "the Tsuchiya 2016 publication shows that the YddG protein from yet a different bacterial species, *Starkeya Novella*—which has only 28% sequence identity with *E. coli* YddG—performs the same function as that of *E. coli* YddG. CIB at 26 (citing Tr. 484:11-486:10 (discussing CX-1481)). From this reference, Ajinomoto submits that "the increased similarity of the [redacted] (95% homologous), Dr. Stephanopoulos testified that the [redacted] would 'behave definitely identically as the *E. coli* [redacted].'" CIB at 26.

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[14] By virtue of being directed at the [redacted] Ajinomoto's doctrine of equivalents argument applies to all of CJ's later strains.

Next, Ajinomoto turns to documents and testimony from CJ to establish equivalence. Ajinomoto argues that "CJ's scientist testified that it '[i]t is known that E. coli and [redacted] types are very similar in species,' agreeing that 'the protein coded by the [redacted] would be useful for whatever it does in E. coli.'" CIB at 27 (citing JX-93C 155:18-156:7). Ajinomoto also relies on a comparison of CJ's own strains, including unaccused strains, to show that "the [redacted] is equivalent to the *E. coli* [redacted], as the enhanced expression of either protein leads to increased tryptophan production." CIB at 27 (citing CX-1529C QA681). In sum, Ajinomoto submits that "the proteins have the same function (increasing resistance to the target product), act in the same way (exporting the target product), and achieve the same result (increased production and accumulation of the target product)." CIB at 27.

CJ asserts that Ajinomoto is estopped from arguing that the [redacted] is equivalent to the protein defined in claim 9 by virtue of certain amendments and arguments Ajinomoto made during prosecution. RIB at 50. CJ bases its estoppel argument on the originally filed claim 1, which the examiner rejected as anticipated. *See* RIB at 50. CJ explains: "the Examiner asserted the *E. coli* YfiK protein of EP710 (RX-0051) fell within the genus of claimed proteins because the YfiK protein 'can be considered a protein having amino acid sequence SEQ ID NO:2 in which several amino acids have been deleted, substituted, inserted or added.'" RIB at 50 (citing RX-303C (Roepe RWS) at QA335; JX-0004 ('655 FH) at 000398-000400). In response to the rejection, CJ notes that Ajinomoto "narrowed its genus of proteins to limit it to the *E. coli* YddG protein (SEQ ID NO: 2) and variants 'encoded by a nucleotide sequence that hybridizes with the nucleotide sequence of SEQ ID NO: 1 under stringent conditions comprising 60°C, 1 x SSC, 0.1% SDS.'" RIB at 51 (citing RX-303C (Roepe RWS) at QA337; JX-0004

('655 FH) at 000630). As CJ points out, that amendment "excluded the *E. coli* YfiK protein of EP710." RIB at 51.

CJ further explains that, when claim 1 was amended, Ajinomoto also introduced new claims 12 and 24, which ultimately issued as claims 9 and 15. *See* RIB at 51. CJ argues that these "new claims were substantially similar to amended claim 1, but they recited different species of the amended genus in separate claims." RIB at 51. Finally, CJ notes that Ajinomoto argued that the amendment overcame the anticipation rejection, and that the examiner withdrew the rejection "by virtue of submission of an amendment." RIB at 51 (citing RX-303C (Roepe RWS) at QA339; JX-0004 ('655 FH) at 000652). From this prosecution background, CJ concludes that Ajinomoto cannot now claim equivalence between the [redacted] and the protein defined in claim 9 because the originally filed claim 1 literally included the [redacted] but the amendment to claim 1 narrowed the protein definition in a way that excluded the [redacted].

Separate from its estoppel argument, CJ argues that Ajinomoto's equivalence argument "fails on every required prong of the DOE inquiry." RIB at 52. First, CJ argues that the [redacted] does not perform in the same way as the protein of claim 9 because it "[redacted] from SEQ ID NO: 2 (*i.e.*, [redacted] to the *E. coli* YddG protein)." RIB at 52–53. While arguing that any argument based on the *S. novella* YddG protein has been waived, CJ also argues that "the *S. novella* YddG was not tested for an ability to export aromatic amino acids, which are the amino acids recited in the claims." RIB at 53 (citing CX-1481 (Tsuchiya) at 1, right col.). CJ submits that there is no basis to infer such an ability is present in *S. novella* or [redacted] proteins because "a single amino acid change can affect the selectivity of YddG." RIB at 53 (citing CX-1481 (Tsuchiya) at 2, right col. ("the

Trp101Ala and Trp162Ala mutants exhibited decreased transport activities for threonine, but not for methionine")).

CJ also argues that the [redacted] has a different "function" and obtains a different "result" from the E. coli YddG protein of SEQ ID NO: 2. In support, CJ argues that "in [redacted]. From these points, CJ concludes that, even if its estoppel argument is rejected, Ajinomoto's equivalence argument fails under the standard doctrine of equivalents inquiry.

The ALJ finds that Ajinomoto has failed to establish that [redacted] is equivalent to the protein defined in claim 9 of the '655 patent. First, the ALJ rejects CJ's estoppel argument. The amendment at issue dealt with an anticipation rejection for the *E. coli* YfiK protein. While Ajinomoto would likely be estopped from reclaiming that particular protein with the current language of claims 9 or 15, there is little, if any, evidence that either the examiner or the Ajinomoto contemplated excluding other proteins from the definitions given in claims 9 and 15. Further, to the extent the amendment can be linked to the now issued claims 9 or 15, that link is to the definition of claim 15, *i.e.*, the protein defined by hybridization conditions. Here, Ajinomoto's equivalence argument is between [redacted]

and the protein of claim 9, which is defined by SEQ ID NO: 2. There is no indication in the prosecution history that the amendment upon which CJ relies for estoppel was connected to the SEQ ID NO: 2 definition. Accordingly, the ALJ finds that it is inappropriate to find estoppel here, where Ajinomoto is addressing a protein not discussed in the prosecution history, and claim language that was not the subject of the amendment.

Nonetheless, the absence of estoppel does not resolve the equivalence issue. Ajinomoto must still establish that [redacted] performs the same function as the protein of claim 9, in the same way, and for the same result. Here, the ALJ finds that [redacted] does not perform in the same way as the protein of claim 9. The evidence shows that the YddG protein participates in the export of aromatic amino acids in *E. coli*, [redacted]. RX-0180 (Airich) at 190; CX-1481 (Tsuchiya) at 1; CIB at 26. Though Ajinomoto criticized this evidence in its reply brief as being directed to the function of [redacted], as opposed to *E. coli* bacteria, the evidence it relies on to argue that the difference is immaterial is not related to the way the proteins functions. Rather, Ajinomoto relies on evidence showing that *E. coli* strains with the [redacted] exhibit increased tryptophan production. In short, Ajinomoto attempts to rely on evidence of the results of the use of the [redacted] to rebut CJ's evidence distinguishing the transport subjects between the two proteins. The ALJ does not find that argument persuasive. Accordingly, the ALJ finds that Ajinomoto has not established equivalence between the [redacted] and the protein defined in claim 9. Because Ajinomoto's infringement case with respect to [redacted] requires that finding of equivalence, the ALJ also finds that Ajinomoto has not established by clear and convincing evidence that CJ's use of [redacted] infringes claim 20 of the '655 patent.

B. Validity

CJ challenges the validity of the '655 patent on multiple bases, including indefiniteness, lack of written description, lack of enablement, anticipation, and obviousness. Further, within each legal ground for invalidity, CJ asserts multiple theories of invalidity. The ALJ addresses each in turn.

1. Indefiniteness

CJ asserts that claim 20 of the '655 patent is indefinite based on the claim term "native promoter," and the claim term "more potent promoter." Consistent with the legal standard for indefiniteness discussed at length *supra*, it is CJ's burden to prove that a person of ordinary skill in the art would be unable to determine the scope of claim 20 with reasonable certainty. Moreover, to the extent this question of law turns on subsidiary issues of fact, CJ must establish those factual issues by clear and convincing evidence.

a) "Native Promoter"

First, CJ argues that claim 10 is invalid by virtue of the term "native promoter." RIB at 67, 69. Specifically, CJ argues that "[a] POSITA could not determine with reasonable certainty the limits of the term "native promoter that precedes the DNA encoding" the YddG protein that is to be replaced in method b) of claim 20 (via claims 9 and 15)." RIB at 69. Further elaborating, CJ explains that "neither the claim nor the specification defines the beginning or the end of the 'native promoter.'" RIB at 69 (RX-0223C (Roepe WS) at QA174-75). CJ also argues that "[t]he '655 Patent does not disclose whether any supplemental promoter elements, such as a CRP-binding site, exist in the *yddG* 'native promoter' or whether such sequences must be removed when replacing the 'native promoter.'" RIB at 69 (RX-0223C at QA231). From these assertions, CJ concludes that a person of ordinary skill in the art "would not know which specific

nucleotides must be replaced in order to replace the 'native promoter' or which specific nucleotides can remain when replacing the 'native promoter.'" RIB at 69 (RX-0223C at QA230). CJ relies exclusively on the testimony of its expert, Dr. Roepe, to support its indefiniteness argument.

In response, Ajinomoto argues that CJ's arguments require an excessive amount of detail with respect to the term "native promoter." CIB at 39. It argues that a person of ordinary skill in the art would not read the term "native promoter" to require explicit definition of "the beginning or the end" of the native promoter. CIB at 39. Ajinomoto notes that CJ's fixation on the beginning and end of the native promoter is consistent with Dr. Roepe's personal definition of "native promoter," which it argues is more stringent than the definition of "native promoter" typically used by those of ordinary skill in the art.

The ALJ finds that CJ has failed to establish that claim 20 of the '655 patent is indefinite due to its recitation of a "native promoter." Both CJ and Ajinomoto offer only a cursory analysis of indefiniteness according to the reasonable certainty standard that governs this dispute. In particular, CJ focuses its argument on the premise that a person of ordinary skill in the art would not have known where the native promoter begins and ends, and which nucleotides would have to be replaced in order to replace the "native promoter" as required by claim 10. Dr. Roepe's opinions, on which CJ relies for support, follow the same reasoning. *See* RX-0223C (Roepe WS) at QA174-75, QA230-231. However, this argument fails for two reasons. First, there is a factual dispute as to whether a person of ordinary skill in the art would have been unable to identify the "native promoter." While Dr. Roepe testifies that a person of ordinary skill in the art would not be able to identify the native promoter, Ajinomoto's expert, Dr. Stephanopoulos testifies to the contrary, and submitted at trial that he was able to identify the native promoter by visual

inspection, and also able to confirm the identity of the native promoter through the use of a neural network program that was available at the time of the invention. While CJ calls Dr. Stephanopoulos's visual inspection hindsight, and submits that the neural network was considered unreliable at the time of the invention, those arguments cannot overcome its failure to establish by clear and convincing evidence that a person of ordinary skill in the art could not have identified the native promoter of the *yddG* gene. This is particularly true here, where there is evidence in the record that Dr. Roepe may have employed a definition for "native promoter" that required more detail than the term would be given by a person of ordinary skill in the art at the time of the invention.

The second failing in CJ's argument is that it is essentially an enablement challenge, not an indefiniteness challenge. Indeed, the bulk of CJ's argument revolves around whether a person of ordinary skill in the art would be able to replace the "native promoter" as required by claim 10, not around whether that same person would understand the scope of the term "native promoter." For this additional reason, CJ's indefiniteness argument fails as to the term "native promoter."

b) "More Potent Promoter"

CJ's second indefiniteness argument is based on the phrase "more potent promoter," which appears in claims 9 and 15, and is incorporated into claim 20 by reference to those claims. RIB at 72. CJ argues that the strength of a given promoter will vary according to the method of evaluation used, that the '655 patent points to the prior art reference Deuschle for examples of how to determine promoter strength, and that Deuschle gives multiple methods of evaluation, which in turn give different results for promoter strength. *See* RIB at 72. Further, CJ asserts that variation given by the different methods disclosed in Deuschle is significant, with one assay

showing that the P_{A1} promoter was either more potent than the P_{N25} promoter, while a different assay showed that the P_{N25} promoter is more potent than the P_{A1} promoter. RIB at 72–73. Following the reasoning of *Dow Chemical* and *Teva*, CJ submits that the absence of any direction in the '655 patent as to which evaluation to use for determining promoter strength renders claim 20 invalid as indefinite.

Ajinomoto does not dispute that multiple methods of evaluation are available for determining promoter strength, nor does Ajinomoto dispute that Deuschle discusses two different methods for determining promoter strength. Instead, Ajinomoto submits that only one of the methods of determining promoter strength in Deuschle is consistent with the '655 patent's explanation that promoter strength "is defined by frequency of acts of RNA synthesis initiation." CIB at 42 (citing JX-3 at 6:15-22). Particularly, Ajinomoto argues that one of the assays described in Deuschle is that of von Gabain and Bujard (1979), which does not measure promoter strength according to "the frequency of acts of RNA synthesis initiation." CIB at 43. Rather, Ajinomoto submits that the von Gabain and Bujard assay measures promoter strength according to the "rate of complex formation with E. coli RNA polymerase as well as in their in vitro strength if compared under competitive conditions." CIB at 44.

The ALJ finds that CJ has not established that the phrase "more potent promoter" renders claim 20 of the '655 patent indefinite. While there appears to be no dispute that multiple methods of evaluation were known and available to a person of ordinary skill in the art at the time of the invention, there is a factual dispute regarding whether those different methods would result in uncertainty as to the scope of claim 20. Particularly, with respect to Deuschle, portions of the reference seem to indicate that the reference was primarily concerned with an *in vivo* method of rating promoter strength. For instance, the title of the reference is "Promoters of *Escherichia*

coli: a hierarchy of *in vivo* strength indicates alternate structures." JX-0063.1. Similarly, the reference states that "[t]he goal of this study was to accurately measure the *in vivo* strength of a group of well-defined promoter sequences and to attempt an interpretation of sequence data based on functional information." JX-0063.4. Yet, the reference also states "[h]ere we describe an experimental system for the accurate determination of promoter strength *in vivo* and *in vitro*." JX-0063.1.

The scope of Deuschle's disclosure is significant because it is the only reference CJ has pointed to that establishes both the uncontroversial point that there are many methods of determining promoter strength, but also that at least two of those methods give inconsistent results with respect to relative promoter strength. It is not enough to show that multiple methods of evaluation exist. CJ must establish that whatever variance exists among those methods would actually result in uncertainty with respect to claim 20. While the '655 patent's specification does refer to multiple "methods," plural, being disclosed in Deuschle, the text of Deuschle itself seems to more strongly support the conclusion that Deuschle described only an *in vivo* method of evaluating promoter strength. Further, CJ has not directly addressed Ajinomoto's argument that the method of von Gabain does not meet the definition for determining promoter strength given in the '655 patent: "frequency of acts of RNA synthesis initiation." Thus, even if Deuschle is read to include the method of von Gabain, there would still be an open question as to whether methods for determining promoter strength consistent with the definition given by the '655 patent actually result in uncertainty in the scope of claim 20.

Accordingly, the ALJ finds that CJ has failed to establish by clear and convincing evidence that claim 20 of the '655 is invalid as indefinite with respect to the phrase "more potent promoter."

2. Written Description

The grounds for CJ's written description arguments track those of its indefiniteness arguments. Here again, CJ asserts that claim 20 of the '655 patent is invalid for lack of written description by virtue of the claim terms "native promoter" and "more potent promoter," which are incorporated into claim 20 by its reference to claims 9 and 15. While CJ relies on similar operative facts for all of its § 112 arguments with respect to these terms, it provides additional detail for the written description arguments, as detailed below.

a) "Native Promoter"

CJ argues that "the specification does not describe the structure or location of the 'native promoter.'" RIB at 70. CJ elaborates that, while the phrase "native promoter" does appear twice in the specification, "the specification never once sets forth its location or structure." RIB at 70 (citing RX-0223C (Roepe WS) at QA238). CJ further argues that, regardless of whether a person of ordinary skill in the art would know the structure of the "native promoter" element, such knowledge cannot be used as a substitute for actual disclosure within the four corners of the patent. RIB at 71.

Ajinomoto counters that the native promoter element is disclosed in Example 4 of the '655 patent, which identifies SEQ ID NO: 9 as containing the upstream region for *yddG*. CIB at 38. Ajinomoto then relies on the testimony of its expert for the proposition that a person of ordinary skill in the art at the time of the invention would be able to identify the native promoter in that sequence. RIB at 38 (citing CX-1977C QA465–472, Tr. 851:17–857:20).

The ALJ finds that CJ has failed to establish by clear and convincing evidence that the phrase "native promoter" lacks written description support in the specification. First, and contrary to CJ's assertions, the '655 patent does identify the structure and location of the native

promoter by virtue of its reference to SEQ ID NO: 9. This is sufficient to distinguish the instant case from *Regents of Univ of Cal v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), upon which CJ relies. In *Regents of Univ. of Cal.*, the patent lacked any structural description of the cDNA that was claimed. *Id.* at 1567. Here, by contrast, the '655 patent includes the description of SEQ ID NO: 9, which CJ does not dispute includes examples of the native promoters of claim 20. Moreover, as Ajinomoto correctly notes, written description is judged from the perspective of a person of ordinary skill in the art, and thus it is appropriate to consider how such a person would have understood the reference to SEQ ID NO: 9 in the '655 specification with respect to the native promoter. The ALJ finds that Ajinomoto has produced evidence that tends to show that a person of ordinary skill in the art would have understood the SEQ ID NO: 9 disclosure to show that the patentee possessed the "native promoter" limitation as it is incorporated into claim 20 of the '655 patent. While CJ is correct that the knowledge of a person of ordinary skill in the art cannot wholly replace disclosure in the specification, written description must nonetheless be judged from the perspective of a person of ordinary skill, and not in a vacuum.

Accordingly, the ALJ finds that CJ has failed to establish by clear and convincing evidence that claim 20 of the '655 patent is invalid for failure to provide written description support for the claim phrase "native promoter."

b) More Potent Promoter"

CJ argues that the phrase "more potent promoter" as incorporated in claim 20 of the '655 patent lacks written description support because the four specific promoters that are disclosed in the specification are insufficient to provide support for the entire genus of "more potent promoters." *See* RIB at 75. Additionally, CJ argues that "the consensus sequence does not provide a structural feature common to members of the genus of 'more potent promoters,'" while

noting that disclosure of a structural feature common to members of a genus would be sufficient to satisfy the written description requirement. *See* RIB at 75–76. In sum, CJ submits that "the '655 Patent specification fails to provide either a representative number of species, a common structural feature, or a specific test method to support the virtually infinite genus of 'more potent promoters' of claim 20 and, therefore, fails to provide written description for that claim." RIB at 76.

Ajinomoto counters that "[g]enus claims are perfectly permissible, so long as they have adequate written description and enablement support." CRB at 18 (citing *Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1338 (Fed. Cir. 2006)). Ajinomoto further argues that "[a] skilled artisan would have recognized that the native *yddG* promoter was a relatively weak promoter, and would have easily been able to identify other promoters that were stronger than the native *yddG* promoter," and also that "the overwhelming evidence leaves no doubt that the consensus sequence is correlated to promoter strength: publications and textbooks have taught this fact for the past three decades." CRB at 19. Ajinomoto argues that the evidence upon which CJ relies regarding consensus sequence are a "handful of scattered exceptions" to the "general rule that the consensus sequence is a stronger promoter than the non-consensus native *yddG* promoter." CRB at 19 (citing CIB at 46; CX-1977C QA542-43; Tr. 413:12-16). Additionally, Ajinomoto argues that "[a] skilled artisan would have recognized that the native *yddG* promoter was a relatively weak promoter, and would have easily been able to identify other promoters that were stronger than the native *yddG* promoter." CRB at 19.

As an initial matter, the ALJ notes that the portion of *Monsanto Co. v. Scruggs* on which Ajinomoto relies is inapposite with respect to written description. That portion Ajinomoto cited deals with enablement, which is a distinct requirement from written description. Similarly, to the

extent Ajinomoto is arguing that a person of ordinary skill in the art would be able to practice the invention, that too goes to enablement, and not written description. However, Ajinomoto has pointed to four examples of promoters in the specification that it contends support the "more potent promoter" limitation, and CJ does not point to any evidence that those promoters are not more potent than the *yddG* native promoter. Thus, the crux of the dispute here is whether the four examples of more potent promoters Ajinomoto has identified in the specification are sufficient to provide written description support for the genus of "more potent promoters."

In *Ariad*, the Federal Circuit explained "that a sufficient description of a genus instead requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010). Ajinomoto does not dispute that the full genus of "more potent promoters" is a broad one, and it does not appear to argue that the four promoters disclosed in the '655 specification are in fact a "representative number" of the species falling within that genus. Rather, Ajinomoto relies on the argument that there is a common structural link among the more potent promoters. That link, it argues, is that a more potent promoter is one that is more similar to the recognized consensus sequence than the native promoter. This argument faces two problems, however. First, as Ajinomoto acknowledges, it is not true that between two promoters, the more potent one will always be closer to the consensus sequence. CJ has produced various evidence supporting that point, and while Ajinomoto may prefer to sweep that evidence under the rug as a "handful of exceptions," it remains true that simply relying on the consensus sequence rule will not necessarily describe the species of the genus "more potent promoters." Second, and more significantly, the '655 patent does not disclose anything to

suggest that the "more potent promoters" are linked to relative similarity to consensus sequence. Instead, Ajinomoto relies exclusively on extrinsic evidence to support its consensus sequence argument with respect to written description support. While written description is measured from the perspective of a person of ordinary skill in the art, the inquiry remains how that person of ordinary skill would interpret the disclosure in the four corners of the patent. Here, the relationship between consensus sequence and promoter potency is found nowhere in the '655 patent. In the absence of any such disclosure, Ajinomoto cannot wholly substitute the knowledge of a skilled artisan to provide that disclosure.

Accordingly, the ALJ finds that claim 20 of the '655 patent is invalid for lack of written description. Specifically, the ALJ finds that claim 20 broadly covers the use of any "more potent promoter" but the '373 Patent fails to provide support for that genus through either a representative number of promoters within that genus, or through disclosure of a common structural link between the species of the genus.

3. Enablement

With respect to enablement, CJ again raises two distinct challenges to claim 20. The first is based on the term "native promoter;" the second is based on the term "more potent promoter."

a) "Native Promoter"

CJ's arguments in support of this challenge are sparse. *See* RIB at 71–72. Indeed, there is no discussion of whether a person of ordinary skill in the art would be able to practice claim 20 of the '655 patent without undue experimentation. Neither does CJ meaningfully address the *Wands* factors that inform the undue experimentation determination. Instead, CJ points to a publication from 2009 where the co-inventors first published the location and structure of the *yddG* native promoter, and argues that Dr. Stephanopoulos's testimony that a person of ordinary

skill in the art would have been able to identify the location and structure of the "native promoter" is unreliable.

Claim 20 of the '655 patent enjoys a presumption of validity. In order to overcome that presumption, CJ is required to establish invalidity by clear and convincing evidence. Here it has clearly failed to do so. At best, CJ has raised areas of contradiction between Ajinomoto's expert Dr. Stephanopoulos, who testified that a person of ordinary skill in the art would be able to identify the *yddG* native promoter and practice claim 20, and [redacted]. That is not enough to meet its clear and convicting evidentiary burden. Moreover, the lack of any citation in CJ's brief to the legal standards governing enablement provides an additional reason to reject CJ's enablement argument. CJ has provided a few evidentiary citations followed by a conclusory statement that claim 20 is not enabled due to the "native promoter" limitation. This is an invitation for the ALJ to fill in the gaps in CJ's legal analysis. The ALJ declines to accept that invitation, as it is the responsibility of the parties to develop and state their own cases.

Accordingly, the ALJ finds that CJ has failed to establish by clear and convincing evidence that claim 20 of the '655 patent lacks enablement due to the claim limitation "native promoter."

b) "More Potent Promoter"

CJ also argues that claim 20 of the '655 patent lacks enablement by virtue of the "more potent promoter" limitation. RIB at 77. Specifically, CJ argues that "[t]he more potent promoter of claim 20 may be of any sequence from any organism and, thus, encompasses a virtually infinite genus of possible promoters." RIB at 77. CJ submits that the four exemplary potent promoters found in the specification are "insufficient to enable the virtually infinite genus of

'more potent promoters' encompassed by claim 20 (via its claims 9 and 15) across its full scope." RIB at 77.

CJ also points to statements by [redacted]. CJ argues that these statements further show that claim 20 is not enabled due to the "more potent promoter" limitation. RIB at 77.

Finally, CJ argues that, "as of the filing date of the '655 Patent, a POSITA knew that correlation to the consensus sequence does not identify a 'more potent promoter.'" RIB at 77. CJ thus submits a person of ordinary skill in the art's ability to identify a consensus sequence is not sufficient to establish enablement.

For its part, Ajinomoto argues that claim 20 is enabled because "the patent itself identifies a number of known strong promoters, ways of measuring promoter strength against the native promoter, and that replacing the native promoter with a more potent promoter results in increased tryptophan production." CIB at 45 (citing CX-1977C QA505-07). Ajinomoto also argues that "a skilled artisan would also have known that the claimed 'more potent promoter' could be created by bringing the -35 region closer to the consensus sequence—[redacted]." CIB at 45–46. Ajinomoto disputes CJ's rejection of the link between consensus sequence and promoter strength, and points various evidence in support of its position. CIB at 46 (citing Tr. 578:7-587:4 (discussing CX-672, CX-1903, and CDX-2122)). Ajinomoto also points to CJ's own documents as evidence that a "more

potent promoter could be readily identified by known methods. CIB at 46 (citing CX-1977C QA524-39; CX-5C.43; JX-92C at 62:1-26).

Finally, with respect to [redacted].

The ALJ finds that CJ has failed to establish by clear and convincing evidence that claim 20 of the '655 patent lacks enablement due to the "more potent promoter" limitation. Like CJ's enablement argument based on "native promoter," here too is CJ's briefing divorced from the standards governing enablement. Indeed, in its reply brief, CJ has simply lumped all three of its § 112 challenges based on "more potent promoter" together, without any indication of which arguments and evidence correspond to which § 112 requirement. *See* RRB at 26–27. The ALJ will not make CJ's case for it. Moreover, to the extent the ALJ can discern a specific enablement argument from CJ's opening brief, the evidence it relies upon has been rebutted by Ajinomoto, and therefore, the ALJ finds that CJ has failed to meet the clear and convincing evidentiary burden required to show that claim 20 lacks enablement due to the "more potent promoter limitation."

c) Enhanced Amino Acid Production

In addition to its "native promoter" and "more potent promoter" enablement arguments, CJ argues that "Claim 20 is not enabled across its full scope because YddG only enhances amino acid production at sufficiently high intracellular concentrations of aromatic amino acids (i.e., at sufficiently high levels of amino acid production)." RIB at 80–81. By contrast, CJ argues that "YddG does not enhance amino acid production at lower intracellular concentrations (*i.e.*, lower levels of amino acid production)." RIB at 81. CJ submits that, because claim 20 does not account for the concentration of aromatic amino acids necessary to enhance production, the claim is not enabled across its entire scope. *See* RIB at 81.

CJ supports the basic foundation of this enablement argument—that enhancement is dependent on sufficiently high levels of aromatic amino acids—with evidence from its expert, Dr. Roepe, and from the '655 patent's co-inventors. *See* RIB at 81 (citing RX-0223C (Roepe WS) at QA489; RX-0029 (Tsyrehzhapova) at 526, left col.). CJ criticizes Ajinomoto's expert, Dr. Stephanopoulos, for a failure to "dispute, or even address, the '655 co-inventors' admissions or Dr. Roepe's testimony about the lack of effectiveness of YddG enhancement at low intracellular concentrations of the aromatic amino acid." RIB at 81. From those arguments, CJ concludes that "it is undisputed that the 'enhanced aromatic amino acid production' of claim 20 is not enabled across the full scope of claim 20." RIB at 81–82.

Ajinomoto, however, does dispute CJ's enablement argument related to the "enhanced aromatic amino acid production" limitation of claim 20. Indeed, Ajinomoto submits that "CJ's position is based wholly on attorney argument or cropped quotes taken out of context. CJ provides no citations for the assertions made in the paragraph spanning pages 80-81 of its brief." CRB at 21. Particularly, Ajinomoto argues that "CJ provides no supporting evidence (in the form of expert opinion or other scientific support) for its conclusory statement that: 'Therefore,

contrary to claim 20, at low levels of amino acid production, enhanced YddG activity has no effect on amino acid production.'" CRB at 21–22 (citing RIB at 81). Moreover, Ajinomoto asserts that the statement is contradicted by the same 2009 publication upon which CJ relies. *See* CRB at 22. Ajinomoto submits that the 2009 publication draws a distinction between enhancing YddG in cells designed to produce aromatic amino acids versus those that are wildtype cells. CRB at 22. Ajinomoto argues that claim 20 is appropriately limited to the former, and thus CJ's argument that claim 20 is not enabled due to the enhanced amino acid production limitation fails. CRB at 22.

The ALJ finds that CJ has failed to establish by clear and convincing evidence that claim 20 of the '655 patent is invalid for lack of enablement due to the enhanced amino acid production limitation. At best, CJ has raised an issue regarding the level of aromatic amino acid concentrations at which enhanced expression of *yddG* will occur. From this one point, CJ summarily concludes that claim 20 lacks enablement. Here again, CJ's argument is divorced from the standards that govern enablement, and the ALJ is left to guess how CJ intended its primary point to interact with those standards. This conclusory approach to enablement does not amount to clear and convincing evidence, nor does it overcome the presumption of validity owed to claim 20. Moreover, Ajinomoto, has pointed to other portions of the 2009 publication upon which CJ relies to establish that even low level aromatic amino acids will enhance the expression of *yddG* in cells that have been appropriately engineered. Ajinomoto also correctly points out that claim 20 is limited to such engineered cells by virtue of the recombinant limitation in the claim. Ajinomoto's argument is unrebutted on that point.

Accordingly, the ALJ finds that CJ has failed to establish by clear and convincing evidence that a person of ordinary skill in the art would be unable to practice claim 20 of the

'655 patent without undue experimentation. Therefore, the ALJ finds that claim 20 of the '655 patent is not invalid for lack of enablement due to the enhanced amino acid production limitation.

4. Functional Variants of Claim 20

CJ advances a fourth category of invalidity arguments under 35 U.S.C. § 112, which are based on the protein definition of claim 15, as it is incorporated into claim 20. *See* RIB at 79–80. Specifically, CJ argues that "[c]laim 20 (via claim 15) lacks written description and enablement because it recites functional (resistance activity) variants of *E. coli* YddG (*i.e.*, proteins encoded by a nucleotide sequence that hybridizes with the complement of the nucleotide sequence of SEQ ID NO: 1 under stringent conditions comprising 60° C., 1xSSC, 0.1% SDS), but the '655 Patent only discloses a single species of this genus (the native *E. coli* YddG protein) and does not identify any common structural features of the genus." RIB at 79–80. CJ submits that, [redacted]. CJ does not distinguish between its written description argument and its enablement argument, and CJ's brief makes no attempt to apply the facts it relies on to the standards governing either of those invalidity defenses. Instead, it simply submits that "[t]he requirements for written description and enablement are described above." CIB at 80 (citing Sections IV(F)(1)(b)(ii) and IV(F)(1)(b)(iii), respectively, *supra*).[15] As the ALJ noted *supra*, this kind of "grab bag" approach to invalidity

[15] While section IV(F)(1)(b)(iii) of CJ's brief includes a cursory recitation of the standard governing enablement, section IV(F)(1)(b)(ii) contains no such discussion of the requirements for a successful written description challenge.

puts the onus on the ALJ to craft either a written description argument, or an enablement argument, or both, from the facts presented by CJ. This is something the ALJ will not do.

At best, CJ's arguments stand for the proposition that claim 20 is flawed because the protein definition incorporated from claim 15 is impermissibly broad. However, breadth alone is insufficient to establish invalidity. Indeed, a broad claim may be enabled if a person of ordinary skill in the art could practice that claim without undue experimentation. Similarly, a broad claim may have written description support if the disclosure of the specification would cause a person of ordinary skill in the art to believe that the inventor actually possessed the full breadth of what he claimed. Without more than an assertion that the protein definition of claim 15 is overly broad, CJ cannot prevail on either a written description or an enablement argument on those grounds.

Additionally, Ajinomoto challenges the factual predicate of CJ's "functional variants" argument. *See* CIB at § IV(E)(1)(c). Ajinomoto submits that "a skilled artisan *would* have recognized structural features necessary to retaining the function required by the claims." CIB at 47. First, Ajinomoto argues that "[t]he '655 patent itself states that YddG is highly homologous to the RhtA protein, a highly hydrophobic protein with 10 predicted transmembrane segments." CIB at 47 (citing JX-3 at 2:22-36). Ajinomoto also argues that "[i]t was well-known that transmembrane domains play a key role in protein functionality." CIB at 47 (citing CX-1977C QA558). And, Ajinomoto points to a portion of the '655 patent explaining "that the permissible types of changes to its amino acid sequence depend on the position or type of amino acid residues and its three-dimensional structure, and that permissible variants should hybridize with high homology to the *yddG* gene under stringent conditions." CIB at 47 (citing JX-3 at 5:14-18, 40-43). In sum, Ajinomoto submits that "a skilled artisan would have been able to employ his

own knowledge about a protein's structure-function relationships, as well as tools generally available in the art, to ascertain which structural features of the YddG protein were central to its function." CIB at 47–48 (citing CX-1977C QA555).

Ajinomoto also discounts CJ's reliance on a 2010 topology publication and the inventors' deposition testimony. Specifically, Ajinomoto submits that "the fact that the inventors undertook an experimental analysis in 2010 does not mean that information about the structure and function of the YddG protein was not known prior to this date." CIB at 48. And more to the point, Ajinomoto submits that, "regardless of whether the inventors tested the activity of YddG protein variants or knew exactly which amino acids played a role in YddG's function, given the disclosure in the '655 patent specification and the information and tools readily available in the art at the time of the '655 patent, a skilled artisan could have identified functional variants of the YddG protein." CIB at 48–49 (citing CX-1977C at QA567).

The ALJ finds that CJ has failed to establish by clear and convincing evidence that the functional variants described in claim 20 render that claim invalid. More specifically, the ALJ finds that CJ has failed to set out a prima facie case of invalidity due to its failure to apply the facts on which it relies to the standards governing the written description or enablement requirements. Additionally, the evidence presented by Ajinomoto undercuts CJ's basic argument that a person of ordinary skill in the art would not be able to recognize or identify the variants that would fall under the protein definition of claim 15.

5. Anticipation by Berg

CJ submits that claim 20 of the '655 patent is inherently anticipated by Berg, B.L. et al., *Genetics* 1990, vol. 125:691-702 ("Berg"). RIB at 83 (citing 0222C (Palsson WS) at QA259). More specifically, CJ submits that Berg discloses an 8-kb fragment, which "necessarily

contained the native *E. coli yddG* gene." RIB at 83–84 (citing . RX-0222C (Palsson WS) at QA262-69). CJ explains this disclosure as follows:

> The information in Berg and an annotated *E. coli* genome sequence show that the *E. coli yddG* gene and its upstream regulatory region are necessarily contained in the 8-kb fragment. *Id.* at QA262; 299-334. The annotated *E. coli* genome also shows this region as encoding the YddG protein of SEQ ID NO: 2, and an alignment reveals corresponding regions with 100% identity to SEQ ID NO: 1. *Id.* at QA262, 323, 349. Additionally, sequence information available for a portion of the Berg fragment that extends into *yddG* is identical with the genomic sequence. *Id.* at QA333, 347. The Berg 8-kb fragment, therefore, necessarily contains the *yddG* gene, encoding YddG, and its native upstream sequence. *Id.* at QA262, 349.

RIB at 84. CJ further asserts that Berg discloses "that the 8-kb *PstI* fragment, which contains the *yddG* gene and its upstream sequence, was cloned or inserted into multicopy expression vectors, which produce 20-200 copies of the *yddG* gene per cell." RIB at 84–85 (citing RX-0222C (Palsson WS) at QA265-67, QA269-72; RX-0145 (Berg) at 694, right col., 695, right col.).

CJ submits that "Berg discloses an *E. coli* bacterium (VJS482) that is capable of accumulating tryptophan as the result of enhanced expression of the *trp* operon due to a mutation in *trpR* (i.e., a deregulation of the tryptophan repressor)," RIB at 84 (citing RX-0222C (Palsson WS) at QA269; RX-0145 (Berg) at 693, Table 1), and that it discloses "transforming VJS482 with multicopy plasmids containing the 8-kb fragment and culturing the transformed bacteria," RIB at 84 (citing RX-0222C (Palsson WS) at QA260-61, 268; RX-0145 (Berg) at 692, right col.; 694, Fig. 2; 695, right col.). CJ asserts that this transformation of VJS482 "would produce more tryptophan than untransformed cells." RIB at 85 (citing RX-0222C (Palsson WS) at QA274).

Ajinomoto dismisses CJ's Berg anticipation argument as conjecture. CIB at 54. First, Ajinomoto notes that Berg "fails to disclose the *yddG* gene, fails to ascribe an activity to the YddG protein, fails to disclose enhancing the YddG protein, and fails to mention producing and accumulating aromatic L-amino acids, including L-tryptophan." CIB at 54 (citing CX-2115C

QA164; RX-145). Accordingly, Ajinomoto submits that CJ's anticipation argument must be based on inherency—a point CJ does not appear to contest.

With respect to CJ's inherency argument and the 8kb DNA fragment, Ajinomoto argues that CJ has only theoretical evidence that the black box of the 8kb fragment actually contains or is capable of expressing the *yddG* gene. CIB at 54–55. Ajinomoto suggests that, contrary to CJ's assertions, "the regulatory sequences (which would be required for expressing the *yddG* gene) may not be intact." CIB at 55 (citing CX-2115C QA57-58, 174; Tr. 699:1-25). Further in this vein, Ajinomoto points to the testimony of its expert, Dr. Stephanopoulos, to explain "why the Berg plasmids could *not* have expressed the YddG protein and why the bands on the Berg gels could *not* represent the YddG protein." CIB at 55. Ajinomoto argues that, first, "the Berg plasmids use the T7 expression system, which could not have transcribed the *yddG* gene." CIB at 55 (citing CX-2115C QA175). Second, Ajinomoto submits that, "even if the T7 system had expressed the *yddG* gene, it would have done so in the reverse direction of the *yddG* gene, creating anti-sense *RNA* which would have silenced any *yddG mRNA* produced by the cell, preventing the translation of the YddG protein." CIB at 55 (citing CX-2115C QA175). Ajinomoto goes on to explain that, "[a]fter activating the T7 transcription system on the Berg plasmids, the authors added rifampicin, which halts the production of any native *E. coli* proteins." CIB at 55 (citing CX-2115C QA178-79). And, Ajinomoto argues that, "[h]ad any proteins been transcribed by the native *E. coli* polymerase, one would have expected to see additional bands on the Berg gel corresponding to this genomic expression, but the gel shows no such bands." CIB at 55 (citing CX-2115C QA194). Ajinomoto also argues that "after the addition of rifampicin, the Berg authors added radioactive labeling, which could bind only newly-produced proteins." CIB at 55 (citing CX-2115C QA198). Additionally, Ajinomoto

submits that "the darkness of the bands on the Berg gel indicates that they could only have been expressed by the strong T7 expression system," and "[t]hus, the bands in the gel were expressed by the Berg plasmids by the T7 expression system, which CJ admits could not have expressed the *yddG* gene." CIB at 55.

The ALJ finds that CJ has failed to establish by clear and convincing evidence that Berg inherently anticipates claim 20 of the '655 patent. Specifically, CJ has failed to demonstrate by clear and convincing evidence that the "black box" region disclosed in Berg actually contains the *yddG* gene of claim 20. CJ's evidence on this point, appears to rely on analysis performed on 8kb fragments from strains other than those used in the Berg publication. Indeed, as CJ's expert Dr. Palsson acknowledges, his analysis is not based on the Berg Strain (VJS773), but rather on derivatives of a related strain. In the absence of clear and convincing evidence that these derivatives are in fact identical to the strain in Berg, at least insofar as claim 20 is concerned, CJ cannot meet its burden to establish that the *yddG* gene is *necessarily present* in the black box region of Berg. Further undermining CJ's anticipation case is its own acknowledgment that only parts or portions of the Berg 8-kb fragment have even been published today. *See* RRB at 28. Accordingly, the ALJ finds that CJ has failed to meet its burden to establish inherent anticipation of claim 20 of the '655 by the Berg reference.

6. Obviousness

CJ submits two obviousness arguments with respect to claim 20 of the '655 patent. First, CJ argues that claim 20 is obvious over U.S. Patent No. 4,742,007 ("the '007 patent") in view of Santiviago *et al.*, *Microbiology* 147: 1897–1907 (2001) ("Santiviago (2001)") and in further view of the asserted '373 patent. *See* RIB at 86–88. Second, CJ argues that claim 20 is obvious over the '007 patent in view of Santiviago (2001), the '373 patent, and Blattner. RIB at 88.

a) The '007 Patent in View of Santiviago and the '373 Patent

First, CJ submits that the '007 patent is prior art under 35 U.S.C. § 102(b). RIB at 86. It also asserts that the '373 patent is prior art under at least § 102(a) and § 102(e). RIB at 86. CJ submits that Santiviago (2001) is prior art under § 102(a). RIB at 86. CJ argues that the '007 patent teaches "that paraquat-resistant Corynebacteria have an increased ability to produce tryptophan," as well as "culturing such bacteria and recovering tryptophan from the cultures." RIB at 86. CJ acknowledges that the '007 patent deals with Corynebacteria, and not *E. coli*, but argues that the '373 patent teaches that the two are interchangeable in the context of tryptophan production. RIB at 86. CJ submits that, "[g]iven the disclosure of the '007 Patent, a POSITA would be motivated to increase the tryptophan production of bacteria by transforming the bacteria with genetic material shown to confer paraquat resistance and have a reasonable expectation of success of doing so." RIB at 86 (citing RX-0222C (Palsson WS) at QA388).

With respect to Santiviago (2001), CJ argues that the reference teaches "a *Salmonella* '*ompD*$^+$ allele' that confers resistance to paraquat in *Salmonella*." RIB at 87. CJ submits that "The *Salmonella* '*ompD*$^+$ allele' is characterized by a 4.4kb *PstI*-fragment containing the *ompD* gene, the *yddG* gene (and at least 200 nucleotides of its native upstream region), and part of the *smvA* gene." RIB at 87. CJ argues that a person of ordinary skill in the art "would reasonably expect *Salmonella ompD*$^+$ allele, which contains the *yddG* gene, to function in *E. coli*" given that both are "Gram-negative bacteria having 'remarkable conservation of gene order.'" RIB 87 (citing RX-0222C (Palsson WS) QA223-24; RX-0163 (Santiviago (2001)) at 1905, left col.). CJ also argues that because of the interchangeability of Corynebacteria and *E. coli* in tryptophan production, "a POSITA would be motivated to transform *E. coli* with the *ompD*$^+$ allele (comprising *yddG*) to confer paraquat resistance (based on Santiviago (2001)), with a reasonable

expectation of increasing tryptophan production (based on the '007 Patent)." RIB at 87 (citing RX-0222C (Palsson WS) QA393-94).

CJ submits that "[c]loning the *ompD*+ allele on a plasmid or integrated into the genome and culturing the resulting recombinant bacteria would have amounted to routine experimentation with predictable outcomes within a POSITA's capabilities." RIB at 87 (RX-0222C (Palsson WS); RX-0166 ('007 Patent) at 3:43-49; JX-0001 ('373 Patent) at 6:62-7:60, 13:17-14:22. Further, "CJ argues that Ajinomoto 'has admitted that the enhanced tryptophan production and resistance inherently result from enhanced YddG activity (i.e., increased production of the YddG protein, exactly the result of the '007/Santiviago combination).'" RIB at 87 (citing JX-0003 ('655 Patent) at abstract, 2:46–52, 4:10–15, 5:57–61; RX-0171C (Hara Decl.) at ¶¶14, 22). In an inherency-type argument, CJ concludes that "performing the obvious step of transforming *E. coli* with an *ompD*$^{+}$ allele to increase tryptophan production, as suggested by the combination of the '007 Patent, Santiviago (2001), and the '373 Patent, would inherently increase YddG activity and enhance tryptophan production and resistance properties." RIB at 87–88.

Ajinomoto responds by noting that the '007 patent "never discusses *E. coli* tryptophan-producing strains, the *yddG* gene or protein, or any proteins related to enhancing tryptophan production." CIB at 56–57 (citing CX-2115C QA130-33; Tr. at 700:18-710:4). Ajinomoto also argues that the '007 patent teaches away from claim 20 by pointing to glyphosate-resistant strains as tryptophan producers. CIB at 57 (citing CX-2115C QA134-40; Tr. at 708:2-15). Accordingly, CJ submits that "a skilled artisan would have been motivated to explore strains with glyphosate resistance, not paraquat (MV) resistance, in relation to enhancing tryptophan production." CIB at 57 (citing CX-2115C QA140-141). Similarly, Ajinomoto submits that "it

was well-known in the art that cellular resistance to one molecule typically did not indicate that the bacterium had resistance to other molecules, or even that it would enhance production of any product, let alone aromatic amino acids." CIB at 57. It also submits that "MV resistance often does *not* indicate the presence of an amino acid export protein." CIB at 57. Ajinomoto's ultimate conclusion is that "the '007 patent does not motivate or suggest to one of skill in the art to seek a correlation between MV resistance and tryptophan production in *E. coli*." CIB at 57.

With respect to the '373 Patent, Ajinomoto submits that it "does not discuss MV." CIB at 57 (citing Tr. at 715:6-8). Instead, Ajinomoto argues that "the '373 patent, which discloses using the glyphosate-resistant *Corynebacteria* strain ATCC 21851, further supports the fact that a skilled artisan would be motivated to use a strain resistant to glyphosate, not MV." CIB at 57 (citing CX-2115C QA268).

With respect to Santiviago 2001, Ajinomoto submits that the reference "is generally directed to the chromosomal region surrounding the *ompD* porin gene and how this region affects MV resistance in *Salmonella* strains." CIB at 58 (citing CX-2115C QA239-42; Tr. at 711:18-712:11, 714:9-21). Ajinomoto further argues that Santiviago 2001 "does not refer to any aromatic amino acids, including tryptophan, or *E. coli* strains, and doesn't ascribe a function to the YddG protein, noting that it is a putative (a hypothetical protein with unknown function) transmembrane permease." CIB at 58 (citing CX-2115C QA241–42). Ajinomoto ultimately submits that "Santiviago 2001 teaches away from the YddG protein having an export function, as it points to the OmpD and SmvA proteins as being responsible for MV resistance." CIB at 58. Ajinomoto gives other examples of Santiviago teaching away from claim 20.

For instance, Ajinomoto argues that "even if a skilled artisan believed that three genes in the OmpD region (OmpD, SmvA, and YddG) played a role in exporting MV, this would further

teach away from YddG being an aromatic amino acid export protein" because "[t]he structure of the MV molecule and the three aromatic amino acids in bacteria are entirely unrelated." CIB at 58. Ajinomoto further explains that "[s]killed artisans understood that proteins typically exported related molecules."

Ajinomoto also argues that "Santiviago 2001 further teaches away from using the OmpD fragment in *E. coli* strains used to produce feed and pharmaceutical-grade tryptophan for human and animal consumption." CIB at 58 (citing CX-2115C at 251-52). Elaborating, Ajinomoto explains that "Santiviago 2001 explicitly states that the discovery of the role of the OmpD fragment is "important" because of its link to enhancing the pathogenicity of *Salmonella* bacteria" and that "[t]he OmpD fragment is unique to *Salmonella.*" CIB at 58. From these points, Ajinomoto concludes that "[a] skilled artisan would not be motivated to combine a fragment unique to *Salmonella* and known to enhance bacterial pathogenicity into *E. coli* for producing commercial tryptophan for humans and animals." CIB at 58–59. Ajinomoto finds further support for this argument in [redacted] CIB at 59 (citing CX-2115C at QA267; CX-698C).

Ultimately, Ajinomoto bases its opposition to CJ's obviousness argument on the contention that "a skilled artisan would not be motivated to combine the teachings of the '007 patent, which relates to *Corynebacteria*, with Santiviago 2001 which deals with pathogenic gene regions in *Salmonella*, to enhance tryptophan production in *E. coli*." CIB at 59.

The ALJ finds that CJ has failed to establish by clear and convincing evidence that claim 20 of the '655 patent is obvious over the '007 Patent in view of Santiviago (2001) and the '373 Patent. As an initial matter, the ALJ notes that there is no dispute that the '007 patent, Santiviago (2001), and the '373 patent are prior art to the '655 patent. Rather the dispute centers around

what those references actually disclose, and whether there was a person of ordinary skill in the art would have been motivated to combine the references. Here, the ALJ finds a lack of evidence supporting a motivation to combine these three references.

CJ relies on the testimony of its expert, Dr. Palsson, to address the motivation to combine. *See* RIB at 86 (citing RX-0222C (Palsson WS) at QA388). However, Dr. Palsson's testimony on motivation to combine is thin at best. In his witness statement, Dr. Palsson addresses the motivation to combine issue as follows:

> **Q388. Did you consider any motivations to combine these references?**
>
> A. Yes. In my opinion, a skilled artisan with the '007 Patent in hand wanting to increase tryptophan production would be motivated to modify tryptophan producing strains with DNA known in the prior art to be related to paraquat resistance. And, given the results of the '007 Patent, the skilled worker would, in my opinion, have a reasonable expectation that such modified strains would both be resistant to paraquat and would have increased tryptophan production and accumulation.

RX-0222C at QA 388. This statement is largely conclusory, and fails to address the fact that neither the '007 patent, nor the Santiviago (2001) reference actually dealt with *E. coli*. While CJ attempts to equate the Corynebacteria results of the '007 patent with *E. coli* based on the disclosure of the '373 patent, and argues that the *Salmonella* based teachings of Santiviago are applicable to *E. coli* based on the fact that both are gram-negative bacteria "having remarkable conservation of gene order," these arguments appear to be based on the benefit of hindsight. Put another way, the tenuous connection between these references, which dealt with different bacteria, and sought to address different problems, appears to be based on the advantage of having claim 20 as a roadmap. Accordingly, given the prohibition on establishing obviousness via the use of hindsight, the ALJ finds that CJ has failed to establish that claim 20 of the '655 patent is obvious over the '007 patent in view of Santiviago (2001) and the '373 patent.

b) The '007 Patent in View of Santiviago, the '373 Patent, and Blattner

In addition to its obviousness argument above, CJ also submits that claim 20 of the '655 patent is obvious in light of the same combination with the addition of Blattner. RIB at 88. CJ explains that "Blattner teaches the full genomic sequence of *E. coli*, including sequences for *E. coli yddG* gene and YddG protein, i.e., corresponding to SEQ ID NO: 1 and SEQ ID NO: 2, respectively. RIB at 88 (citing RX-0146 (Blattner) at 1454, col. 3; RX-0222C (Palsson WS) QA102-07). From this disclosure, CJ argues that, "[b]ecause Santiviago (2001) discloses that the *ompD*$^+$ allele contains, the *yddG* and *ompD* genes, a POSITA would be motivated to use the *E. coli* counterparts of all three genes." RIB at 88 (citing RX-0222C (Palsson WS) at QA414).

CJ offers no explanation for its assertion that a person of ordinary skill in the art would be motivated to use the *E. coli* counterparts except to point to internal documents from CJ [redacted] that are dated years after the filing date of the '655 patent. *See* RIB at 88 (citing RX-0222C (Palsson WS) at QA415-21; [redacted]; RX-0232C_TR (December 2008 Report) at 40-41). CJ makes no attempt to explain why these documents, which are not contemporaneous with priority date of claim 20, are evidence of a motivation to combine during the relevant time period. Accordingly, in the absence of any reliable evidence that mere disclosure of the full genomic sequence of *E. coli* would lead a person of ordinary skill in the art to adapt the teachings of Santiviago (2001) to *E. coli*, the ALJ finds that CJ has failed to establish by clear and convincing evidence that claim 20 of the '655 patent is obvious over the '007 patent in view of Santiviago (2001), the '373 patent, and Blattner.

c) Secondary Consideration of Nonobviousness

With respect to secondary considerations of nonobviousness, Ajinomoto submits that "the scientific community recognizes the YddG protein as one of the commonly accepted

necessary genetic modifications needed for enhanced tryptophan production." CIB at 60 (citing CX-2115C QA350-55; CX-474; CX-475; CX-476; CX-601). Ajinomoto also argues that it has "received the Russian Federation Government Prize in Science and Technology for "[t]he development and implementation of innovative biotechnological production processes of natural amino acids for agriculture.'" CIB at 60 (citing CX-2115C QA357; CX-1483). And finally, Ajinomoto argues that CJ has copied its invention. *See* CIB at 60.

In response, CJ submits that Ajinomoto has failed to establish a nexus between the Russian award and claim 20 of the '655 patent. *See* RIB at 89. CJ also addresses an "unexpected results" argument that Ajinomoto did not raise in its initial post-hearing brief.

The ALJ finds that Ajinomoto has not provided sufficient evidence to establish secondary considerations of nonobviousness with respect to claim 20. As CJ points out, there must be a nexus between any praise or recognition and the actual claim at issue. In pointing to the Russian award, Ajinomoto has failed to connect that award to claim 20 of the '655 patent. As Ajinomoto seems to acknowledge, the award was given for "its innovative research achievements in the last 12 years, including the 'innovative biotechnical production processes for producing amino acids.'" CRB at 28. This broad description does not offer any insight into the extent that claim 20 was the reason Ajinomoto was given the award. There is simply no evidence from which the ALJ can conclude that a nexus exists between that award and claim 20 of the '655 patent.

To the extent Ajinomoto raised unexpected results as a secondary indicia of nonobviousness in its reply brief after foregoing that argument in its initial brief, that argument has been waived.

Finally, Ajinomoto has failed to prove copying by CJ of the invention of claim 20 of the '655 patent. At best, Ajinomoto has shown that CJ had knowledge of its own work related to the

'655 patent. *See* CIB at 60. The ALJ disagrees that [redacted] "is a tacit admission of copying." *See* CIB at 60. And the fact that [redacted] is also not an admission of copying. *See id.*

As noted *supra*, the ALJ found that CJ had failed to establish a prima facie case of obviousness based on a failure to demonstrate a motivation to combine the prior art references upon which it relied. Thus, the absence of secondary consideration of nonobviousness will not alter the ALJ's ultimate finding that CJ has failed to establish by clear and convincing evidence that claim 20 of the '655 patent is invalid as obvious.

VIII. DOMESTIC INDUSTRY

A. Legal Standard

In patent based proceedings under section 337, a complainant must establish that an industry "relating to the articles protected by the patent . . . exists or is in the process of being established" in the United States. 19 U.S.C. § 1337(a)(2). Under Commission precedent, the domestic industry requirement of Section 337 consists of a "technical prong" and an "economic prong." *Certain Data Storage Systems and Components Thereof*, Inv. No. 337-TA-471, Initial Determination Granting EMC's Motion No. 471-8 Relating to the Domestic Industry Requirement's Economic Prong (unreviewed) at 3 (Public Version, October 25, 2002) The "economic prong" of the domestic industry requirement is satisfied when the economic activities set forth in subsections (A), (B), and/or (C) of subsection 337(a)(3) have taken place or are taking place with respect to the protected articles. *Certain Printing and Imaging Devices and Components Thereof*, Inv. No. 337-TA-690, Commission Op. at 25 (February 17, 2011)

("*Printing and Imaging Devices*"). With respect to the "economic prong," 19 U.S.C. § 1337(a)(2) and (3) provide, in full:

> (2) Subparagraphs (B), (C), (D), and (E) of paragraph (1) apply only if an industry in the United States, relating to the articles protected by the patent, copyright, trademark, mask work, or design concerned, exists or is in the process of being established.
>
> (3) For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned–
>
> (A) significant investment in plant and equipment;
>
> (B) significant employment of labor or capital; or
>
> (C) substantial investment in its exploitation, including engineering, research and development, or licensing.

Id.

Given that these criteria are in the disjunctive, satisfaction of any one of them will be sufficient to meet the domestic industry requirement. *Certain Integrated Circuit Chipsets and Products Containing Same*, Inv. No. 337-TA-428, Order No 10 at 3, Initial Determination (Unreviewed) (May 4, 2000), citing *Certain Variable Speed Wind Turbines and Components Thereof*, Inv. No. 337-TA-376, Commission Op. at 15, USITC Pub. 3003 (Nov. 1996). The Commission has embraced a flexible, market-oriented approach to domestic industry, favoring case-by-case determination "in light of the realities of the marketplace" that encompass "not only the manufacturing operations" but may also include "distribution, research and development and sales." *Certain Dynamic Random Access Memories*, Inv. No. 337-TA-242, USITC Pub. 2034, Commission Op. at 62 (Nov. 1987) ("*DRAMs*").

To meet the technical prong, the complainant must establish that it practices at least one claim of the asserted patent. *Certain Point of Sale Terminals and Components Thereof*, Inv. No. 337-TA-524, Order No. 40 (April 11, 2005). The test for claim coverage for the purposes of the

technical prong of the domestic industry requirement is the same as that for infringement. *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1375 (Fed. Cir. 2003); *see also Certain Doxorubicin and Preparations Containing Same*, Inv. No. 337-TA-300, Initial Determination at 109 (U.S.I.T.C., May 21, 1990) ("*Certain Doxorubicin*"), *aff'd*, Views of the Commission at 22 (October 31, 1990). "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." *(Id.)* As with infringement, the first step of claim construction is a question of law, whereas the second step of comparing the article to the claims is a factual determination. *Markman*, 52 F.3d at 976. The technical prong of the domestic industry can be satisfied either literally or under the doctrine of equivalents. *Certain Excimer Laser Systems for Vision Correction Surgery and Components Thereof and Methods for Performing Such Surgery*, Inv. No. 337-TA-419, Order No. 43 (July 30, 1999). The patentee must establish by a preponderance of the evidence that the domestic product practices one or more claims of the patent. *See Bayer AG v. Elan Pharm. Research Corp.*,, 212 F.3d 1241, 1247 (Fed. Cir. 2000).

The Commission recently determined that the technical prong is not limited to subsections (A) and (B), but that any complainant seeking to establish a domestic industry under subsection (C) must also meet the technical prong. *Certain Computers and Computer Peripheral Devices, and Components Thereof, and Products Containing Same*, Inv. No. 337-TA-841, Comm'n Op. (December 20, 2013). Specifically, the Commission stated

> Based on the *InterDigital* and *Microsoft* decisions, a complainant alleging the existence of a domestic industry under 19 U.S.C. §1337(a)(3)(C) must show the existence of articles. As discussed extensively earlier, the substantial investment, once protected articles have been shown, is in the exploitation of the intellectual-property rights, "including engineering, research and development, or licensing.

Id. at 40. The Commission further stated, however, that "[w]e reject the [] production-driven requirement, which is in conflict with the plain language of the statute and its legislative history." *Id.*

Congress enacted 19 U.S.C. § 1337(a)(3) in 1988 as part of the Omnibus Trade and Competitiveness Act. *See Certain Plastic Encapsulated Integrated Circuits,* Inv. No. 337-TA-315, USITC Pub. No. 2574 (Nov. 1992), Initial Determination at 89 (October 16, 1991) (unreviewed in relevant part). The first two sub-paragraphs codified existing Commission practice. *See id.* at 89; *see also Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Commission Op. at 39 (June 29, 2007). Under Commission precedent, these requirements could be met by manufacturing the articles in the United States, *see, e.g.*, *DRAMs*, Commission Op. at 61, or other related activities, *see Schaper Mfg. Co. v. U.S. Int'l Trade Comm'n*, 717 F.2d 1368, 1373 (Fed. Cir. 1983) ("[I]n proper cases, 'industry' may encompass more than the manufacturing of the patented item. . . .").

In addition to subsections (A) and (B), there is also subsection (C). "In amending section 337 in 1988 to include subsection (C), Congress intended to liberalize the domestic industry requirement so that it could be satisfied by all 'holders of U.S. intellectual property rights who are engaged in activities genuinely designed to exploit their intellectual property' in the United States." *Certain Multimedia Display and Navigation Devices and Systems and Components Thereof, and Products Containing Same*, Inv. No. 337-TA-694, Commission Op. at 7 (August 8, 2011) (quoting *Certain Digital Processors and Digital Processing Systems, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-559, Final Initial Determination at 93 (unreviewed in relevant part) (May 11, 2007).

In *Printing and Imaging Devices*, the Commission held that "under the statute, whether the complainant's investment and/or employment activities are 'significant' is not measured in the abstract or absolute sense, but rather is assessed with respect to the nature of the activities and how they are 'significant' to the articles protected by the intellectual property right." *Printing and Imaging Devices*, Commission Op. at 26. The Commission further stated that:

> the magnitude of the investment cannot be assessed without consideration of the nature and importance of the complainant's activities to the patented products in the context of the marketplace or industry in question . . . . whether an investment is 'substantial' or 'significant' is context dependent. (*Id.* at 31.)

Indeed, the Commission has emphasized that "there is no minimum monetary expenditure that a complainant must demonstrate to qualify as a domestic industry under the 'substantial investment' requirement" of section 337(a)(3)(C). *Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, Commission Op. at 25 (May 16, 2008). Moreover, the Commission has stated that the complainant need not "define or quantify the industry itself in absolute mathematical terms." *Id.* at 26.

Section 337(a)(3)(C) provides for domestic industry based on "substantial investment" in the enumerated activities, including licensing of a patent. *See Certain Digital Processors and Digital Processing Systems, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-559, Initial Determination at 88 (May 11, 2007) ("*Certain Digital Processors*"). Mere ownership of the patent is insufficient to satisfy the domestic industry requirement. *Certain Digital Processors* at 93. (citing the Senate and House Reports on the Omnibus Trade and Competitiveness Act of 1988, S.Rep. No. 71). However, entities that are actively engaged in licensing their patents in the United States can meet the domestic industry requirement. *Certain Digital Processors* at 93. The complainant must receive revenue, *e.g.* royalty payments, from its

licensing activities. *Certain Digital Processors,* at 93-95 ("Commission decisions also reflect the fact that a complainant's receipt of royalties is an important factor in determining whether the domestic industry requirement is satisfied . . . [t]here is no Commission precedent for the establishment of a domestic industry based on licensing in which a complainant did not receive any revenue from alleged licensing activities. In fact, in previous investigations in which a complainant successfully relied solely on licensing activities to satisfy section 337(a)(3), the complainant had licenses yielding royalty payments.") (citations omitted). *See also Certain Video Graphics Display Controllers and Products Containing Same*, Inv. No. 337-TA-412, Initial Determination at 13 (May 14, 1999) (*"Certain Video Graphics Display Controllers"*); *Certain Integrated Circuit Telecommunication Chips and Products Containing Same Including Dialing Apparatus*, Inv. No. 337-TA-337, U.S.I.T.C. Pub. No. 2670, Initial Determination at 98 (March 3, 1993) (*"Certain Integrated Circuit Telecommunication Chips"*); *Certain Zero-Mercury-Added Alkaline Batteries, Parts Thereof and Products Containing Same*, Inv. No. 337-TA-493, Initial Determination at 142 (June 2, 2004) (*"Certain Zero-Mercury-Added Alkaline Batteries"*); *Certain Semiconductor Chips*, Order No. 13 at 6 (January 24, 2001); *Certain Digital Satellite System DSS Receivers and Components Thereof*, Inv. No. 337-TA-392, Initial and Recommended Determinations at 11 (December 4, 1997) ("*Certain Digital Satellite System DSS Receivers"*).

In *Certain Multimedia Display & Navigation Devices & Systems, Components Thereof, & Products Containing Same*, Inv. No. 337-TA-694, Comm'n Op. (Aug. 8, 2011) ("*Navigation Devices*"), the Commission stated that a complainant seeking to rely on licensing activities must satisfy three requirements: (1) the investment must be "an investment in the exploitation of the asserted patent;" (2) the investment must relate to licensing; and (3) the investment "must be

domestic, *i.e.*, it must occur in the United States." *Id.* at 7-8. The Commission stated that "[o]nly after determining the extent to which the complainant's investments fall within these statutory parameters can we evaluate whether complainant's qualifying investments are 'substantial,' as required by the statute." *Id.* at 8.

Under the first of the three requirements, the complainant must show a nexus between the licensing activity and the asserted patent. *Id.* at 9. When the asserted patent is part of a patent portfolio, and the licensing activities relate to the portfolio as a whole, the Commission requires that the facts be examined to determine the strength of the nexus between the asserted patent and the licensing activities. *Id.* The Commission provided a non-exhaustive list of factors to consider, such as (1) whether the licensee's efforts relate to "an article protected by" the asserted patent under Section 337 (a)(2)-(3); (2) the number of patents in the portfolio; (3) the relative value contributed by the asserted patent to the portfolio; (4) the prominence of the asserted patent in licensing discussions, negotiations, and any resulting licensing agreement; and (5) the scope of technology covered by the portfolio compared to the scope of the asserted patent. *Id.* at 9-10. The Commission explained that the asserted patent may be shown to be particularly important or valuable within the portfolio where there is evidence that: (1) it was discussed during licensing negotiations; (2) it has been successfully litigated before by the complainant; (3) it is related to a technology industry standard; (4) it is a base patent or pioneering patent; (5) it is infringed or practiced in the United States; or (6) the market recognizes the patent's value in some other way. *Id.* at 10-11.

Once a complainant's investment in licensing the asserted patent in the United States has been assessed in the manner described above, the next inquiry is whether the investment is "substantial." 19 U.S.C. § 1337(a)(3)(C). The Commission takes "a flexible approach whereby a

complainant whose showing on one or more of the three section 337(a)(3)(C) requirements is relatively weak may nevertheless establish that its investment is 'substantial' by demonstrating that its activities and/or expenses are of a large magnitude." *Multimedia Display and Navigation Devices*, Comm'n Op. at 15. The Commission has indicated that whether an investment is "substantial" may depend on:

> (1) the nature of the industry and the resources of the complainant;
>
> (2) the existence of other types of "exploitation" activities;
>
> (3) the existence of license-related "ancillary" activities;
>
> (4) whether complainant's licensing activities are continuing; and
>
> (5) whether complainant's licensing activities are the type of activities that are referenced favorably in the legislative history of section 337(a)(3)(C).

Id. at 15-16. The complainant's return on its licensing investment (or lack thereof) may also be circumstantial evidence of substantiality. *Id.* at 16. In addition, litigation expenses may be evidence of the complainant's investment, but "should not automatically be considered a 'substantial investment in . . . licensing,' even if the lawsuit happens to culminate in a license." *John Mezzalingua Assocs., Inc. v. Int'l Trade Comm'n*, 660 F.3d 1322 (Fed. Cir. 2011).

B. Technical Prong

1. '373 Patent

Ajinomoto identifies its domestic industry products as "tryptophan production strains WA-05 and WA-08 and the tryptophan products made from these strains." CIB at 70. [redacted] to Ajinomoto's pharmaceutical-grade L-tryptophan in North Carolina, and the [redacted] to its plans to manufacture feed-grade tryptophan in Eddyville, Iowa. CIB at 70. Ajinomoto submits that the evidence has shown "that [redacted] tryptophan-producing *E. coli* microorganisms" and that "[redacted]

[redacted] are 'tryptophan feedback resistant and serine feedback resistant,' [redacted]." CIB at 71. Ajinomoto acknowledges that CJ's challenge to its domestic industry case is based on whether [redacted] the K_i value limitations of the '373 patent. CIB at 71.

With respect to the [redacted], Ajinomoto relies on [redacted].

Ajinomoto notes that claims 2–3 and 5–7 depend from claim 1, and that the additional limitations required by each are not contested by CJ. CIB at 73. Ajinomoto similarly notes that to the extent claim 10 differs from claim 1, those differences are not the subject of CJ's challenges to its domestic industry case. CIB at 74–75. Accordingly, Ajinomoto submits that the technical prong domestic industry dispute revolves around whether the alleles in [redacted] the K_i value limitations common to claims 1, 2–3, 5–7, and 10.

In response, CJ argues that Ajinomoto's [redacted] not meet the limitations of claims 1–3, 5–7, or 10 of the '373 patent for [redacted]. RIB at 15–16. Additionally, with respect to [redacted], CJ argues that [redacted]. To the extent Ajinomoto relies on [redacted], CJ argues that [redacted]. CJ

argues that [redacted] have a K_i value outside the range of claims 1-3, 5-7, and 10 of the '373 Patent. RIB at 16. Accordingly, CJ concludes that "[redacted] practice any of claims 1-3, 5-7, or 10 of the '373 Patent," and that Ajinomoto has not satisfied the technical prong of the domestic industry requirement. RIB at 16.

The ALJ finds that Ajinomoto has not established that it meets the technical prong of the domestic industry requirement. [redacted] Because Ajinomoto's domestic industry products must practice each element of at least one claim of the '373, but here fail to meet the K_i for serine limitations, the ALJ need not address the additional dispute concerning [redacted] allele.

Accordingly, the ALJ finds that Ajinomoto has not satisfied the technical prong of the domestic industry requirement.

2. '655 Patent

Ajinomoto asserts that it satisfies the technical prong of the domestic industry requirement because [redacted] claims 9–12, 14–18,

and 20 of the '655 patent. CIB at 34. Ajinomoto submits that all of CJ's challenges to its domestic industry case are based on the "resistance" limitation of its domestic industry claims. *Id.* Ajinomoto points to evidence establishing that its strains meet the "recombinant," "protein definition," and "enhancement" limitations of claims 9 and 15. *See* CIB at 34–36. As Ajinomoto notes, CJ does not challenge these elements of its technical prong domestic industry case.

With respect to the "resistance" limitation, Ajinomoto submits that [redacted] the claimed YddG protein" and that "[e]nhanced activity of this protein leads to resistance to aromatic amino acids and their analogs." CIB at 36. [redacted]. Ajinomoto relies extensively on the arguments it made with respect to the "resistance" limitation as applied to CJ's strains in its infringement case. *See* CIB at 36 (citing to § IV(C)(2)(c) of its brief). After addressing independent claims 9 and 15, Ajinomoto walks through the additional limitations of dependent claims 10–12, 14, 16–18, and 20, explaining that each of these additional limitations is also satisfied [redacted]. CIB at 37–38.

In response, CJ submits that [redacted] and that Ajinomoto "has provided no evidence that [redacted] the required resistance." RIB at 63–64. CJ submits that Ajinomoto's reliance on [redacted]

[redacted]. RIB at 65. CJ dismisses Ajinomoto's expert, Dr. Stephanopoulos's, opinions as conclusory and lacking evidentiary support. RIB at 65–66.

As noted by the parties, the sole dispute regarding the technical prong of Ajinomoto's domestic industry case as it relates to the '655 patent is largely identical to the dispute regarding the "resistance limitation" of claims 9 and 15 as applied to CJ's production strains in Ajinomoto's infringement case. More particularly, the dispute is whether it is sufficient to show enhanced protein activity to establish resistance to L-phenylalanine, fluoro-phenylalanine or 5fluoro-DL-tryptophan. In the context of infringement, the ALJ determined that Ajinomoto could not satisfy its evidentiary burden by inferring resistance from the [redacted]. The same reasoning is dispositive here. Accordingly, the ALJ finds that Ajinomoto has not established that its production strains meet the resistance limitation of the claims it relies on to establish domestic industry, and therefore, has failed to establish a domestic industry with respect to the '655 patent.

C. Economic Prong

On April 17, 2017, the ALJ issued an initial determination granting summary determination to Ajinomoto that it satisfied the economic prong of the domestic industry requirement as to both the '373 and '655 patents. Order No. 18. The Commission declined to review that initial determination. Comm'n Not. (May 17, 2017) (EDIS Doc. 612005). Accordingly, Ajinomoto has satisfied the economic prong of the domestic industry requirement.

IX. CONCLUSIONS OF LAW

1. The Commission has personal jurisdiction over the parties and subject-matter and *in rem* jurisdiction over the accused products.

2. The importation or sale requirement of section 337 is satisfied.

3. The accused products do not infringe the asserted claims of the '373 or the '655 patents, either literally or under the doctrine of equivalents.

4. Claim 10 of the '373 patent is invalid under 35 U.S.C. § 112, first paragraph, for lack of written description.

5. Claim 10 of the '373 patent is invalid under 35 U.S.C. § 112, second paragraph, for indefiniteness.

6. Claim 10 of the '373 patent is not invalid under 35 U.S.C. § 103 for obviousness.

7. Claim 20 of the '655 patent is invalid under 35 U.S.C. § 112, first paragraph, for lack of written description.

8. Claim 20 of the '655 patent is not invalid under 35 U.S.C. § 112, first paragraph, for lack of enablement.

9. Claim 20 of the '655 patent is not invalid under 35 U.S.C. § 112, second paragraph, for indefiniteness.

10. Claim 20 of the '655 patent is not invalid under 35 U.S.C. § 102 for anticipation.

11. Claim 20 of the '655 patent is not invalid under 35 U.S.C. § 103 for obviousness.

12. The domestic industry requirement has not been met for the '373 or the '655 patents.

13. It has been established that no violation exists of section 337 for the asserted claims of the '373 and the '655 patents.

X. INITIAL DETERMINATION & ORDER ON VIOLATION

Based on the foregoing, it is the INITIAL DETERMINATION of the ALJ that no violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, has occurred in the importation into the United States, the sale for importation, or 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 certain claims of U.S. Patent Nos. 6,180,373; and 7,666,655.

Further, this Initial Determination, together with the record of the hearing in this investigation consisting of:

(1) the transcript of the hearing, with appropriate corrections as may hereafter be ordered, and

(2) the exhibits received into evidence in this investigation, as listed in the attached exhibit lists in Appendix A,

are CERTIFIED to the Commission. In accordance with 19 C.F.R. § 210.39(c), all material found to be confidential by the undersigned under 19 C.F.R. § 210.5 is to be given *in camera* treatment.

The Secretary shall serve a public version of this ID upon all parties of record and the confidential version upon counsel who are signatories to the Protective Order (Order No. 1.) issued in this investigation.

XI. RECOMMENDED DETERMIANTION ON REMEDY & BOND

A. Remedy and Bonding

The Commission's Rules provide that subsequent to an initial determination on the question of violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, the administrative law judge shall issue a recommended determination containing findings of fact and recommendations concerning: (1) the appropriate remedy in the event that the Commission finds a violation of section 337, and (2) the amount of bond to be posted by respondents during Presidential review of Commission action under section 337(j). *See* 19 C.F.R. § 210.42(a)(1)(ii).

1. Limited Exclusion Order

Under Section 337(d), the Commission may issue either a limited or a general exclusion order. A limited exclusion order ("LEO") directed to respondents' infringing products is among the remedies that the Commission may impose, as is a general exclusion order that would apply to all infringing products, regardless of their manufacturer. *See* 19 U.S.C. § 1337(d).

Ajinomoto argues that, if the Commission finds CJ in violation of section 337, a LEO covering all of CJ's infringing products should issue. With respect to the '337 patent specifically, Ajinomoto argues that there is no legal basis for withholding an LEO because the '373 patent will expire during the Presidential Review Period. CIB at 99.

CJ does not dispute that an LEO should issue if the Commission finds a violation of section 337 on the basis of the '655 patent. *See* RIB at 90–91. However, CJ does argue that an LEO should not issue on the basis of the '373 patent due to the fact that it will expire during the Presidential Review period. RIB at 90–91. CJ also seeks to have a certification provision included in any LEO that does issue. RIB at 91.

Consistent with Order No. 11, the ALJ does not agree that the expiration date of the '373 patent should preclude the issuance of an LEO in this investigation with respect to that investigation. Additionally, the ALJ can discern no meaningful justification in CJ's briefing for including a certification provision in any LEO that may issue. Accordingly, should the Commission find a violation, the ALJ recommends that the Commission issue a LEO against Respondents' accused products.

2. Cease and Desist Order

Ajinomoto argues that a cease and desist order should issue against CJ because CJ maintains commercially significant inventories of Accused Products. CIB at 99–100 (citing RX-300C, QA 73-76; *see also* CX-1454C.18).

CJ counters that the stipulation between it and Ajinomoto regarding CJ's inventory in the United States is insufficient to establish that its inventory is "commercially significant." RIB at 91. CJ essentially presents its opposition as failure of proof on Ajinomoto's part. CJ also argues that there is no evidence that Respondents CJ CheilJedang Corp. and PT. CheilJedang Indonesia maintain any domestic inventory, commercially significant or otherwise. RIB at 92.

Should the Commission find a violation, the ALJ recommends the issuance of a CDO prohibiting Respondent CJ America, Inc. from selling its accused products because it maintains a commercially significant inventory of the accused products in the United States. CX-1454C; *see also Certain Agricultural Tractors*, Inv. No. 337-TA-380, Comm'n Op. at 31, USITC Pub. No. 3026 (Mar. 1997) ("[C]ease and desist orders are warranted with respect to domestic respondents that maintain commercially significant U.S. inventories of the infringing product."). The ALJ agrees, however, that Ajinomoto's evidence addresses only CJ America, Inc.'s inventory, and thus any CDO should be limited to that entity. *See* CX-1454C; CIB at 99–100

("As of April 20, 2017, CJ America held approximately [redacted] of Accused Products in inventory in the U.S.").

3. Bond During Presidential Review Period

The Administrative Law Judge and the Commission must 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 issue a remedy. The purpose of the bond is to protect the complainant from any injury. 19 C.F.R. § 210.42(a)(1)(ii), § 210.50(a)(3).

Ajinomoto seeks a bond requirement in the amount of 100% of the entered value on the basis that "a comparison between the pricing of CJ's products with Ajinomoto's products is insufficient to protect Ajinomoto from injury." CIB at 100.

CJ argues that no bond is appropriate, noting first that Ajinomoto sought a 35% bond in its pre-hearing brief, but now seeks a 100% bond given its failure to produce evidence supporting the 35% calculation. RRB at 49–50.

Should the Commission find a violation, the ALJ does not recommend any bond. Ajinomoto appears to have abandoned its request for a 35% bond in favor of a 100% bond. However it has not shown that calculating a price differential bond would be impractical, and its new argument that only a 100% bond could sufficiently protect it from injury is contradicted by its earlier position. *See* CIB at 100.

B. Conclusion

In accordance with the discussion of the issues contained herein, it is the RECOMMENDED DETERMINATION ("RD") of the ALJ should the Commission find a

violation, that the Commission issues an LEO against CJ's accused products, and a CDO against CJ America, Inc. The ALJ does not recommend any bond.

Within seven days of the date of this document, each party shall submit to the office of the Administrative Law Judge a statement as to whether or not it seeks to have any portion of this document deleted from the public version. The parties' submissions must be made by hard copy by the aforementioned date.

Any party seeking to have any portion of this document deleted from the public version thereof must submit to this office (1) a copy of this document with red brackets indicating any portion asserted to contain confidential business information by the aforementioned date and (2) a list specifying where said redactions are located. The parties' submission concerning the public version of this document need not be filed with the Commission Secretary.

SO ORDERED.

Theodore R. Essex
Administrative Law Judge

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 **FINAL INITIAL DETERMINATION** has been served by hand upon the following parties as indicated, on **September 1, 2017**.

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainants: Ajinomoto Co., Inc. and Ajinomoto Heartland, Inc.

Mareesa A. Frederick, Esq.
FINNEGAN, HENDERSON, FARABOW, GARRETT, & DUNNER, L.L.P.
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Washington, DC 20001

- ☐ Via Hand Delivery
- ☑ Via Express Delivery
- ☐ Via First Class Mail
- ☐ Other:_____

On Behalf of Respondents: CJ CheilJedang Corp.; CJ America, Inc.; and PT CheilJedang Indonsia

Matthew J. Rizzolo, Esq.
ROPES & GRAY LLP
2099 Pennsylvania Avenue, NW
Washington, D.C. 20006

- ☐ Via Hand Delivery
- ☑ Via Express Delivery
- ☐ Via First Class Mail
- ☐ Other:_____

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of	
CERTAIN L-TRYPTOPHAN, L -TRYPTOPHAN PRODUCTS, AND THEIR METHODS OF PRODUCTION	Investigation No. 337-TA-1005

NOTICE OF COMMISSION DETERMINATION NOT TO REVIEW AN INITIAL DETERMINATION GRANTING COMPLAINANTS' UNOPPOSED MOTION FOR SUMMARY DETERMINATION THAT THEY SATISFY THE ECONOMIC PRONG OF THE DOMESTIC INDUSTRY REQUIREMENT

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination ("ID") (Order No. 18) of the presiding administrative law judge ("ALJ") granting Complainants' unopposed motion for summary determination that they satisfy the economic prong of the domestic industry requirement for both asserted patents.

FOR FURTHER INFORMATION CONTACT: Houda Morad, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 708-4716. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server at *https://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted Investigation No. 337-TA-1005 on June 14, 2016, 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 FR 38735-6 (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 certain claims of U.S. Patent No. 7,666,655 and U.S.

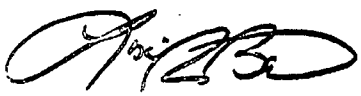
Patent No. 6,180,373 (collectively, "the asserted patents"). *Id.* The notice of investigation identified CJ CheilJedang Corp. of Seoul, Republic of Korea; CJ America, Inc. of Downers Grove, Illinois; and PT CheilJedang Indonesia of Jakarta, Indonesia (collectively "CJ" or "Respondents") as respondents in this investigation. *See id.* The Office of Unfair Import Investigations is not a party to the investigation.

On March 10, 2017, Complainants filed an unopposed motion for summary determination that they satisfy the economic prong of the domestic industry requirement under 19 U.S.C. 1337(a)(2) and (3) ("Complainants' Motion"). Complainants identified pharmaceutical grade L-tryptophan and feed-grade L-tryptophan as the domestic industry products. *See* Memorandum in Support of Complainants' Motion at 1. On April 17, 2017, the ALJ issued the subject ID (Order No. 18) 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 at 23. The ALJ found that "[b]ased on the undisputed facts presented by Ajinomoto, . . . Ajinomoto has shown that it has a domestic industry in existence with respect to the production of pharmaceutical-grade L-tryptophan at its North Carolina plant, and has shown that it is in the process of establishing a domestic industry with respect to feed-grade L-tryptophan in its [Iowa] plant." *Id.* at 25. No party petitioned for review.

The Commission has determined not to review the subject ID.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.



Lisa R. Barton
Secretary to the Commission

Issued: May 17, 2017

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 **NOTICE** has been served on the following parties, as indicated, on **May 17, 2017**.

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainants Ajinomoto Co., Inc. and Ajinomoto Heartland, Inc.:

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Washington, DC 20001

☐ Via Hand Delivery
☐ Via Express Delivery
☒ Via First Class Mail
☐ Other:_____

On Behalf of Respondents CJ CheilJedang Corp., CJ America, Inc., and PT CheilJedang Indonesia:

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ROPES & GRAY LLP
2099 Pennsylvania Ave., NW
Washington, DC 20006

☐ Via Hand Delivery
☐ Via Express Delivery
☒ Via First Class Mail
☐ Other:_____

PUBLIC VERSION

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**

ORDER NO. 18: (1) WITHDRAWING ORDER 17[1]

(2) INITIAL DETERMINATION GRANTING COMPLAINANTS' MOTION FOR SUMMARY DETERMINATION THAT THEY HAVE SATISFIED THE ECONOMIC PRONG OF THE DOMESTIC INDUSTRY REQUIREMENT.

(April 17, 2017)

On March 10, 2017, Complainants Ajinomoto Co., Inc. and Ajinomoto Heartland, Inc. (collectively, "Ajinomoto" or "Complainants") moved for summary determination that they have satisfied the "economic prong" of the domestic industry requirement of 19 U.S.C. 1337(a)(2) and (3). Motion Dkt. No. 1005-016. Pursuant to Ground Rule 3.2, Complainants indicate that Respondents CJ CheilJedang Corp., CJ America, Inc., and PT. CheilJedang Indonesia (collectively "CJ" or "Respondents") do not oppose Ajinomoto's motion. The Commission Investigative Staff ("Staff") is not participating in this investigation.

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[1] Order 17, which omitted section I(B) and a portion of section IV, is hereby withdrawn. This Initial Determination shall replace the one given in Order 17.

I. BACKGROUND

A. Institution and Procedural History

By publication of a notice in the *Federal Register* on June 14, 2016, pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, the Commission instituted this investigation to determine:

> whether there is a violation of subsection (a)(1)(B)(ii) of section 337 in the importation into the United States, the sale for importation, or 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 one or more of claims 4, 7, 8 and 20 of the '655 patent and claim 10 of the '373 patent, and whether an industry in the United States exists or is in the process of being established as required by subsection (a)(2) of section 337

81 Fed. Reg. 38736 ("NOI") (June 14, 2016). On July 14, 2016, the Administrative Law Judge ("ALJ") set a 16-month target date of October 16, 2017, and indicated that an evidentiary would commence at 9:00AM on Monday, March 6, 2017, and conclude no later than Friday March 10, 2017. Order 4 (July 14, 2016). On December 1, 2016, the ALJ issued an initial determination extending the target date to December 18, 2017, and moved the evidentiary hearing to May 15–19, 2017. Order 8 (Dec. 1, 2016). There have been no additional changes to the target date or the scheduling of the evidentiary hearing in this matter.

B. Asserted Patents & Claims

Consistent with the notice of institution, claim 10 of the '373 patent, and claims 4, 7, 8 and 20 of the '655 patent are the asserted claims in this investigation.

1. Claim 10 of the '373 Patent

The '373 Patent is titled: "Microorganisms for the production of tryptophan and process for the preparation thereof." '373 Patent at Title. At a broad level, the patent claims to disclose

"A tryptophan producing strain of microorganism is selected from *E. coli* and Corynebacteria and is tryptophan feedback resistant and serine feedback resistant. The 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. The 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." *Id.* at Abstract. Claim 10 of the '373 Patent provides:

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

Id. at claim 10.

2. Claims 4, 7, 8 and 20 of the '655 Patent

The '655 Patent is titled: "Escherichia bacteria transformed with the yddG gene to enhance L-amino acid producing activity" '655 Patent at Title. At a broad level, the patent claims to disclose "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." *Id.* at Abstract. The asserted claims of the '655 Patent provide:

> 4. A method for producing an aromatic L-amino acid, which comprises cultivating the bacterium of claims 1, 2, or 3 in a culture medium and collecting from the culture medium the aromatic L-amino acid.
>
> 7. The method according to claim 4, wherein the aromatic L-amino acid is L-tryptophan.
>
> 8. The method according to claim 7, wherein the bacterium has enhanced expression of genes for tryptophan biosynthesis as compared to a wild-type of said bacterium.
>
> 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.

Id. at claims 4, 7, 8, 20. For relevant context, unasserted independent claims 1, 9, and 15 provide:

> 1. A recombinant *Escherichia coli* bacterium that has the ability to produce and accumulate an aromatic L-amino acid, 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, wherein said protein is as defined in the following (A), (B), or (C):
>
> (A) a protein which consists of the amino acid sequence of SEQ ID NO: 2;
>
> (B) a protein which consists of the amino acid sequence of SEQ ID NO: 2 except wherein one to five amino acids are deleted, substituted, inserted, or added; or
>
> (C) a protein which consists of the amino acid sequence that is encoded by a nucleotide sequence that hybridizes with the complement of the nucleotide sequence of SEQ ID NO: 1 under stringent conditions comprising 60° C., 1×SSC, 0.1% SDS;
>
> wherein said protein defined in (A), (B), or (C) has an activity to make said bacterium resistant to L-phenylalanine, fluoro-phenylalanine or 5-fluoro-DL-tryptophan and wherein the activity of said protein defined in (A), (B), or (C) is enhanced by:
>
> a) transformation of said bacterium with a DNA encoding said protein and expressing the protein in said bacterium,

b) replacing the native promoter that precedes the DNA encoding said protein on the chromosome of the bacterium with a more potent promoter, or

c) introduction of multiple copies of the DNA encoding said protein into the chromosome of said bacterium and expressing the protein in said bacterium.

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 5fluoro-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., 1×SSC, 0.1% SDS and said protein has the activity to make the bacterium resistant to L-phenylalanine, fluoro-phenylalanine or 5fluoro-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.

Id. at claims 1, 9, 15.

C. Stipulated Facts Regarding the Economic Prong of the Domestic Industry

On March 10, 2017, the parties submitted a Joint Stipulation Regarding the Economic Prong of the Domestic Industry Requirement. *See* EDIS Doc. ID 605262 ("Jt. Stip.") (Mar. 10, 2017). Those stipulations include 53 distinct paragraphs. *See id.* A portion of those stipulations are reproduced herein:

> 7. Ajinomoto contends that it has been the world's leading producer of amino acids for over 100 years and continues to lead the industry in amino acid research and development, global sales, and distribution.
>
> 8. In its amino acid line, Ajinomoto sells two grades of L-tryptophan: pharmaceutical-grade L-tryptophan and feed-grade L-tryptophan. *See* Ex. 1 (Lish Dep. Tr. At 26:20-27:9, 28:5-21, 30:19-31:4); Ex. 2 (Lish Dep. Ex. 5 at ¶ 3); Ex. 3 (Schreiner Dep. Tr. at 26:7-11).[2]
>
> 9. The domestic manufacture of pharmaceutical-grade L-tryptophan is carried out by Ajinomoto North America, Inc. ("AJINA"), a wholly owned subsidiary of AJICO. *See* Ex. 2 (Lish Dep. Ex. 5 at ¶¶ 2, 3).
>
> 10. AJINA manufactures pharmaceutical grade L-tryptophan in the United States at facilities that are located in Raleigh, North Carolina (the "North Carolina Plant"). *See* Ex. 1 (Lish Dep. Tr. at 30:19-31:4); Ex. 2 (Lish Dep. Ex. 5 at ¶¶ 3, 7).
>
> 11. Ajinomoto has been manufacturing pharmaceutical-grade L-tryptophan at the North Carolina Plant since 2007. *See* Ex. 1 (Lish Dep. Tr. at 47:16-18); Ex. 2 (Lish Dep. Ex. 5 at ¶ 4).
>
> 12. Due to Ajinomoto's investments in the U.S., [redacted]. *See* Ex. 1 (Lish Dep. Tr. at 33:15-35:16, 51:18-22); Ex. 2 (Lish Dep. Ex. 5 at ¶ 5); Ex. 4 (Lish Dep. Ex. 6 (AJITRP-ITC-010771)); Exs. 5-14 (AJITRP-ITC-013118–AJITRP-ITC-013127).
>
> 14. The North Carolina Plant has been in operation since 1982. *See* Ex. 1 (Lish Dep. Tr. at 26:20-27:9, 28:5-21); Ex. 2 (Lish Dep. Ex. 5 at ¶ 6). A presentation summarizing the North Carolina Plant's history and recent production is attached as Ex. 15 (AJITRP-ITC-002590). *See also* Ex. 1 (Lish Dep. Tr. at 26:20-27:9, 28:5-21); Ex. 2 (Lish Dep. Ex. 5).
>
> 15. Ajinomoto has spent [redacted] to purchase fixed assets for the North Carolina Plant, [redacted]

[2] References to exhibit numbers in the joint stipulations refer to the exhibits submitted with those stipulations.

[redacted]. *See* Ex. 1 (Lish Dep. Tr. at 26:20-27:9, 28:5-21, 46:6-47:15, 51:18-22); Ex. 2 (Lish Dep. Ex. 5 at ¶ 6); Ex. 15 (AJITRP-ITC-002590 at 002597); Ex. 4 (Lish Dep. Ex. 6 (AJITRP-ITC-010771)).

16. Together, these facilities at the North Carolina Plant total [redacted]. *See* Ex. 1 (Lish Dep. Tr. at 26:20-27:9, 28:5-21, 51:18-22); Ex. 2 (Lish Dep. Ex. 5 at ¶ 6; Ex. 15 (AJITRP-ITC-002590 at 002597); Ex. 4 (Lish Dep. Ex. 6 (AJITRP-ITC-010771)).

17. The current replacement value of the North Carolina Plant is over [redacted]. *See* Ex. 1 (Lish Dep. Tr. at 74:19-75:12); Ex. 2 (Lish Dep. Ex. 5 at ¶ 6); Ex. 16 (Lish Dep. Ex. 8 (AJITRP-ITC-013460)).

18. From April 2015 to January 2016, the North Carolina Plant has produced [redacted] of pharmaceutical-grade L-tryptophan, and has sold [redacted] totaling [redacted] in sales. *See* Ex. 1 (Lish Dep. Tr. at 51:18-24); Ex. 2 (Lish Dep. Ex. 5 at ¶ 7); Ex. 4 (Lish Dep. Ex. 6 (AJITRP-ITC-010771)); Exs. 12-14 (AJITRP-ITC-013125-013127).

19. It costs Ajinomoto [redacted] to produce 1 kilogram of pharmaceutical-grade L-tryptophan in the North Carolina Plant. *See* Ex. 1 (Lish Dep. Tr. at 26:20-27:9, 41:6-16); Ex. 2 (Lish Dep. Ex. 5 at ¶ 7). The cost to AJINA to manufacture [redacted] of pharmaceutical-grade L-tryptophan from April 2015 to January 2016 is [redacted]. *See* Ex. 1 (Lish Dep. Tr. at 26:20-27:9, 41:6-16); Ex. 2 (Lish Dep. Ex. 5 at ¶ 7).

20. AJINA manufactures a number of amino acids and amino-acid products at the North Carolina Plant. Ex. 1 (Lish Dep. Tr. at 26:20-27:9, 35:4-12); Ex. 2 (Lish Dep. Ex. 5 at ¶ 8); Ex. 15 (AJITRP-ITC-002590 at 002596). For the most part, the equipment at the plant can be used interchangeably to manufacture all the amino-acid products, including pharmaceutical-grade L-tryptophan. Based on the amount of time spent per year to manufacture pharmaceutical-grade L-tryptophan, [redacted] of the manufacturing facility can be attributed to the production of pharmaceutical-grade L-tryptophan. *See* Ex. 1 (Lish Dep. Tr. at 26:20-27:9, 43:15-44:13, 51:18-22, 55:3-57:25, 58:10-59:10, 61:17-63:21); Ex. 2 (Lish Dep. Ex. 5 at ¶ 8); Ex. 4 (Lish Dep. Ex. 6 (AJITRP-ITC-010771)); Ex. 17 (AJITRP-ITC-010852).

21. [redacted]. *See* Ex. 1 (Lish Dep. Tr. at 45:46-9).

22. Other departments involved in the manufacture of pharmaceutical-grade L-tryptophan include [redacted]. *See* Ex. 1 (Lish Dep. Tr. at 51:18-24, 60:21-61:9); Ex. 2 (Lish Dep. Ex. 5 at ¶ 8); Ex. 4 (Lish Dep. Ex. 6 (AJITRP-ITC-010771)). Based on the

amount of time spent per year to manufacture pharmaceutical-grade L-tryptophan, [redacted] of these departments can be attributed to the production of pharmaceutical-grade L-tryptophan. *See* Ex. 1 (Lish Dep. Tr. at 26:20-27:9, 45:10-46:5, 51:18-24); Ex. 2 (Lish Dep. Ex. 5 at ¶ 8); Ex. 4 (Lish Dep. Ex. 6 (AJITRP-ITC-010771)). [redacted]. *See* Ex. 1 (Lish Dep. Tr. at 45:19-46:5).

23. Ajinomoto has incurred considerable expenses in the United States for equipment used to make pharmaceutical-grade L-tryptophan in the North Carolina Plant. [redacted] *See* Ex. 2 (Lish Dep. Ex. 5 at ¶ 9). Starting from 1979, Ajinomoto's equipment and fixed asset expenses at the North Carolina Plant total [redacted]. *See id.*; Ex. 1 (Lish Dep. Tr. at 26:20-27:9, 46:6-47:15, 51:18-24); (Lish Dep. Ex. 6 (AJITRP-ITC-010771)). Based on current equipment and facility utilization, [redacted] can be attributed to the manufacture of pharmaceutical-grade L-tryptophan. *See* Ex. 1 (Lish Dep. Tr. at 46:6-47:15, 51:18-24); Ex. 2 (Lish Dep. Ex. 5 at ¶ 9); Ex. 4 (Lish Dep. Ex. 6 (AJITRP-ITC-010771)). In current dollars, this cost as determined by insurance value lists the North Carolina Plant at [redacted] can be attributed to L-tryptophan. *See* Ex. 1 (Lish Dep. Tr. at 51:18-24, 74:19-75:12); Ex. 2 (Lish Dep. Ex. 5 at ¶ 9); Ex. 16 (Lish Dep. Ex. 8 (AJITRP-ITC-013460)); Ex. 4 (Lish Dep. Ex. 6 (AJITRP-ITC-010771)). In addition to the interchangeable equipment, there is also specialized equipment used only in the manufacture of pharmaceutical-grade L-tryptophan, [redacted]. *See* Ex. 2 (Lish Dep. Ex. 5 at ¶ 9); Exs. 18-32 (AJITRP-ITC-010774–AJITRP-ITC-010776, AJITRP-ITC-010787–AJITRP-ITC-010789, AJITRP-ITC-010824, AJITRP-ITC-010825, AJITRP-ITC-010830–AJITRP-ITC-010833, AJITRP-ITC-010836–AJITRP-ITC-010838).

24. Therefore, the total investments in plant and equipment used by Ajinomoto to manufacture and manage pharmaceutical-grade L-tryptophan include [redacted] of space and [redacted]. *See* ¶¶ 20, 22, 23.

26. Ajinomoto has a significant domestic workforce dedicated to manufacturing pharmaceutical-grade L-tryptophan. [redacted] *See* Ex. 1 (Lish Dep. Tr. at 26:20-27:9, 28:5-21, 49:2-19, 51:18-24); Ex. 2 (Lish Dep. Ex. 5 at ¶ 11); Ex. 15 (AJITRP-ITC-002590 at 002591); Ex. 4 (Lish Dep. Ex. 6 (AJITRP-ITC-010771)).

27. [redacted] *See* Ex. 2 (Lish Dep. Ex. 5 at ¶ 12).

See id.; Ex. 1 (Lish Dep. Tr. at 26:20-27:9; 51:18-24); Ex. 4 (Lish Dep. Ex. 6 (AJITRP-ITC-010771)).

Id.

Id.

Id.

28. Based on the amount of time spent per year to manufacture pharmaceutical-grade L-tryptophan, on average, to manufacturing pharmaceutical-grade L-tryptophan. *Id.*

29. AJINA paid in salary and benefits in 2014 (for first 10 months of fiscal year). *See* Ex. 1 (Lish Dep. Tr. at 26:20-27:9; 51:18-24, 76:12-77:21); Ex. 33 (Lish Dep. Ex. 9 (AJITRP-ITC-013441)); Ex. 34 (Lish Dep. Ex. 10 (AJITRP-ITC-013421)); Ex. 4 (Lish Dep. Ex. 6 (AJITRP-ITC-010771)); Ex. 35 (AJITRP-ITC-013134); Ex. 2 (Lish Dep. Ex. 5 at ¶ 12).

30. Based on the amount of time spent per year to manufacture pharmaceutical-grade L-tryptophan, in 2014 (for first 10 months of fiscal year) can be attributed to the manufacture of pharmaceutical-grade L-tryptophan. *See* Ex. 1 (Lish Dep. Tr. at 26:20-27:9; 51:18-24); Ex. 4 (Lish Dep. Ex. 6 (AJITRP-ITC-010771)); Ex. 2 (Lish Dep. Ex. 5 at ¶ 12).

31. *See* Ex. 2 (Lish Dep. Ex. 5 at ¶ 13). *See id.*; Ex. 1 (Lish Dep. Tr. at 26:20-27:9; 51:18-22, 60:21-61:9); Ex. 4 (Lish Dep. Ex. 6 (AJITRP-ITC-010771)).

32. Based on the amount of time spent per year to perform services related to pharmaceutical-grade L-tryptophan, those employees dedicate, on average, at least to supporting pharmaceutical-grade L-tryptophan. *See* Ex. 1 (Lish Dep. Tr. at 26:20-27:9; 51:18-22); Ex. 4 (Lish Dep. Ex. 6 (AJITRP-ITC-010771)); Ex. 2 (Lish Dep. Ex. 5 at ¶ 13).

33. AJINA paid in salary and benefits in 2014 (for first 10 months of fiscal year). *See* Ex. 1 (Lish Dep. Tr. at 26:20-27:9; 51:18-22, 76:12-77:21); Ex. 33 (Lish Dep. Ex. 9 (AJITRP-ITC-

013441)); Ex. 34 (Lish Dep. Ex. 10 (AJITRP-ITC-013421)); Ex. 4 (Lish Dep. Ex. 6 (AJITRP-ITC-010771)); Ex. 35 (AJITRP-ITC-013134); Ex. 2 (Lish Dep. Ex. 5 at ¶ 13).

34. [redacted] in 2014 [redacted] (for first 10 months of fiscal year) can be attributed to the manufacture and sale of pharmaceutical-grade L-tryptophan. *See* Ex. 1 (Lish Dep. Tr. at 26:20-27:9; 51:18-24); Ex. 4 (Lish Dep. Ex. 6 (AJITRP-ITC-010771)); Ex. 2 (Lish Dep. Ex. 5 at ¶ 13).

35. Therefore, the total labor and capital investments used by Ajinomoto to annually manufacture and sell pharmaceutical-grade L-tryptophan totals [redacted]. *See* ¶¶ 28, 30, 32, 34.

37. [redacted] At that time, Ajinomoto began formulating plans to produce feed-grade L-tryptophan at its Eddyville, Iowa facility ("the Eddyville Plant"). *See* Ex. 36 (Schreiner Dep. Ex. 4 at ¶ 4); Ex. 3 (Schreiner Dep. Tr. at 26:7-17).

38. Ajinomoto recently announced that its Eddyville Plant will be the first facility to produce feed-grade L-tryptophan in the United States. *See* Ex. 3 (Schreiner Dep. Tr. at 19:4-13); Ex. 36 (Schreiner Dep. Ex. 4 at ¶ 4). Articles, press releases, and contracts with the State of Iowa evidencing Ajinomoto's planned investments in the U.S. feed-grade L-tryptophan market are found in Ex. 37 (AJITRP-ITC-002657); Ex. 38 (AJITRP-ITC-002696); Ex. 39 (AJITRP-ITC-002588); Ex. 40 (AJITRP-ITC-002730). *See also* Ex. 3 (Schreiner Dep. Tr. at 25:17-26:5, 32:6-33:24); Ex. 36 (Schreiner Dep. Ex. 4 at ¶ 4).

41. The Eddyville Plant does not currently manufacture feed-grade L-tryptophan. *See* Ex. 36 (Schreiner Dep. Ex. 4 at ¶ 6). Heartland's domestic manufacture of feed-grade L-tryptophan is expected to begin at Heartland's Eddyville Plant in the spring of 2017. *See id.*; Ex. 3 (Schreiner Dep. Tr. at 25:17-24, 33:3-12); Ex. 39 (AJITRP-ITC-002588).

42. Ajinomoto has committed to enhance and add facilities to the Eddyville Plant to produce around 3,000 tons of feed-grade L-tryptophan a year, beginning in 2017. *See* Ex. 3 (Schreiner Dep. Tr. at 25:17-20, 33:3-12, 47:5-13-49:9); Ex. 36 (Schreiner Dep. Ex. 4 at ¶ 7); Ex. 39 (AJITRP-ITC-002588). [redacted] *See* Ex. 36 (Schreiner Dep. Ex. 4 at ¶ 7). The construction schedule for the expansion is attached as Ex. 43 (AJITRP-ITC-002678 at 002686). *See also id.*; Ex. 3 (Schreiner Dep. Tr. at 25:17-26:5, 67:19-68:13); Ex. 44 (Schreiner Dep. Ex. 7 (AJITRP-ITC-010691)). And final, approved architectural drawings for the expansion are found in Ex. 43 (AJITRP-ITC-002678 at 002683, 002684). *See also*

Ex. 3 (Schreiner Dep. Tr. at 25:17-26:5, 61:8-62:2, 63:4-64:5); Ex. 36 (Schreiner Dep. Ex. 4 at ¶ 7); Ex. 45 (Schreiner Dep. Ex. 5 (AJITRP-ITC-013476)).

44. The total expansion costs for the Eddyville Plant are approximately $42 million. *See* Ex. 36 (Schreiner Dep. Ex. 4 at ¶ 8). [redacted] the portion directly related to producing feed-grade L-tryptophan is [redacted] and includes investments in equipment, facilities, and engineering services. *See id.*; Ex. 3 (Schreiner Dep. Tr. at 25:17-26:5, 51:25-52:14); Ex. 43 (AJITRP-ITC-002678 at 002680, 002685, 002693). [redacted] *See* Ex. 36 (Schreiner Dep. Ex. 4 at ¶ 8); Ex. 46 (AJITRP-ITC-010724). [redacted] *See* Ex. 3 (Schreiner Dep. Tr. at 25:17-26:5, 31:17-25, 51:25-52:20); Ex. 36 (Schreiner Dep. Ex. 4 at ¶ 8); Ex. 46 (AJITRP-ITC-010724). [redacted] *See* Ex. 3 (Schreiner Dep. Tr. at 25:17-26:5); Ex. 36 (Schreiner Dep. Ex. 4 at ¶ 8).

45. Heartland manufactures a number of amino acids and amino-acid products at the Eddyville Plant. *See* Ex. 36 (Schreiner Dep. Ex. 4 at ¶ 9). For the most part, the equipment at the plant can be used interchangeably to manufacture those amino-acid products, including feed-grade L-tryptophan. *Id.* Based on existing and proposed floorplans, [redacted] of the manufacturing facility will be attributed to the production of feed-grade L-tryptophan. *See id.*; Ex. 3 (Schreiner Dep. Tr. at 25:17-26:5, 54:7-19, 61:8-62:2, 63:13-64:5); Ex. 45 (Schreiner Dep. Ex. 5 (AJITRP-ITC-013476)); Ex. 43 (AJITRP-ITC-002678 at 002683, 002684). Other departments that will be involved in the manufacture of feed-grade L-tryptophan include [redacted]. *See* Ex. 36 (Schreiner Dep. Ex. 4 at ¶ 9). Current estimates indicate that [redacted] of these departments will be attributed to the planned production of feed-grade L-tryptophan. *See id.*; Ex. 3 (Schreiner Dep. Tr. at 25:17-26:5, 54:20-55:22, 61:8-62:2, 63:13-64:5); Ex. 43 (AJITRP-ITC-002678 at 002683, 002684); Ex. 45 (Schreiner Dep. Ex. 5 (AJITRP-ITC-013476)).

46. Ajinomoto has incurred considerable expenses in the United States for equipment used to make amino acid products in the Eddyville Plant. *See* Ex. 36 (Schreiner Dep. Ex. 4 at ¶ 10). Some of this equipment will be used to manufacture feed-grade L-tryptophan. *Id.* [redacted] of those existing assets will be attributed to the manufacture of feed-grade L-tryptophan. *See id.*; Ex. 3 (Schreiner Dep. Tr. at 25:17-26:5, 46:21-24, 56:23-57:3); Ex. 47 (AJITRP-ITC-010624).

47. Ajinomoto expects to produce, sell, and distribute feed-grade L-tryptophan for [redacted]. *See* Ex. 3 (Schreiner Dep. Tr. at 25:17-26:5, 57:7-58:19); Ex. 36 (Schreiner Dep. Ex. 4 at ¶ 11). Based on that estimate, Ajinomoto expects to spend [redacted]. *See* Ex. 3 (Schreiner Dep. Tr. at 25:17-26:5, 33:3-12, 47:5-49:9); Ex. 36 (Schreiner Dep. Ex. 4 at ¶ 11); Ex. 39 (AJITRP-ITC-002588); Ex. 43 (AJITRP-ITC-002678 at AJITRP-ITC-002681).

48. Therefore, the total investments in plant and equipment to be used by Ajinomoto to manufacture feed-grade L-tryptophan will include [redacted]. *See* ¶¶ 44, 45.

50. Ajinomoto will have a significant domestic workforce dedicated to manufacturing feed-grade L-tryptophan. [redacted] *See* Ex. 3 (Schreiner Dep. Tr. at 25:17-26:5, 59:22-60:4); Ex. 36 (Schreiner Dep. Ex. 4 at ¶ 13); Ex. 48 (AJITRP-ITC-010673). [redacted] *See* Ex. 3 (Schreiner Dep. Tr. at 59:18-21-60:4, 64:9-16, 66:6-67:6); Ex. 36 (Schreiner Dep. Ex. 4 at ¶ 13); Ex. 49 (Schreiner Dep. Ex. 6 (AJITRP-ITC-013474)). Collectively, [redacted] will be paid [redacted] in salary and benefits and will spend [redacted] dedicated to the production of feed-grade L-tryptophan. *See* Ex. 3 (Schreiner Dep. Tr. at 64:9-16, 67:7-15); Ex. 36 (Schreiner Dep. Ex. 4 at ¶ 13); Ex. 49 (Schreiner Dep. Ex. 6 (AJITRP-ITC-013474)).

51. [redacted]. *See* Ex. 36 (Schreiner Dep. Ex. 4 at ¶ 14); Ex. 48 (AJITRP-ITC-010673). [redacted] *See* Ex. 36 (Schreiner Dep. Ex. 4 at ¶ 14); Ex. 48 (AJITRP-ITC-010673). Based on fermenter usage, Heartland estimates that [redacted] to manufacturing feed-grade L-tryptophan, corresponding to [redacted]. *See* Ex. 3 (Schreiner Dep. Tr. at 25:17-26:5, 60:13-25, 64:9-16, 66:6-67:15); Ex. 36 (Schreiner Dep. Ex. 4 at ¶ 14); Ex. 49 (Schreiner Dep. Ex. 6 (AJITRP-ITC-013474)).

52. Therefore, the total labor and capital investments that will be used by Ajinomoto to annually manufacture feed-grade L-tryptophan totals [redacted]. *See* ¶¶ 50, 51.

II. AJINOMOTO'S DOMESTIC INDUSTRY ASSERTIONS

Ajinomoto's motion is limited to the economic prong of the domestic industry requirement of 19 U.S.C. § 1337(a)(2) and (3). Mem. at 1. It asserts that its domestic industry is based on domestic manufacturing activity. *Id.* Specifically, Ajinomoto submits that it has "manufactured pharmaceutical grade L-tryptophan in its manufacturing facility in North Carolina ("North Carolina Plant") since 2007" through its wholly owned subsidiary Ajinomoto North America. *Id.* It goes on to assert that the North Carolina plant produced [redacted] of pharmaceutical-grade L-tryptophan between April 2015 and January 2016. *Id.* (citing Statement of Undisputed Material Facts ("SMF") at ¶ 12. Ajinomoto further avers that it is "in the process of expanding its plant facilities in Eddyville, Iowa facility ("the Eddyville Plant") to begin manufacturing feed-grade L-tryptophan by Spring 2017." *Id.* at 2. Taken together, Ajinomoto submits that these activities show that it both has a domestic industry in existence, and is also in the process of establishing an additional domestic industry. *Id.* at 2–3. Ajinomoto addresses each of these domestic industry arguments in turn.

A. Ajinomoto's North Carolina Domestic Industry Activity – Pharmaceutical-Grade L-tryptophan

1. Plant and Equipment

Ajinomoto first submits that it has made significant investments in plant and equipment with respect to its North Carolina plant. *Id.* at 6. Ajinomoto submits that it manufactures pharmaceutical grade L-tryptophan at its North Carolina plant. *Id.* (citing SMF ¶ 4). Specifically, Ajinomoto submits that "[f]rom April 2015 to January 2016, the North Carolina Plant has produced [redacted] of pharmaceutical-grade L-tryptophan." *Id.* (citing SMF ¶ 12). It further alleges that "[d]ue to Ajinomoto's investments in the U.S., [redacted]" *Id.* (citing SMF ¶ 6).

Ajinomoto submits that its North Carolina plant has been in operation since 1982, and that it has spent [redacted] to purchase various assets connected to the plant. *Id.* at 6 (citing SMF ¶ 8–9). These assets [redacted]. *Id.* at 6–7 (citing SMF ¶¶ 9–10). Ajinomoto asserts that "[t]he current replacement value of the North Carolina Plant is [redacted]." *Id.* at 7 (citing SMF ¶ 11).

Ajinomoto notes that it manufactures various amino acids at its North Carolina plant. *Id.* at 7 (citing SMF ¶ 14). In order to attribute a portion of the plant's usage to the manufacture of pharmaceutical-grade L-tryptophan specifically, Ajinomoto relies on the amount of time spent per year manufacturing the L-tryptophan. *Id.* According to that attribution method, it represents [redacted] of its North Carolina plant can be attributed to the production of pharmaceutical-grade L-tryptophan. *Id.* Ajinomoto notes that [redacted] *Id.* (citing SMF ¶ 15).

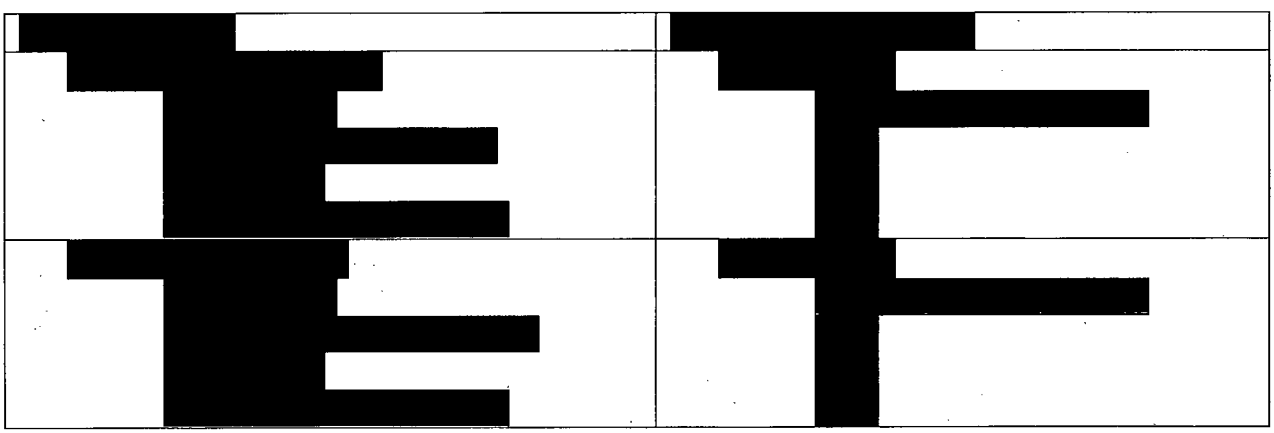
Separate from the actual manufacturing of L-tryptophan, Ajinomoto submits that other departments in its North Carolina plant also play a significant role in its domestic industry for L-tryptophan. These departments include [redacted] *Id.* (citing SMF ¶ 16). Again, based on the amount of time spent per year manufacturing pharmaceutical-grade L-tryptophan, Ajinomoto submits [redacted] of its North Carolina plant can be attributed to these departments' activities supporting the production L-tryptophan. *Id.* Ajinomoto notes that [redacted]. *Id.*

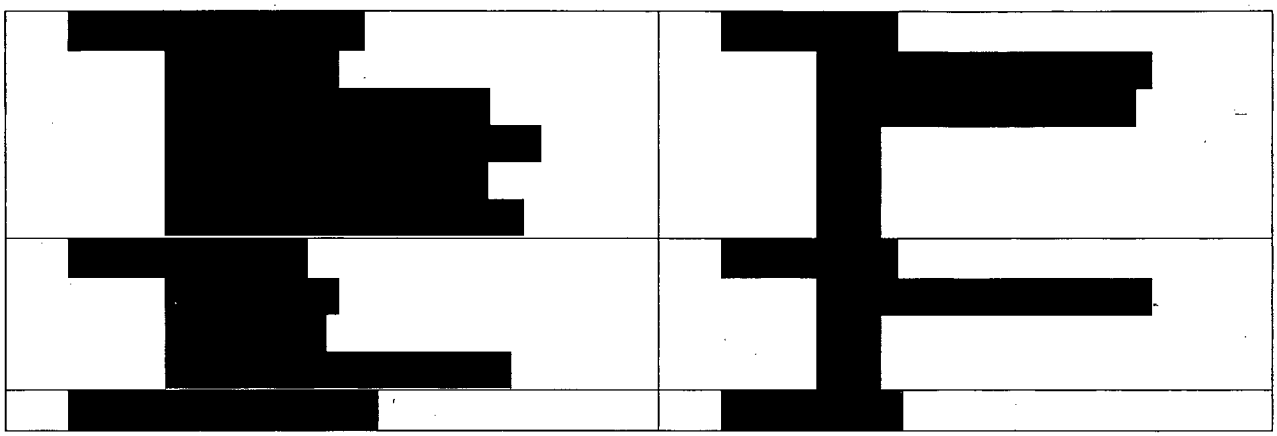
With respect to equipment expenses related to the production of L-tryptophan at the North Carolina plant, Ajinomoto submits that, [redacted] can be attributed to the manufacture of pharmaceutical-grade L-tryptophan. *Id.* (citing SMF ¶ 17). Based on the current insurance value for the North Carolina plant of [redacted] can be attributed to the manufacture of pharmaceutical-grade L-tryptophan in inflation-adjusted dollars. *Id.* at 8 Separate from the equipment which Ajinomoto proportionally attributes to L-tryptophan production, it also submits that tis North Carolina plant includes specialized equipment used only for manufacturing pharmaceutical-grade L-tryptophan worth [redacted]. *Id.*

In sum, Ajinomoto submits that "the total investments in plant and equipment used by Ajinomoto to manufacture pharmaceutical-grade L-tryptophan include [redacted] and [redacted]." *Id.* (citing SMF ¶ 18).

2. Labor and Capital

Ajinomoto submits that it makes and has made significant investments in labor and capital related to the manufacture of pharmaceutical-grade L-tryptophan. *Id.* (citing SMF ¶ 19). More specifically, [redacted]. *Id.* (citing SMF ¶ 20). Ajinomoto breaks down these employees' job descriptions as follows:





Id. at 9 (citing SMF ¶ 21). Again using an allocation method based on the amount of time spent per year manufacturing pharmaceutical-grade L-tryptophan, Ajinomoto submits that "[redacted], on average, to manufacturing pharmaceutical-grade L-tryptophan." *Id.* (citing SMF ¶ 22). It further submits that it paid [redacted] in salary and benefits in 2014, [redacted] (for the first 10 months of the fiscal year). Employing the same allocation methodology again, Ajinomoto submits [redacted] in 2014 and [redacted] of those salary and benefits payments can be attributed to the manufacture of pharmaceutical-grade L-tryptophan. *Id.* (citing SMF ¶ 24).

Ajinomoto also asserts that [redacted] from other departments contribute the manufacture and sales of pharmaceutical-grade L-tryptophan at the North Carolina plant. *Id.* (citing SMF ¶ 25). Ajinomoto asserts [redacted] is attributable to supporting pharmaceutical-grade L-tryptophan. *Id.* (citing SMF ¶ 26). Ajinomoto also asserts [redacted] in 2014 [redacted] (for the first 10 months of the fiscal year) of those employees' salary can be attributed to the manufacture and sale of pharmaceutical-grade L-tryptophan. *Id.* at 9–10 (citing SMF ¶ 28).

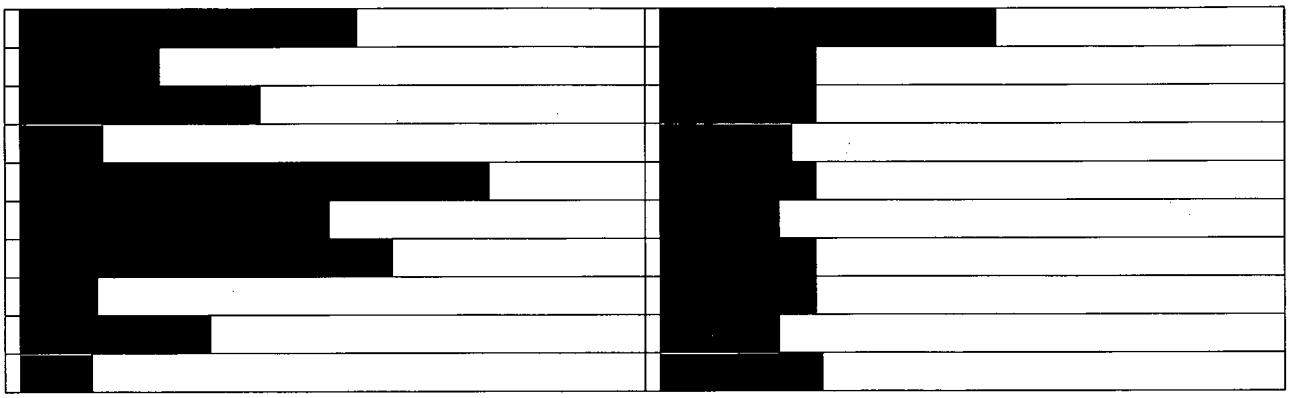
In sum, Ajinomoto submits that "the total labor and capital investments used by Ajinomoto to annually manufacture and sell pharmaceutical-grade L-tryptophan totals [redacted]." *Id.* at 10 (citing SMF ¶ 29).

B. Ajinomoto's Iowa Domestic Industry Activity – Feed-Grade L-tryptophan

1. Plant and Equipment

Ajinomoto submits that it "has made and will continue to make significant expenditures to expand the Eddyville [Iowa] Plant to begin the manufacture of feed-grade L-tryptophan in the United States, including significant investment in plant and equipment that will be used in the process for manufacturing feed-grade L-tryptophan." *Id.* (citing SMF ¶ 33). Presently, Ajinomoto's Eddyville plant does not manufacture feed-grade L-tryptophan. *Id.* at 11 (citing SMF ¶ 35). Ajinomoto expects the Eddyville plant to begin manufacturing feed-grade L-tryptophan in the spring of 2017. *Id.* Ajinomoto anticipates that through enhancements and additional facilities, the Eddyville plant will eventually be able to produce 3,000 tons of feed-grade L-tryptophan each year. *Id.* (citing SMF ¶ 36). It also clarifies that the feed-grade Tryptophan produced at the Eddyville plant will serve the U.S. market. *Id.* Ajinomoto submitted the construction schedule and architectural drawings for the additions and enhancements to its Eddyville plant. Mot. Ex. 43.

Ajinomoto estimates the expansion costs for the Eddyville plant at [redacted]. *Id.* (citing SMF ¶ 38). Ajinomoto allocates [redacted] to the production of feed-grade L-tryptophan, and breaks down those expenditures as follows:



Id. (citing SMF ¶ 38). Ajinomoto asserts that "[b]ased on existing and proposed floorplans, [redacted] of the manufacturing facility will be attributed to the production of feed-grade L-tryptophan." *Id.* at 12 (citing SMF ¶ 39). Ajinomoto also allocates an additional [redacted] of other departments to the planned production of feed-grade L-tryptophan. *Id.*

Ajinomoto asserts that [redacted], of existing equipment in the Eddyville plant can be attributed to the planned manufacture of feed-grade L-tryptophan. *Id.* (citing SMF ¶ 40). It also asserts that it "expects to produce, sell, and distribute feed-grade L-tryptophan for [redacted]," and that it "expects to spend [redacted]." *Id.* (citing SMF ¶ 40).

In sum, Ajinomoto estimates its total investments in plant and equipment at its Eddyville plant to comprise "[redacted]

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[3] Ajinomoto states that [redacted] Mem. at 11. Thus, it is unclear what [redacted] Ajinomoto is referring to.

[redacted] *Id.* (citing SMF ¶ 42).

2. Labor and Capital

With respect to labor and capital investments in the Eddyville plant, Ajinomoto submits that [redacted] will be added to [redacted] at the Eddyville plant to support the production of feed-grade L-tryptophan. *Id.* at 13 (citing SMF ¶ 44). Ajinomoto asserts that [redacted] "will be paid [redacted] in salary and benefits and will spend [redacted] dedicated to the production of feed-grade L-tryptophan." *Id.* In addition to [redacted], Ajinomoto that [redacted] at the Eddyville plant will support the manufacture and sales of feed-grade L-tryptophan. *Id.* (citing SMF ¶ 45). Ajinomoto submits that "[redacted] to manufacturing feed-grade L-tryptophan, corresponding to [redacted]." *Id.*

In sum, Ajinomoto asserts that "the total labor and capital investments that will be used by Ajinomoto to annually manufacture feed-grade L-tryptophan in the United States totals [redacted]." *Id.* (citing SMF ¶ 46).

Based on the above assertions, Ajinomoto requests "that the ALJ determine that Ajinomoto has satisfied the economic prong of the domestic industry requirement." *Id.* at 14.

III. LEGAL STANDARDS

A. Summary Determination

Pursuant to Commission Rule 210.18, summary determination ". . . shall be rendered if pleadings and any depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a summary determination as a matter of law." 19 C.F.R. § 210.18(b); *see also DeMarini Sports, Inc. v. Worth, Inc.*, 239 F.3d 1314, 1322 (Fed. Cir. 2001); *Wenger Mfg., Inc. v. Coating Machinery Sys., Inc.*, 239 F.3d 1225, 1231 (Fed. Cir. 2001). The evidence "must be viewed in the light most favorable to the party opposing the motion . . . with doubts resolved in favor of the nonmovant." *Crown Operations Int'l, Ltd. v. Solutia, Inc.*, 289 F.3d 1367, 1375 (Fed. Cir. 2002); *see also Xerox Corp. v. 3Com Corp.*, 267 F.3d 1361, 1364 (Fed. Cir. 2001) ("When ruling on a motion for summary judgment, all of the nonmovant's evidence is to be credited, and all justifiable inferences are to be drawn in the nonmovant's favor."). "Issues of fact are genuine only if the evidence is such that a reasonable [fact finder] could return a verdict for the nonmoving party." *Id.* at 1375 (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). The trier of fact should "assure itself that there is no reasonable version of the facts, on the summary judgment record, whereby the nonmovant could prevail, recognizing that the purpose of summary judgment is not to deprive a litigant of a fair hearing, but to avoid an unnecessary trial." *EMI Group N. Am., Inc. v. Intel Corp.*, 157 F.3d 887, 891 (Fed. Cir. 1998). "Where an issue as to a material fact cannot be resolved without observation of the demeanor of witnesses in order to evaluate their credibility, summary judgment is not appropriate." *Sandt Technology, Ltd. v. Resco Metal & Plastics Corp.*, 264 F.3d 1344, 1357 (Fed. Cir. 2001) (Dyk, J., concurring). "In other words, '[s]ummary judgment is authorized when it is quite clear what the truth is,' [citations omitted], and the law requires judgment in favor of the movant based

upon facts not in genuine dispute." *Paragon Podiatry Laboratory, Inc. v. KLM Laboratories, Inc.*, 984 F.2d 1182, 1185 (Fed. Cir. 1993).

B. Domestic Industry – Economic Prong

In patent-based proceedings under section 337, a complainant must establish that an industry "relating to the articles protected by the patent . . . exists or is in the process of being established" in the United States. 19 U.S.C. § 1337(a)(2). Under Commission precedent, the domestic industry requirement of Section 337 consists of a "technical prong" and an "economic prong." *Certain Data Storage Systems and Components Thereof*, Inv. No. 337-TA-471, Initial Determination Granting EMC's Motion No. 471-8 Relating to the Domestic Industry Requirement's Economic Prong (unreviewed) at 3 (Public Version, Oct. 25, 2002).

The "economic prong" of the domestic industry requirement is satisfied when the economic activities set forth in subsections (A), (B), and/or (C) of subsection 337(a)(3) have taken place or are taking place with respect to the protected articles. *Certain Printing and Imaging Devices and Components Thereof*, Inv. No. 337-TA-690, Commission Op. at 25 (February 17, 2011) ("*Printing and Imaging Devices*"). With respect to the "economic prong," 19 U.S.C. § 1337(a)(2) and (3) provide, in full:

> (2) Subparagraphs (B), (C), (D), and (E) of paragraph (1) apply only if an industry in the United States, relating to the articles protected by the patent, copyright, trademark, mask work, or design concerned, exists or is in the process of being established.
>
> (3) For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned–
>
> (A) significant investment in plant and equipment;
>
> (B) significant employment of labor or capital; or

> (C) substantial investment in its exploitation, including engineering, research and development, or licensing.

Id.

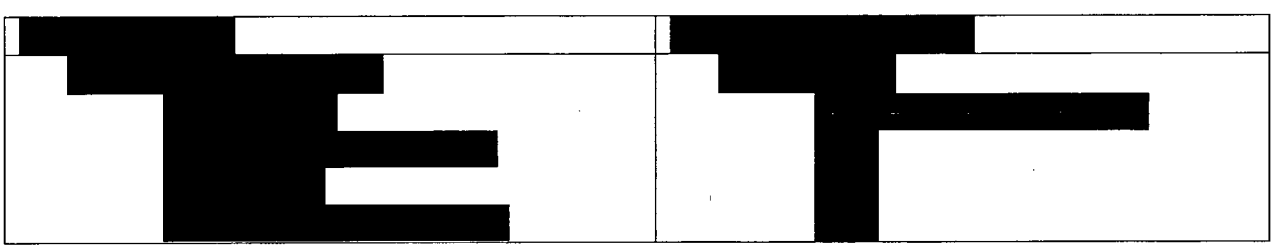
Given that these criteria are in the disjunctive, satisfaction of any one of them will be sufficient to meet the domestic industry requirement. *Certain Integrated Circuit Chipsets and Products Containing Same*, Inv. No. 337-TA-428, Order No 10 at 3, Initial Determination (Unreviewed) (May 4, 2000), citing *Certain Variable Speed Wind Turbines and Components Thereof*, Inv. No. 337-TA-376, Commission Op. at 15, USITC Pub. 3003 (Nov. 1996). The Commission has embraced a flexible, market-oriented approach to domestic industry, favoring case-by-case determination "in light of the realities of the marketplace" that encompass "not only the manufacturing operations" but may also include "distribution, research and development and sales." *Certain Dynamic Random Access Memories*, Inv. No. 337-TA-242, USITC Pub. 2034, Commission Op. at 62 (Nov. 1987) ("*DRAMs*").

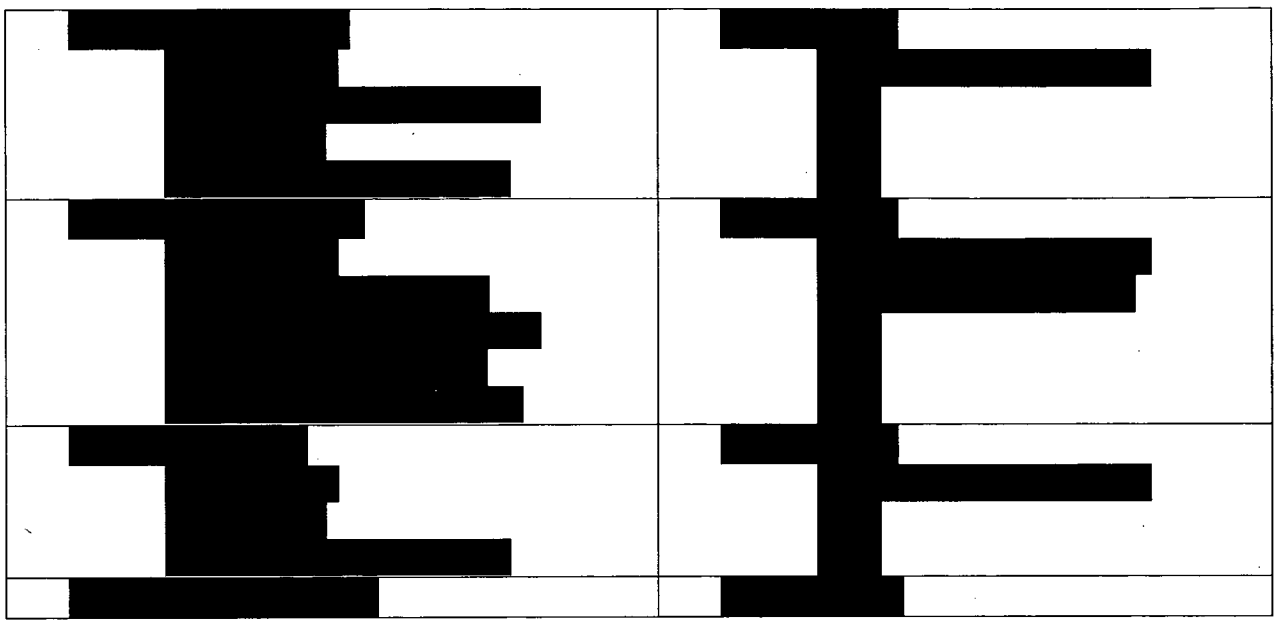
In *Printing and Imaging Devices*, the Commission held that "under the statute, whether the complainant's investment and/or employment activities are 'significant' is not measured in the abstract or absolute sense, but rather is assessed with respect to the nature of the activities and how they are 'significant' to the articles protected by the intellectual property right." *Printing and Imaging Devices*, Commission Op. at 26. The Commission further stated that: "the magnitude of the investment cannot be assessed without consideration of the nature and importance of the complainant's activities to the patented products in the context of the marketplace or industry in question . . . . whether an investment is 'substantial' or 'significant' is context dependent. *Id.* at 31.

IV. RESOLUTION

Consistent with the facts laid out in the Joint Stipulation, as well as the undisputed statement of material facts submitted with Ajinomoto's motion, it is the initial determination of the ALJ that Ajinomoto has satisfied the economic prong of the domestic industry requirement with respect to the '373 patent through significant investment in plant and equipment, 19 U.S.C. § 1337(a)(3)(A), and employment of labor or capital, 19 U.S.C. § 1337(a)(3)(B). It is also the initial determination of the ALJ that Ajinomoto has satisfied the economic prong of the domestic industry requirement with respect to the '655 patent through significant investment in plant and equipment, 19 U.S.C. § 1337(a)(3)(A), and employment of labor or capital, 19 U.S.C. § 1337(a)(3)(B). Both patents, from a broad perspective, are directed to methods of producing amino acids such as L-tryptophan.

The record shows that Ajinomoto produces pharmaceutical-grade L-tryptophan in its North Carolina plant. SMF ¶ 4; Ex. 1 (Lish Dep. Tr. at 30:19-31:4); Ex. 2 (Lish Dep. Ex. 5 at ¶¶ 3, 7). The record further shows [redacted] of the North Carolina plant's facilities and [redacted] in plant equipment can be attributed to the production of pharmaceutical-grade L-tryptophan. SMF ¶¶ 14, 16, 18; Ex. 1 (Lish Dep. Tr. at 26:20-27:9, 43:15-44:13, 51:18-22, 55:3-57:25, 58:10-59:10, 61:17-63:21); Ex. 2 (Lish Dep. Ex. 5 at ¶ 8); Ex. 4 (Lish Dep. Ex. 6 (AJITRP-ITC-010771)); Ex. 17 (AJITRP-ITC-010852). Additionally, the record shows that the North Carolina plant employs the following categories of workers who have at least some responsibility for producing pharmaceutical-grade L-tryptophan:





SMF ¶ 21; Ex. 1 (Lish Dep. Tr. at 26:20-27:9, 28:5-21, 49:2-19, 51:18-24); Ex. 2 (Lish Dep. Ex. 5 at ¶ 11); Ex. 15 (AJITRP-ITC-002590 at 002591); Ex. 4 (Lish Dep. Ex. 6 (AJITRP-ITC-010771)). The record supports Ajinomoto's assertion that [redacted] can be attributed to the production of pharmaceutical-grade L-tryptophan, and [redacted] in 2014 [redacted] of those employees' salary and benefits payments can be attributed to the manufacture of pharmaceutical-grade L-tryptophan. SMF ¶ 22–24; Ex. 1 (Lish Dep. Tr. at 26:20-27:9; 51:18-24, 76:12-77:21); Ex. 33 (Lish Dep. Ex. 9 (AJITRP-ITC-013441)); Ex. 34 (Lish Dep. Ex. 10 (AJITRP-ITC-013421)); Ex. 4 (Lish Dep. Ex. 6 (AJITRP-ITC-010771)); Ex. 35 (AJITRP-ITC-013134); Ex. 2 (Lish Dep. Ex. 5 at ¶ 12). Combined with contributions from employees in other departments at the North Carolina plant, the record shows that Ajinomoto employs [redacted] to produce pharmaceutical-grade L-tryptophan at its North Carolina plant. SMF ¶¶ 25–29.

With respect to a domestic industry in the process of being established, the record shows that Ajinomoto is in the process of building a plant in Eddyville, Iowa for the production of feed-

grade L-tryptophan. SMF ¶ 31; Ex. 36 (Schreiner Dep. Ex. 4 at ¶ 4); Ex. 3 (Schreiner Dep. Tr. at 26:7-17). The record further supports Ajinomoto's assertion [redacted] in the Eddyville plant will be attributable to the production of feed-grade L-tryptophan, and that, an up-front capital investment of [redacted] is a reasonable estimate of its total expenditures on the Eddyville plant. SMF ¶¶ 39–42; Ex. 3 (Schreiner Dep. Tr. at 25:17-26:5, 54:7-19, 61:8-62:2, 63:13-64:5); Ex. 36 (Schreiner Dep. Ex. 4 at ¶ 9); Ex. 39 (AJITRP-ITC-002588); Ex. 45 (Schreiner Dep. Ex. 5 (AJITRP-ITC-013476)); Ex. 43 (AJITRP-ITC-002678 at 002683, 002684). With respect to labor and capital at the Eddyville plant, the record supports Ajinomoto's assertion that its total labor and capital investments that will be used to annually manufacture feed-grade L-tryptophan will total [redacted]. SMF ¶ 44–46.

Based on the undisputed facts presented by Ajinomoto, the ALJ finds Ajinomoto has shown that it has a domestic industry in existence with respect to the production of pharmaceutical-grade L-tryptophan at its North Carolina plant, and has shown that it is in the process of establishing a domestic industry with respect to feed-grade L-tryptophan in its Eddyville plant. The ALJ finds that Ajinomoto has made these showings via § 1337(a)(3)(A) and (B), through significant investments in plant and equipment, and significant employment of labor and capital.

Accordingly, it is the INITIAL DETERMINATION of the ALJ that Motion No. 1005-016 is **GRANTED.**

Pursuant to 19 C.F.R. § 210.42(h), this initial determination shall become the determination of the Commission unless a party files a petition for review of the initial

[redacted]

determination pursuant to 19 C.F.R. § 210.43(a) or the Commission, pursuant to 19 C.F.R. § 210.44, orders on its own motion a review of the initial determination or certain issues herein.

Within seven days of the date of this document, each party shall submit to the Office of the Administrative Law Judges a statement as to whether or not it seeks to have any portion of this document deleted from the public version. Any party seeking to have any portion of this document deleted from the public version thereof shall also submit to this office a copy of this document with red brackets indicating any portion asserted to contain confidential business information. The parties' submissions may be made by facsimile and/or hard copy by the aforementioned date. The parties' submissions concerning the public version of this document need not be filed with the Commission Secretary.

SO ORDERED.

Theodore R. Essex
Administrative Law Judge

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 **ORDER NO. 18** has been served by hand upon the following parties as indicated, on **May 9, 2017**.

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainants: Ajinomoto Co., Inc. and Ajinomoto Heartland, Inc.

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☑ Via First Class Mail
☐ Other:_____

On Behalf of Respondents: CJ CheilJedang Corp.; CJ America, Inc.; and PT CheilJedang Indonsia

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☐ Other:_____