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-____

COMPLAINT UNDER SECTION 337 OF THE TARIFF ACT OF 1930, AS AMENDED

Complainants:	Proposed Respondents:
Ajinomoto Co., Inc. 15-1, Kyobashi 1-chome Chuo-Ku, Tokyo, 104-8315, JAPAN Telephone: +81-3-5250-8111 Ajinomoto Heartland Inc. 8430 W. Bryn Mawr Avenue, Suite 650 Chicago, Illinois 60631-3421 Telephone: 773-380-7000 Facsimile: 773-380-7006	CJ CheilJedang Corp. CJ CheilJedang Center 330, Dongho-ro, Jung-Gu Seoul, REPUBLIC OF KOREA CJ America, Inc. 3500 Lacey Road, Suite 230 Downers Grove, Illinois 60515-5423 USA PT CheilJedang Indonesia Menara Jamsostek, 21st Floor, JL. Jend. Gatot Subroto Kav.38 Jakarta 12710 INDONESIA
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I. INTRODUCTION

1.1 Complainants Ajinomoto Co., Inc. ("Ajinomoto") and Ajinomoto Heartland, Inc. ("Heartland") (collectively, "Complainants") request that the United States International Trade Commission commence an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 ("Section 337"), to remedy the unlawful importation into the United States, sale for importation into the United States, or sale within the United States after importation by the owner, importer, or consignee (or agents thereof), of certain bulk L-tryptophan or L-tryptophan products ("Accused Products") that infringe valid and enforceable United States patents owned by Ajinomoto and licensed to Heartland.

1.2 The proposed Respondents are CJ CheilJedang Corp. ("CJ Corp."), CJ America, Inc. ("CJ America"), and PT CheilJedang Indonesia ("CJ Indonesia") (collectively, "CJ" or "Proposed Respondents"). Upon information and belief, Proposed Respondents have engaged in unfair acts in violation of Section 337 through and in connection with the unauthorized and unlawful importation into the United States, sale for importation into the United States, or sale within the United States after importation of Accused Products that infringe one or more claims of United States Patent Nos. 7,666,655 ("the '655 patent") and 6,180,373 ("the '373 patent") (collectively, "the Asserted Patents").

1.3 Complainants assert that Proposed Respondents directly infringe and induce the infringement of at least claims 4, 7, 8, and 20 of the '655 patent; and at least claim 10 of the '373 patent (collectively, "the Asserted Claims").

1.4 Certified copies of the Asserted Patents accompany this Complaint as Exhibits 1 and 2, respectively. Ajinomoto owns by assignment the entire right, title, and interest in and to these patents. Certified copies of the recorded assignments accompany this Complaint as Exhibits 3 and 4, respectively.

1.5 As required by Section 337(a)(2) and defined by Section 337(a)(3), an industry in the United States exists and is in the process of being established relating to articles covered by the Asserted Patents.

1.6 Complainants seek a permanent limited exclusion order, pursuant to Section 337(d), excluding from entry into the United States all of Proposed Respondents' Accused Products that infringe one or more claims of the Asserted Patents. Complainants also seek permanent cease and desist orders, pursuant to Section 337(f), directing each Proposed Respondent to cease and desist from importing, marketing, advertising, demonstrating, warehousing inventory for distribution, offering for sale, selling, distributing, licensing, or using the Accused Products in the United States.

II. COMPLAINANTS

A. Ajinomoto Co., Inc.

2.1 Ajinomoto is a corporation organized under the laws of Japan, having a principal place of business at 15-1, Kyobashi 1-chome, Chuo-ku, Tokyo 104-8315, Japan.

2.2 Ajinomoto was founded 106 years ago, and currently employees over 30,000 people in 26 countries and areas around the word. From its origin, Ajinomoto has been focused on amino acid technologies, launching the first commercially-engineered amino acid product—monosodium glutamate ("MSG")—in 1909. The product, which was called "AJI-NO-MOTO," was based upon the pioneering patent that was issued to Dr. Kikunae Ikeda in 1908. This ground-breaking work led to the worldwide recognition of Ajinomoto as a leader in cutting-edge technology in the field of amino acid research, development, and production.

2.3 Since 1960, amino acids have been added to animal feed as a means of improving the growth of livestock. Ajinomoto launched its feed-use amino acids business in 1965, and has since built an international production and supply network as the world's leading manufacturer

of feed-grade amino acids. In 2011, Ajinomoto established Ajinomoto Animal Nutrition Group ("AANG"), a wholly owned subsidiary specializing in the animal nutrition business.

2.4 Ajinomoto maintains its position as the world's leader in this field through significant investments in research and development related to creating superior fermentation technology. Increasingly efficient and productive microorganisms used in fermentation are created through continuing efforts of Ajinomoto's research institutes, and methods for maximizing amino acid production using these new microorganisms comprise core technologies developed over many years by Ajinomoto. A copy of Ajinomoto's 2015 Annual Report accompanies this Complaint as Exhibit 5.

B. Ajinomoto Heartland Inc.

2.5 Heartland is a wholly-owned subsidiary of AANG (and hence Ajinomoto), existing under the laws of the state of Illinois with its principal place of business at 8430 W. Bryn Mawr Avenue, Suite 650, Chicago, Illinois. Representing Ajinomoto in North America, Heartland manufactures and distributes cost effective feed-grade amino acids and is the frontrunner in amino acid nutritional research and technical expertise. In 1986, Heartland began the production of feed-grade amino acids for animal use in Eddyville, Iowa (the "Eddyville Plant"). The Eddyville Plant is expected to begin production of feed-grade L-tryptophan in Spring, 2017, and has already begun purchasing equipment and engineering services for this significant investment for the American market.

2.6 Heartland prides itself on utilizing new and improved methods and strategies to manufacture products for a number of industries, including agriculture. By working with Ajinomoto, Heartland is able to provide the United States market with innovative technologies, products, and expertise.

III. PROPOSED RESPONDENTS

A. CJ CheilJedang Corp.

3.1 On information and belief, Proposed Respondent CJ CheilJedang Corp. ("CJ Corp.") is a corporation organized under the laws of the Republic of Korea, with its principal place of business in Seoul, Republic of Korea. CJ Corp. is in the business of manufacturing, exporting/importing, and selling a broad range of products, including but not limited to infringing products containing L-tryptophan, such as bulk feed-grade L-tryptophan. *See* Exhibit 6.

3.2 On information and belief, CJ Corp., alone or in concert with others, manufactures the Accused Products in Indonesia or another foreign country, sells them for importation into the United States, imports them into the United States, and sells them after importation into the United States. *See* Exhibit 7.

B. CJ America, Inc.

3.3 Proposed Respondent CJ America, Inc. ("CJ America") is a New York corporation with a principal place of business in Los Angeles, California. CJ America is the United States headquarters of CJ Corp. *See* Exhibit 8. On information and belief, CJ America is responsible for CJ Corp.'s business activities in the United States involving at least the production and sale of food ingredients (including MSG and nucleotide food enhancers), and animal nutrition products (including feed-grade amino acids). *See id.*

3.4 On information and belief, CJ America, alone or in concert with others, manufactures the Accused Products in Indonesia or another foreign country, sells them for importation into the United States, imports them into the United States, and sells them after importation into the United States. *See* Exhibit 7.

C. PT CheilJedang Indonesia

3.5 Proposed Respondent PT CheilJedang Indonesia ("CJ Indonesia") is an Indonesian entity with a principal place of business at Jakarta, Indonesia. On information and belief, CJ Indonesia, alone or in concert with others, manufactures the Accused Products in Indonesia, sells them for importation into the United States, imports them into the United States, and sells them after importation into the United States. *See* Exhibit 7.

IV. THE TECHNOLOGY AND PRODUCTS AT ISSUE

4.1 The technology at issue relates generally to the production of amino acids by fermentation of microorganisms, such as *Escherichia coli* ("*E. coli*"). As will be described in detail below, the Asserted Patents are directed to particular bacterial strains and their methods of use for the production of amino acids, including L-tryptophan.

4.2 Bacteria, such as *E. coli*, can synthesize all 20 amino acids, whereas animals and humans cannot. Those amino acids that cannot be synthesized in adequate amounts (or still yet, cannot be synthesized at all) by animals and humans are called "essential" amino acids. Essential amino acids must be obtained from external sources, such as through the consumption of food. L-tryptophan is an essential amino acid. Adding L-tryptophan as a feed supplement can supply the nutritional balance needed to effectively enhance animal growth, by supplying, for instance, an essential amino acid not or insufficiently present in the animal's feed.

4.3 Pursuant to 19 C.F.R. § 210.12(a)(12), the Accused Products are CJ's feed-grade L-tryptophan products that, without permission, implement Ajinomoto's patented technologies as described and claimed in the Asserted Patents. Such L-tryptophan products include, but are not limited to, CJ's BestAmino™ brand L-tryptophan products. *See* Exhibit 7.

V. THE ASSERTED PATENTS

A. The '655 Patent

1. Identification of the Patent and Ownership by Ajinomoto

5.1 U.S. Patent No. 7,666,655, entitled "*Escherichia* Bacteria Transformed with the *yddG* Gene to Enhance L-Amino Acid Producing Activity," issued on February 23, 2010. The '655 patent issued from U.S. Application No. 10/302,997, filed November 25, 2002. The inventors of the '655 patent are 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.

5.2 Ajinomoto is the owner, by valid assignment, of the entire right, title, and interest in and to the '655 patent. Prior to issuance, the '655 inventors assigned all right, title and interest in U.S. Application No. 10/302,997 to Ajinomoto. This assignment is recorded at the United States Patent and Trademark Office at Reel/Frame 013831/0803. *See* Exhibit 3. The '655 patent is valid, enforceable, and is currently in full force and effect.

5.3 Pursuant to Rule 210.12(c) of the Commission's Rules of Practice and Procedure, this Complaint is accompanied by Appendices A and B containing: A) a certified copy of the prosecution history of the '655 patent; and B) a copy of each reference mentioned in that prosecution history.

2. Non-Technical Description of the Invention of the '655 Patent

5.4 The invention of the '655 patent relates generally to improved methods for the production of aromatic L-amino acids through the enhanced expression of the YddG protein in *E. coli*. *See, e.g.,* '655 patent at col. 2:40-57 and 4:20-31. In general terms, the patented methods

utilize novel, genetically modified *E. coli* to enhance the production of the YddG protein, which in turn increases aromatic L-amino acid production. *See id.*

5.5 One of the normal metabolic reactions of many bacteria, including *E. coli*, is the ability to synthesize L-amino acids. Ajinomoto's research identified the *yddG* gene (and nucleotide sequence) as encoding for a protein (the YddG protein) that, when enhanced, increases the production of certain aromatic L-amino acids. *See id.* at col. 2:46-57.

5.6 Ajinomoto introduced genetic modifications into *E. coli* to enhance the expression of the *yddG* gene. *See* '655 patent at Example 4. Enhanced expression of the *yddG* gene increases the expression of the corresponding amino acid sequence of that protein, which results in an increase in the amount of YddG protein. *See id.* at col. 6:12-16. As a result, bacteria with genetic modifications that result in enhanced *yddG* gene expression also exhibit enhanced aromatic L-amino acid production. *See id.* at col. 4:20-31, Example 3, and Example 5. The '655 patent describes and claims processes that use *E. coli* wherein expression of the *yddG* gene is enhanced in an improved process of making L-tryptophan. *See id.*

5.7 In addition to the claimed methods that are asserted in this proceeding, the '655 patent claims recombinant *E. coli* producer strains in which the expression of the *yddG* gene has been enhanced.

3. Foreign Counterparts to the '655 Patent

5.8 The following foreign patent(s) and patent application(s) correspond to the '655 patent:

Country	Application No.	Filing Date	Patent No.	Issued Date	Status
Argentina	P020104508	2002/11/22	AR037415B1	2009/11/18	Registered
Australia	2002355022	2002/11/21	2002355022	2008/01/04	Registered
Brazil	PI0214330-5	2002/11/21	PI0214330-5	2015/06/16	Registered
Canada	2468179	2002/11/21	2468179	2013/05/21	Registered
China	2827470.9	2002/11/21	ZL02827470.9	2010/04/28	Registered

China	20101032502.1	2010/02/26	ZL201010132502.1	2012/06/20	Registered
EPO	02788636.5	2002/11/21	1449918	2010/06/09	Registered
France	02788636.5	2002/11/21	1449918	2010/06/09	Registered
Germany	02788636.5	2002/11/21	60236684.4	2010/06/09	Registered
Ireland	02788636.5	2002/11/21	1449918	2010/06/09	Registered
Japan	2003-545813	2002/11/21	04305184B1	2009/05/15	Registered
Korea	10-2004-7007796	2002/11/21	10-1023925	2011/03/15	Registered
Mexico	PA/a/2004/004874	2002/11/21	283289	2011/01/25	Registered
Netherlands	02788636.5	2002/11/21	1449918	2010/06/09	Registered
Poland	P-369471	2002/11/21	207852	2011/03/14	Registered
Russian	2002121670	2002/08/14	2222596	2004/01/27	Registered
Russian	2001131571	2001/11/23	-	-	Withdrawn
Switzerland	2788636.5	2002/11/21	1449918	2010/06/09	Registered
UK	02788636.5	2002/11/21	1449918	2010/06/09	Registered
WIPO	PC/JP02/12203	2002/11/21	-	-	-

5.9 On information and belief, no other foreign patents or patent applications corresponding to the '655 patent have been filed, abandoned, withdrawn, or rejected.

B. The '373 Patent

1. Identification of the Patent and Ownership by Ajinomoto

5.10 U.S. Patent No. 6,180,373, entitled "Microorganisms for the Production of Tryptophan and Process for the Preparation Thereof," issued on January 30, 2001. The '373 patent issued from U.S. Patent Application No. 08/411,760, filed September 23, 1993. The inventors of the '373 patent are Günter Wich, Walfred Leinfelder, and Keith Backman.

5.11 Ajinomoto is the owner, by valid assignment, of the entire right, title and interest in and to the '373 patent. Prior to issuance, the '373 inventors assigned all right, title, and interest in U.S. Application No. 08/411,760 to Consortium für elektrochemische Industrie GmbH ("Consortium"). Consortium assigned all right, title, and interest in the '373 patent to Wacker Chemie AG ("Wacker"), and Wacker subsequently assigned all right, title, and interest in the '373 patent to Ajinomoto. These assignments are recorded at the United States Patent and

Trademark Office at Reel/Frame 7698/0540, 19725/0609 and 37429/0748. *See* Exhibit 4. The '373 patent is valid, enforceable, and is currently in full force and effect.

5.12 Pursuant to Rule 210.12(c) of the Commission's Rules of Practice and Procedure, this Complaint is accompanied by Appendices C and D containing: C) a certified copy of the prosecution history of the '373 patent; and D) a copy of each reference mentioned in that prosecution history.

2. Non-Technical Description of the Invention of the '373 patent

5.13 The invention of the '373 patent generally relates to improvements in bacterial strains used for the production of L–tryptophan. *See, e.g.*, '373 patent at col. 2:1-34. More specifically, the patent describes and claims an improved method for producing L-tryptophan that utilizes strains of *E. coli* and *Corynebacteria* that are genetically engineered to be resistant to feedback inhibition. *See id.* In essence, the claimed strains ignore the metabolic "stop signals" that would normally limit the production of L-tryptophan.

5.14 In *E. coli* and *Corynebacteria* strains used for the production of L-tryptophan, the activities of certain enzymes responsible for L-tryptophan biosynthesis are normally subject to regulation via feedback inhibition. *See* '373 patent at col. 3:19-35 and 5:30-6:9. Feedback inhibition occurs when the activity of a certain enzyme is inhibited by a direct or indirect product of that enzyme. In *E. coli* and *Corynebacteria*, feedback inhibition can inhibit the activity of two of the enzymes that catalyze key steps in the L-tryptophan biosynthetic pathway, anthranilate synthase and phosphoglycerate dehydrogenase. *See id.*

5.15 The '373 patent describes and claims methods for achieving improved tryptophan yields by using tryptophan producing strains of *E. coli* and *Corynebacteria* that have been genetically engineered to express versions of both the anthranilate synthase and phosphoglycerate dehydrogenase enzymes that are modified so as to be resistant to feedback

inhibition. *See, e.g., id.* at col. 2:1-34 and Examples 1, 2, and 5. Other claims, not asserted in this proceeding, are directed to the genetically engineered microorganisms that are utilized in practicing the claimed method.

3. Foreign Counterparts to the '373 Patent

5.16 The following foreign patent(s) and patent application(s) correspond to the '373 patent:

Country	Application No.	Filing Date	Patent No.	Issued Date	Status
Australia	19930048190	1993/09/23	673374	1996/11/07	Expired
Brazil	PI9307125	1993/09/23	-	-	Rejected
Canada	19932145630	1993/09/23	2145630	2003/09/09	Expired
China	19931017586	1993/09/21	1065909	2001/05/16	Expired
Czech	19950000667	1993/09/23	282396	1997/07/16	Expired
EPO	93920811	1993/09/23	662143	1996/06/19	Expired
Finland	19950001439	1995/03/27	951439	2001/03/30	Expired
France	19930920811	1993/09/23	0662143	1996/06/19	Expired
Germany	59303039	1993/09/23	59303039	1996/07/25	Expired
Hungary	9500884	1993/09/23	218139	2000/06/28	Expired
Israel	19930920811	1993/09/23	0662143	1996/06/19	Expired
Japan	19930508668	1993/09/23	3032013	2000/04/10	Expired
Philippines	1-1993-46966	1993/09/27	PH1-1193-46966	196/09/27	Registered
Russia	19950113171	1993/09/23	2111247	1998/05/20	Expired
Slovakia	19950000341	1993/09/23	279854	1999/04/13	Expired
Taiwan	241303	1993/05/02	24133	1995/02/21	Expired
Thailand	9301001093	1993/06/22	12476	2002/04/17	Expired
UK	19930920811	1993/09/23	0662143	1996/06/19	Expired
WIPO	WOEP93002588	1993/09/23	-	-	-

5.17 On information and belief, no other foreign patents or patent applications corresponding to the '373 patent have been filed, abandoned, withdrawn, or rejected.

VI. UNLAWFUL AND UNFAIR ACTS OF PROPOSED RESPONDENTS

6.1 Upon information and belief, Proposed Respondents' Accused Products are bulk feed-grade L-tryptophan products that directly infringe at least the Asserted Claims (*i.e.*, claims 4, 7, 8, and 20 of the '655 patent; and claim 10 of the '373 patent). Discovery may reveal that Proposed Respondents infringe additional claims of the Asserted Patents.

6.2 On information and belief, Proposed Respondents manufacture the Accused Products outside the United States, specifically, at least in Indonesia. Proposed Respondents sell for importation, import into the United States, or sell within the United States after importation, the Accused Products.

6.3 On information and belief, and by way of example, Proposed Respondents directly infringe or induce the infringement of one or more of the Asserted Claims by selling for importation, importing into the United States, offering for sale, or selling bulk feed-grade tryptophan such as CJ's BestAmino™ brand L-tryptophan products within the United States. Exemplary claim charts demonstrating how this representative Accused Product infringes claims 4 and 20 of the '655 patent and claim 10 of the '373 patent are attached to the Complaint as Exhibits 9 and 10, respectively. Further discovery may reveal additional infringing products.

VII. SPECIFIC INSTANCES OF UNFAIR IMPORTATION AND SALE

7.1 Upon information and belief, there is substantial evidence to demonstrate that Proposed Respondents' feed-grade L-tryptophan is imported into the United States. For example, Heartland obtained a sample of Proposed Respondents' bulk feed-grade L-tryptophan in the United States. *See* Confidential Exhibit 11 at ¶¶ 16-18. According to the product packaging, the sample was manufactured in Indonesia by PT. CheilJedang Indonesia, under the license of CJ Corp, and was distributed in the United States by CJ America. *See id.*

7.2 Ajinomoto had the CJ Sample characterized to determine the bacteria used by Proposed Respondents to make their feed-grade L-tryptophan. *See id.* at ¶ 16; and Confidential Exhibit 12 at ¶¶ 4-5.

7.3 On information and belief, that characterization demonstrates that Proposed Respondents utilize methods to produce their feed-grade L-tryptophan that incorporate a recombinant *E. coli* strain claimed in the '655 patent. An exemplary claim chart showing how

Proposed Respondents' feed-grade L-tryptophan is the product of a process that meets each element of method claims 4 and 20 of the '655 patent is attached as Exhibit 9, as explained by the Declaration of Yoshihiko Hara. *See* Confidential Exhibit 12 at ¶¶ 6-14.

7.4 Upon information and belief, the characterization also demonstrates that Proposed Respondents' bulk feed-grade L-tryptophan products were produced using a recombinant *E. coli* bacterium as claimed in the '373 patent. An exemplary claim chart showing how Proposed Respondents' feed-grade L-tryptophan is the product of a process that meets each element of method claim 10 of the '373 patent is attached as Confidential Exhibit 10 as clarified by the Declaration of Yoshihiko Hara. *See id.* at ¶¶ 6-9 and 15-17.

7.5 The Accused Products are sold for importation, imported into the United States, or sold after importation into the United States by Proposed Respondents. By these acts, Proposed Respondents have violated 19 U.S. C. § 1337, because the feed-grade L-tryptophan in question is the product of a patented process.

7.6 Discovery is expected to reveal additional specific acts of Proposed Respondents' importation, sale for importation, or sale after importation of the Accused Products.

VIII. CLASSIFICATION UNDER THE HARMONIZED TARIFF SCHEDULE

8.1 The Accused Products are believed to fall within at least the following classifications of the Harmonized Tariff Schedule of the United States:

Heading/subheading	Article Description
2933.99.8290	Aromatic or modified aromatic heterocyclic compounds with nitrogen hetero-atom(s) only: other

8.2 These classifications are intended for illustration only and are not intended to restrict the scope of any exclusion order or other remedy ordered by the Commission.

IX. LICENSEES

9.1 Ajinomoto Heartland Inc. holds an exclusive license to the Asserted Patents to manufacture, use, and sell feed-grade L-tryptophan in the United States. Heartland is in the process of establishing a domestic industry through plans and concrete steps to begin manufacturing feed-grade L-tryptophan in Spring 2017. Ajinomoto North America, Inc. ("AJINA"), a wholly owned subsidiary of Ajinomoto, uses the patented technology of the '655 and '373 patents to manufacture, use, and sell pharmaceutical-grade L-tryptophan in the United States, establishing a domestic industry.

X. THE DOMESTIC INDUSTRY

10.1 An industry as required by Section 337(a)(2) and defined by Section 337(a)(3) exists, and is in the process of being established, in the United States in connection with articles protected by the Asserted Patents and by processes claimed by the Asserted Patents.

A. Technical Prong

10.2 The domestic manufacture of L-tryptophan is carried out by AJINA, Complainant Ajinomoto's wholly owned U.S. subsidiary. AJINA manufactures pharmaceutical grade L-tryptophan in the United States using the strains or methods that are described and claimed in the '655 and '373 patents. *See* Confidential Exhibit 12 at ¶¶ 18-25. AJINA's manufacture of L-tryptophan takes place at facilities that are located in Raleigh, North Carolina (the "North Carolina Plant"). *See id.* at ¶ 18.

10.3 Ajinomoto began selling feed-grade tryptophan in the United States in the early-2000's. Ajinomoto currently produces feed-grade tryptophan for the U.S. market in France and imports and sells that product in the United States through its U.S. subsidiary, Heartland. The products from France are manufactured using the strains or methods that are described and

claimed in the '655 and '373 patents. Heartland's domestic manufacture of feed-grade L-tryptophan is expected to begin at Heartland's Eddyville Plant in the Spring of 2017 and will also use the strains or methods that are described and claimed in the '655 and '373 patents. *See* Confidential Exhibit 12 at ¶¶ 18-25; *see also* Exhibit 13.

10.4 Claim charts demonstrating how Complainants' current and future L-tryptophan products (pharmaceutical- and feed-grade) are covered by an exemplary claim of each of the Asserted Patents are attached as Confidential Exhibits 14, 15, 16, and 17, as explained by the Declaration of Yoshihiko Hara. *See* Confidential Exhibit 12 at ¶¶ 18-25. Because Complainants' current and future L-tryptophan products are and will be manufactured as described and claimed in '655 and '373 patents, they are "the product of [a] patented process" under 19 U.S.C. § 1337(a)(B)(ii).

10.5 Therefore, Complainants' current and future L-tryptophan products are and will be protected by the '655 and '373 patents, and a domestic industry for those articles exists.

B. Economic Prong

10.6 Ajinomoto satisfies the requirements of 35 U.S.C. § 1337(a)(2), (a)(3) because a domestic industry relating to the technology protected by the Asserted Patents exists in the United States and is in the process of being established in the United States. Ajinomoto 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. In its amino acid line, Ajinomoto sells two grades of tryptophan: pharmaceutical-grade L-tryptophan and feed-grade L-tryptophan. Ajinomoto currently sells both pharmaceutical-grade and feed-grade tryptophan in the United States (collectively the "Domestic Industry Products"). The Domestic Industry Products practice at least one claim of the Asserted Patents.

10.7 Ajinomoto, through its wholly owned subsidiary AJINA, produces and sells pharmaceutical-grade tryptophan at the North Carolina Plant. The North Carolina Plant began manufacturing pharmaceutical-grade tryptophan in 2007 and continues to this date. *See* Confidential Exhibit 18 at ¶ 4.

10.8 As set forth in Confidential Exhibit 18, Ajinomoto has made and continues to make significant investment in plant and equipment used in the process for manufacturing pharmaceutical-grade tryptophan. *See* Confidential Exhibit 18 at ¶¶ 6-10.

10.9 Ajinomoto has made and continues to make significant investments in labor and capital in connection with the manufacture of pharmaceutical-grade tryptophan. *See* Confidential Exhibit 18 at ¶¶ 11-14. Ajinomoto employs a significant number of employees in its North Carolina facility who devote substantial man-hours toward the manufacture of pharmaceutical-grade tryptophan. *See id.* Further details of Ajinomoto's significant investments in the employment of labor or capital are provided in Confidential Exhibit 18.

10.10 Since the early-2000's, Ajinomoto has invested in developing a U.S. market for feed-grade L-tryptophan. As a result of Ajinomoto's investments and efforts developing and educating the market, the feed-grade tryptophan market in the United States is growing at a rapid pace. To meet this demand, Ajinomoto has committed significant expenditures to expand the Eddyville Plant to begin the manufacture of feed-grade Tryptophan in the United States according to the process claimed in the Asserted Patents in Spring 2017. *See* Confidential Exhibit 19.

10.11 As set forth in Confidential Exhibit 19, Ajinomoto has made and will continue to make significant investment in plant and equipment that will be used in the process for

manufacturing feed-grade tryptophan. *See id.* at ¶¶ 6-12. Ajinomoto's investment in plant and equipment is further set forth in Confidential Exhibit 19.

10.12 Ajinomoto will make significant investments in labor and capital that will be used in connection with the manufacture of feed-grade tryptophan. *See id.* at ¶¶ 13-15. Further details of Ajinomoto's investment in labor and capital are provided in Confidential Exhibit 19.

10.13 Ajinomoto has also made and continues to make substantial investments in the exploitation of the Asserted Patents. Ajinomoto conducts research and development and provides support activities to exploit the Domestic Industry Products. See Confidential Exhibit 11 at ¶¶ 3-13. Further details regarding Ajinomoto's domestic investments in the exploitation of the Asserted Patents are found in Confidential Exhibit 11.

XI. RELATED LITIGATION

11.1 Pursuant to Commission Rule 210.12(a)(5), Complainants certify that the Asserted Patents, or the subject matter thereof, have not been the subject of any previous court or agency litigation.

XII. RELIEF REQUESTED

12.1 WHEREFORE, by reason of the foregoing, Complainants request that the United States International Trade Commission:

(a) institute an immediate investigation, pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, with respect to violations of Section 337 based on Proposed Respondents' unlawful importation into the United States, sale for importation into the United States, or sale within the United States after importation of certain feed-grade L-tryptophan products that infringe one or more claims of United States Patent Nos. 7,666,655 and 6,180,373;

(b) schedule and conduct a hearing on the unlawful acts and, following the hearing, determine that there has been a violation of Section 337.

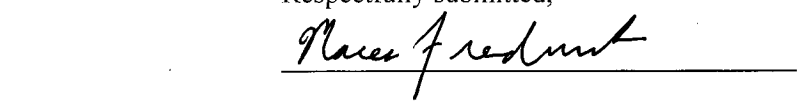
(c) issue a permanent exclusion order, pursuant to Section 337(d) of the Tariff Act of 1930, as amended, excluding from entry into the United States all of Proposed Respondents' L-tryptophan products that infringe one or more of the claims of United States Patent Nos. 7,666,655 and 6,180,373;

(d) issue permanent cease and desists orders, pursuant to Section 337(f) of the Tariff Act of 1930, as amended, directing each Proposed Respondent to cease and desist from the importation, marketing, advertising, demonstrating, warehousing of inventory for distribution, sale and use of L-tryptophan products that infringe one or more claims of United States Patent Nos. 7,666,655 and 6,180,373; and

(e) grant such other and further relief as the Commission deems just and proper based on the facts determined by the investigation and the authority of the Commission.

Dated: May 10, 2016

Respectfully submitted,



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