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DOCKET NUMBER 2647

Office of the Secretary Int'l Trade Commission

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January 27, 2009

CBI#: 09-103

VIA HAND DELIVERY

The Honorable Marilyn R. Abbott
Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

2009 JAN 28 AM 9:21 RECEIVED U.S. INTERNATIONAL TRADE COMMISSION OFFICE OF THE SECRETARY

Re: Non-Shellfish Derived Glucosamine and Products Containing Same

Dear Secretary Abbott:

Enclosed for filing on behalf of Complainant Cargill, Inc. ("Cargill") are the following documents in support of Cargill's request that the Commission commence an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337. A request for confidential treatment of Confidential Exhibits 2, 3, 8, 8A, 8B, 9, 9A, 31, 32, 33, 34, and 35 are included with this submission.

Accordingly, Cargill submits the following documents:

1. An original and twelve (12) copies of the verified Complaint and an original and six (6) copies of the accompanying confidential exhibits and six (6) copies of the accompanying non-confidential exhibits (original and one (1) copy unbound of confidential and non-confidential exhibits, without tabs), pursuant to Commission Rules 201.6(c), 210.4(f)(3)(i) and 210.8(a);

2. Six (6) additional copies of the Complaint and accompanying Confidential and Non-Confidential exhibits for service upon each proposed respondent once appropriate subscriptions to a protective order have been filed, pursuant to Commission Rules 210.4(f)(3)(i), 210.8(a) and 210.11(a);

3. A certified copy of U.S. Patent No. 7,049,433 ("the '433 patent") as an Exhibit in the original Complaint and legible copies included with all copies of the Complaint as Exhibit 1;

4. A certified copy of the assignments involving the patent at issue as an Exhibit in the original Complaint and legible copies included with all copies of the Complaint as Exhibit 5;

5. One (1) certified copy and three (3) additional copies of the prosecution history of the '433 patent (Application Serial No. 10/326,549) (Appendix A), pursuant to Commission Rule 210.12(c)(2);

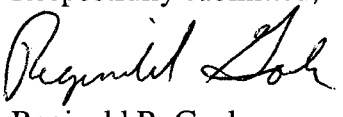
6. Four (4) copies of each reference document identified in the prosecution history of the '433 patent (Appendix B), pursuant to Commission Rule 210.12(c)(3);

7. One (1) copy of the Complaint and the accompanying non-confidential exhibits for service upon the Chinese Embassy in Washington, DC, pursuant to Commission Rules 210.8(a) and 210.11(a)(1); and

8. A letter and certification requesting confidential treatment of Confidential Exhibits 2, 3, 8, 8A, 8B, 9, 9A, 31, 32, 33, 34, and 35, pursuant to Commission Rules 201.6(b) and 210.5(d).

Thank you for your attention to this matter. Please contact the undersigned if there are any questions pertaining to this submission.

Respectfully submitted,



Reginald R. Goeke

Enclosures

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January 27, 2009

VIA HAND DELIVERY

The Honorable Marilyn R. Abbott
Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

Re: Non-Shellfish Derived Glucosamine and Products Containing Same

Dear Secretary Abbott:

This firm represents Complainant Cargill, Inc. ("Cargill") in the filing of a complaint pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337.

In accordance with Commission Rules 201.6 and 210.5, 19 C.F.R. §§ 201.6 and 210.5, Cargill requests confidential treatment of the business information contained in Confidential Exhibits 2, 3, 8, 8A, 8B, 9, 9A, 31, 32, 33, 34, and 35.

The information for which confidential treatment is sought is proprietary commercial information not otherwise publicly available. Specifically, Confidential Exhibits 2, 31, and 33 contain proprietary commercial information regarding Cargill's patented process. Exhibit 3 contains confidential information concerning Cargill's investments in research and development, plant and equipment, revenues, and the number of Cargill employees related to domestic industry products. Confidential Exhibits 8, 8A, and 8B reflect the identity and information of Cargill's outside investigators. Exhibits 9 and 9A contain information obtained through Cargill's investigation concerning a proposed respondent and its production facility. Exhibits 32, 34, and 35 are claim charts that demonstrate how Cargill's process, as well as that of several named respondents, practices certain claims of the patent at issue.

The information described above qualifies as confidential business information pursuant to Rule 201.6(a) because:

a. it is not available to the public;

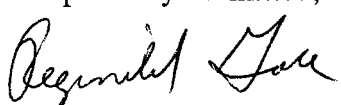
b. unauthorized disclosure of such information could cause substantial harm to the competitive position of Cargill and/or a third party; and

c. its disclosure could impair the Commission's ability to obtain information necessary to perform its statutory function.

Attached is the requisite certification relating to confidentiality.

We appreciate your assistance in this matter. Please contact the undersigned if there are any questions about this request.

Respectfully submitted,



Reginald R. Goeke

CERTIFICATION

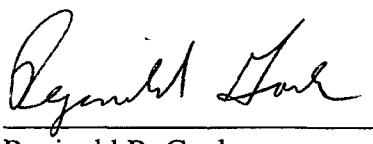
I, Reginald R. Goeke, Attorney for Cargill, Incorporated, declare:

1. I am duly authorized to execute this certification;

2. I have reviewed Confidential Exhibits 2, 3, 8, 8A, 8B, 9, 9A, 31, 32, 33, 34, and 35, for which confidential treatment has been requested; and

3. To the best of my knowledge, information and belief, founded after reasonable inquiry, substantially identical information is not available to the public.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed this 27th day of January 2009 in Washington, DC.



Reginald R. Goeke

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, DC

In the Matter of	)	
NON-SHELLFISH DERIVED GLUCOSAMINE AND PRODUCTS CONTAINING SAME	)	Inv. No. 337-TA-_____

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

Complainant:

Cargill, Incorporated
15407 McGinty Rd W
Wayzata, Minnesota 55391
1-800-CARGILL (227-4455)

Counsel for Complainant:

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Chicago, IL 60606-4637
Tele: 312-701-8979
Fax: 312-706-8530

Proposed Respondents:

Nantong Foreign Trade Medicines & Health Products Co., Ltd.
6/F Commercial Building
15 Middle Quingnian Rd.
Nantong, Jiangsu, China 226006

DNP International, Inc.
12802 Leffingwell Ave., Bldg E
Santa Fe Springs, CA 90670

Tiancheng International, Inc. (USA)
2851 E Philadelphia St.
Ontario, CA 91761-8553

Hygieia Health Co., Ltd.
Building # 54
5/F 1089 Qinzhou Road (N)
Shanghai, China 200233

TSI Health Sciences, Inc.
7168 Expressway
Missoula, MT 59808-8587

Ethical Naturals, Inc.
330 Sir Francis Drake Blvd., Suite H
San Anselmo, CA 94960

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3. Declaration of Barry Burnett (Confidential)

4. Excerpts from Cargill's website and other information describing Regenasure® Glucosamine.

5. Certified copies of the assignment documents for the '433 patent

6. Certified copy of abandoned U.S. Patent Application Ser. No. 09/785,695, the parent application of the '433 patent

7. NFT website materials

8. Declaration of Cargill Investigator (Confidential)

   A. Résumé of Cargill Investigator (Confidential)

   B. Results of analysis for non-shellfish glucosamine samples and accompanying documentation provided by Nantong Foreign Trade Medicines and Health Products Co., Ltd. ("NFT") (Confidential)

   C. Packing slip-invoice and certificate of analysis for non-shellfish glucosamine purchased from DNP International, Inc. ("DNP")

   D. Certificates of analysis for non-shellfish glucosamine samples provided by TSI Health Sciences, Inc. (USA) ("TSI (USA)")

   E. Packing list-invoice and certificate of analysis for non-shellfish glucosamine purchased from Ethical Naturals, Inc. ("ENI")

9. Declaration of William Gruber (Confidential)

   A. Photographs of glucosamine facility in China (Confidential)

10. Photographs comparing NFT and DNP non-shellfish glucosamine

11. Email from DNP to Cargill counsel (April 24, 2008) regarding purchases of non-shellfish glucosamine by DNP from Tiancheng International, Inc. (USA) ("Tiancheng USA") and Cargill counsel letter to DNP (May 8, 2008)

12. Cargill counsel letter to Tiancheng USA (July 17, 2008)

13. Tiancheng USA counsel letter to Cargill counsel (July 28, 2008) and other correspondence between the parties

14. DNP website and other materials

15. Hygieia website and other materials

16. Hygieia trademark application: GlucosaGreen

17. TSI Website and other materials

18. Hygieia-TSI corporate ownership chart and other information depicting Hygieia-TSI affiliation

19. Cargill letter to TSI (November 27, 2007)

20. TSI counsel letter to Cargill (January 11, 2008) and other correspondence between the parties

21. Cargill counsel letter to TSI counsel (April 3, 2008) and TSI counsel letter to Cargill counsel (April 17, 2008)

22. Hygieia counsel letter to Cargill (April 30, 3008)

23. Documentation demonstrating shared Shanghai offices of Hygieia and TSI

24. Documentation demonstrating shared U.S. offices of Hygieia and TSI

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26. ENI trademark application: GreenGrown

27. Photographs of ENI GreenGrown® non-shellfish glucosamine packaging

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    C. Report of Analysis of Sample 80506101(Lot # SPE7006A)

    D. Report of Analysis of Sample 80506102 (Lot # RHPS6049A)

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J. Report of Analysis of Sample 80506108 (Lot # 080421)

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29. Claim chart showing NFT and DNP-Tiancheng USA's non-shellfish glucosamine practices claim 1 of the '433 patent

30. Hygieia U.S. patent application

31. Declaration of Francis H. Verhoff (Confidential)

32. Claim chart showing Hygieia and TSI's non-shellfish glucosamine practices claim 1 of the '433 patent (Confidential)

33. Declaration of Charles Damschen (Confidential)

34. Claim chart showing ENI's non-shellfish glucosamine practices claim 1 of the '433 patent (Confidential)

35. Comparison of claim 1 of the '433 patent with Cargill's Regenasure® Glucosamine (Confidential)

PHYSICAL EXHIBITS: NON-SHELLFISH GLUCOSAMINE

A. DNP

B. Hygieia and TSI

C. ENI

D. Cargill

APPENDICES SUBMITTED PURSUANT TO 19 C.F.R. § 210.12(c)(2) AND (c)(3)

Appendix A	Certified copy of prosecution history for U.S. Patent No. 7,049,433 ("the '433 patent")
Appendix B	Copies of patents and references mentioned in the '433 patent prosecution History

I. INTRODUCTION

1. This Complaint is filed by Complainant Cargill, Incorporated ("Complainant" or "Cargill"), pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, based upon the unlawful importation into the United States, the sale for importation into the United States, and/or the sale within the United States after importation, of non-shellfish derived glucosamine and products containing same ("non-shellfish glucosamine").

2. The proposed respondents are Nantong Foreign Trade Medicines and Health Products Co., Ltd., DNP International, Inc., Tiancheng International, Inc. (USA), Hygieia Health Co., Ltd., TSI Health Sciences, Inc. (USA), and Ethical Naturals, Inc. (collectively "Respondents"). The accused non-shellfish glucosamine infringes, or is made or produced under, or by means of, a process covered by (collectively "infringes"), claims 1 to 10 of U.S. Patent No. 7,049,433 ("the '433 patent"). A certified copy of the '433 patent is attached as Exhibit 1.

3. Cargill is the owner, by valid assignment, of all right, title and interest in and to the '433 patent. In view of the pattern of violations and in order to prevent circumvention of a limited exclusion order, Cargill seeks as permanent relief a general exclusion order, pursuant to Section 337(d), excluding from entry into the United States all non-shellfish glucosamine that infringes one or more of the claims of the '433 patent. In the alternative, Cargill seeks as permanent relief a limited exclusion order excluding from entry into the United States all non-shellfish glucosamine that is imported into the United States, sold for importation, and/or sold within the United States after importation by Respondents, and that infringes one or more of the claims of the '433 patent. Complainant also seeks a permanent cease and desist order, pursuant to Section 337(f), prohibiting Respondents from importing, selling, offering for sale (including

via the internet or electronic mail), advertising (including via the internet or electronic mail), distributing or soliciting within the United States any non-shellfish glucosamine which infringes one or more claims of the '433 patent.

II. THE PARTIES

A. Complainant Cargill, Inc.

4. Complainant Cargill is a privately owned, Delaware corporation with its principal place of business at 15407 McGinty Rd W, Wayzata, Minnesota 55391.

5. Cargill was incorporated in 1930, and is an international provider of food, agricultural and risk management products and services employing almost 158,000 employees. Among other businesses, Cargill develops, manufactures, and markets science-based, health promoting ingredients and ingredient systems for makers of food, dietary and pharmaceutical products.

6. In particular, Cargill has long been recognized as an innovator in the development of acidulants. Acidulants are additives that give a sharp taste to foods, assist in the setting of gels, and act as preservatives. One of Cargill's acidulant products is Regenasure® D-Glucosamine Hydrochloride ("Regenasure® Glucosamine").

7. Glucosamine is used as a nutraceutical supplement and can be used as a food additive. Prior to Cargill's invention of the process described herein, glucosamine had been manufactured almost exclusively from the exoskeltons of invertebrates, such as shellfish. Cargill invented a process for developing non-shellfish derived glucosamine, also referred to as "vegan" glucosamine. Such non-shellfish glucosamine is safe for users having shellfish allergies and is free of heavy metal and other contaminants associated with shellfish-derived glucosamine.

Cargill's non-shellfish glucosamine product is sold under the trade name Regenasure® Glucosamine.

B. Proposed Respondents

8. Upon information and belief, several foreign companies have attempted to manufacture or are actively manufacturing non-shellfish glucosamine that infringes one or more of the asserted claims of the '433 patent. As of this date, Cargill is aware of at least three manufacturing and distribution chains of non-shellfish glucosamine products imported into the United States that infringe one or more of the asserted claims of the '433 patent. In the first chain, Nantong Foreign Trade Medicines & Health Products Co., Ltd. ("NFT"), manufactures glucosamine and distributes it in the United States through at least DNP International, Inc. and Tiancheng International, Inc. Those respondents are described in paragraphs 9-12. In the second chain, Hygieia Health Ltd. ("Hygieia") (potentially in combination with other related companies) manufactures glucosamine and distributes it in the United States at least through its related company TSI Health Sciences, Inc. ("TSI"). Those respondents are described in paragraphs 13-14. In the third chain, Ethical Naturals, Inc. ("ENI") distributes glucosamine in the United States that on information and belief is manufactured in China. Cargill does not presently know who manufactures that product for ENI. On information and belief, NFT and Hygieia, and likely others, are part of a significant and evolving network of nutritional supplement manufacturers operating in China and possibly elsewhere engaged in the manufacturing and trade of non-shellfish glucosamine imported into the United States.

1. Nantong Foreign Trade Medicines & Health Products Co., Ltd.

9. Upon information and belief, proposed respondent Nantong Foreign Trade Medicines & Health Products Co., Ltd. ("NFT"), is a corporation organized under the laws of

China, and has a principal place of business at 6/F Commercial Building, 15 Middle Quingnian Rd., Nantong, Jiangsu, China 226006.

10. Upon information and belief, NFT manufactures non-shellfish glucosamine, which NFT imports and/or sells for importation into, and sale after importation in, the United States. Specifically, on information and belief, NFT sells non-shellfish glucosamine for importation, and/or provides samples for importation, to DNP International, Inc. and Tiancheng International, Inc. (USA) ("Tiancheng (USA)"), among others, for sale in the United States.

2. DNP International, Inc.

11. Upon information and belief, proposed respondent DNP International, Inc. ("DNP") is a corporation organized under the laws of California and has a principal place of business at 12802 Leffingwell Ave., Bldg E, Santa Fe Springs, CA 90670. Upon information and belief, DNP imports, distributes, and/or sells non-shellfish glucosamine obtained from NFT both directly and via Tiancheng (USA), after importation in the United States.

3. Tiancheng International, Inc. (USA)

12. Upon information and belief, proposed respondent Tiancheng (USA) is a corporation organized under the laws of California and has a principal place of business at 2851 E Philadelphia St., Ontario, CA 91761-8553. Upon information and belief, Tiancheng (USA) imports, distributes, and/or sells non-shellfish glucosamine obtained from NFT after importation in the United States.

4. Hygieia Health Co., Ltd.

13. Upon information and belief, proposed respondent Hygieia Health Co., Ltd. ("Hygieia") is a corporation organized under the laws of Hong Kong with its global headquarters at Unit A/6F Two Chinachem Plaza, 68 Connaught Road, Central, Hong Kong, and has its

principal place of business at Building # 54, 5/F 1089 Qinzhou Road (N), Shanghai, China 200233. Upon information and belief, Hygieia manufactures non-shellfish glucosamine, which Hygieia imports and/or sells for importation into, and sale after importation in, the United States. Specifically, on information and belief, Hygieia sells non-shellfish glucosamine for importation to its affiliated party, TSI Health Sciences, Inc. (USA), for sale in the United States.

5. TSI Health Sciences, Inc. (USA)

14. Upon information and belief, proposed respondent TSI Health Sciences, Inc. (USA) ("TSI (USA)"), an affiliate of Hygieia, is a corporation organized under the laws of Montana and has a principal place of business at 7168 Expressway, Missoula, Montana 59808-8587. Upon information and belief, TSI (USA) imports, distributes, and/or sells non-shellfish glucosamine after importation in the United States.

6. Ethical Naturals, Inc.

15. Upon information and belief, proposed respondent Ethical Naturals, Inc. ("ENI"), is a corporation organized under the laws of California and has a principal place of business at 330 Sir Francis Drake Blvd., Suite H, San Anselmo, CA 94960. Upon information and belief, ENI imports, distributes, and/or sells non-shellfish glucosamine after importation in the United States.

III. NON-TECHNICAL DESCRIPTION OF THE PATENTED TECHNOLOGY

16. Glucosamine is a naturally occurring molecule produced by many organisms, including humans. Glucosamine is an important constituent of mammalian connective tissue such as joints.

17. Glucosamine is also a principal component of chitin. Chitin is the main structural component of the exoskeletons of invertebrates, such as crustaceans, insects and spiders. Chitin is also present in the cell walls of most fungi and many algae.

18. Most commercially available glucosamine is derived from the exoskeleton of shellfish. However, many individuals are allergic to shellfish. Similarly, many individuals, including vegetarians, have dietary restrictions on the consumption of animal- or shellfish-derived glucosamine. In addition, the quality and purity of most commercially available glucosamine vary greatly due to the tremendous variability in the growth conditions of shellfish. For example, shellfish-derived glucosamine frequently has a high ash content. Of particular concern to many consumers is the amount of heavy metals that can be present in shellfish-derived glucosamine.

19. Glucosamine derived from vegetarian sources, such as fungal biomass, does not raise such concerns, since fungal biomass growth conditions can be closely monitored. Therefore, there is a need for vegetarian-derived glucosamine.

20. Until recently, however, extracting glucosamine from fungal chitin was impractical and expensive. *See* Declaration of John A. Bohlmann ("Bohlmann Decl.") (Confidential Exhibit 2). This is because the production of glucosamine from fungal biomass is highly complex, and involves multiple chemical reactions which are highly interrelated, difficult to separate, and which compete with each other to a large extent. Each of these reactions occurs at different rates under different combinations of acid type, acid concentration, temperature and length of time of reaction, affecting the total yield of glucosamine from the chitin in the fungal biomass. It has taken Cargill research scientists over two years and hundreds of experiments and trials wherein the acid types, acid concentrations, temperature, and reaction times were varied over a broad range in order to understand the multiple chemistries and reaction kinetics involved in converting chitin in fungal biomass to glucosamine, and determine the appropriate acid types, ranges of acid concentration, temperature and length of reaction required to achieve a

commercially viable yield of glucosamine of greater than 50 percent of total chitin in the fungal biomass.

21. In addition to the technical challenges involved in converting chitin from fungal biomass to glucosamine, the process also involves considerable variable and fixed costs. *See* Confidential Exhibit 2 (Bohlmann Decl.). Among the variable costs are expensive, highly regulated and corrosive acids, such as hydrochloric acid, which require expensive disposal procedures if they cannot be recycled. Among the many fixed costs are capital equipment capable of withstanding the highly corrosive reaction parameters used in acid hydrolysis of chitin to glucosamine. It required dozens of pilot scale runs, as well as significant plant-scaled experience, in order for Cargill scientists and engineers to arrive at a commercially efficient process that both overcomes the numerous technical difficulties involved in obtaining a high yield of glucosamine from fungal biomass chitin, and keeps fixed and variable costs at commercially viable levels.

22. The methods claimed in the '433 patent provide easy, cost-effective means for extracting glucosamine from fungal biomass. The '433 patent identifies the acid concentration, temperature and time required to convert chitin in fungal biomass to glucosamine. Such methods are commercially efficient, and yield glucosamine at greater than 50% of the total chitin content of the fungal biomass.

23. There are many advantages of developing glucosamine using the methods claimed in the '433 patent. First, fungal biomass is an abundant source for glucosamine, which avoids seasonal supply issues associated with shellfish-derived glucosamine. Fungal biomass is a frequent byproduct of industrial fermentation processes, such as the production of citric acid from corn steep liquor or hydrolyzed corn starch. In a typical citric acid fermentation process,

fungal organisms, such as *Aspergillus niger*, are cultivated in a corn-derived sucrose- or glucose-containing medium to produce citric acid.

24. Second, fungal biomass is a consistent and safe source for glucosamine, which has less ash and heavy metal content than shellfish-derived glucosamine. Because it is derived from fungal organisms used in the production of citric acid under strictly controlled conditions in fermentation plants located in the United States, Regenasure® Glucosamine offers U.S. consumers a safe, reliable source of glucosamine.

25. Third, use of fungal biomass derived from industrial processes such as citric acid fermentation to obtain glucosamine also provides an efficient, "green" way to recycle industrial byproducts.

26. Regenasure® Glucosamine is manufactured from a common, naturally occurring, renewable source, and is produced in accordance with current food Good Manufacturing Practices ("GMPs") under a comprehensive Hazard Analysis and Critical Control Points ("HACCP") program. Regenasure® Glucosamine was subjected to a battery of quality and safety testing, and has secured the FDA's GRAS ("Generally Recognized As Safe") recognition. Cargill devoted considerable resources toward this extensive effort, both in terms of financial expenditures and time. *See* Declaration of Barry Burnett ("Burnett Decl.") (Confidential) (Confidential Exhibit 3). Regenasure® Glucosamine is manufactured according to the methods claimed in the '433 patent in granulated and powder forms of non-shellfish glucosamine that easily can be incorporated into dietary supplements and various foods and beverages. As such, Regenasure® Glucosamine has revolutionized the market for glucosamine in the United States. Regenasure® Glucosamine has become the leading glucosamine dietary and food and beverage

supplement in the United States. *See* Exhibit 4 (excerpts from Cargill's website and other information describing Regenasure® Glucosamine).

27. Glucosamine is commonly found in several salt forms, including glucosamine hydrochloride (glucosamine HCl) and glucosamine sulfate (glucosamine 2KCl). The different glucosamine salts can be obtained by making glucosamine HCL according to the methods claimed in the '433 patent, which is then dry mixed with another salt to obtain the desired glucosamine-salt blend. Thus, non-shellfish glucosamine made according to the methods claimed in the '433 patent comprises any salt form of non-shellfish glucosamine, including, *inter alia*, glucosamine HCL, glucosamine sulfate, and glucosamine phosphate. In all cases, the starting raw material is glucosamine HCL obtained according to the invention claimed in the '433 patent. To meet consumer demand, Cargill makes and sells both glucosamine HCL and glucosamine sulfate. *See* Confidential Exhibit 2 (Bohlmann Decl.).

IV. THE PATENT AT ISSUE

A. United States Patent No. 7,049,433

28. On May 23, 2006, the PTO issued U.S. Patent No. 7,049,433 ("the '433 patent"), entitled "Glucosamine and Method of Making Glucosamine from Microbial Biomass," to Weiyu Fan, John A. Bohlmann, James R. Trinkle, James Donald Steinke, Ki-Oh Hwang, and Joseph P. Henning. Cargill is the owner, by valid assignment, of all right, title and interest in and to the '433 patent. Certified copies of the assignment documents for the '433 patent are attached to the Complaint as Exhibit 5.

29. The '433 patent issued from U.S. Patent Application Serial No. 10/326,549, filed December 19, 2002 ("the '549 application"). The '549 application is a continuation of Application No. 09/785,695, filed on February 16, 2001, now abandoned, a copy of which is

attached to the Complaint as Exhibit 6. The prosecution history of the '433 patent and copies of each patent and applicable pages of each technical reference mentioned in the prosecution history are being submitted with this Complaint. *See* Appendices A and B.

30. The '433 patent has 13 claims, including two independent claims (claims 1 and 11) and 11 dependent claims. Of those claims, claim 1 and dependent claims 2-10 are being asserted in this action. Additional claims may be asserted after discovery. Each of the asserted claims is a method claim.

B. Foreign Counterpart Patents

31. The following foreign counterpart patents or applications correspond to the '433 patent:

U.S. Patent No.	Country	Filing Date	Status	Issue Date	Foreign Patent or Appl. No.
7,049,433					
	Brazil	**02/15/2002**	**Pending**		
	Canada	**02/15/2002**	**Pending**		
	China	**02/15/2002**	**Issued**	**11/21/2007**	**ZL 02806321**
	China	**02/15/2002 (divisional)**	**Pending**		
	EPC	**02/12/2002**	**Pending**		
	Japan	**02/12/2002**	**Abandoned**		

32. Except as listed above, no other foreign applications or patents corresponding to the '433 patent have been filed, abandoned or rejected.

C. Licenses Under the Patents

33. At present, Cargill does not license the '433 patent to any third parties.

D. Non-Technical Description of the '433 Patent

34. The '433 patent is directed to methods for producing fungal-derived glucosamine compositions from chitin present in the fungal biomass. Chitin is a naturally occurring polysaccharide. Polysaccharides are organic polymers formed by long repeating units of monosaccharides. Specifically, chitin has the repeating structure of an unbranched glucosamine polymer. Glucosamine can be derived from chitin by a reaction called hydrolysis, in which the repeating polymeric units in chitin are broken up or separated into individual components of glucosamine

35. Practicing the methods of the '433 patent, glucosamine can be extracted from the chitin present in fungal biomass in a cost-effective manner through acid hydrolysis. The process generally includes reacting a fungal biomass in a strong acidic solution at a reaction temperature greater than 80°C. The reaction period should be at least four hours. Because the glucosamine thus obtained typically contains particulate impurities, as well as small amounts of glucose and other sugars, subsequent purification steps are usually necessary to obtain a satisfactory product.

36. Claim 1 of the '433 patent is directed to a method of obtaining glucosamine from fungal biomass, wherein the method comprises first obtaining the fungal biomass and then reacting the fungal biomass in an acidic solution with an acid concentration of greater than 5 percent by weight at a reaction temperature of greater than 80° C, for a reaction time of greater than 4 hours, in order to convert chitin in the fungal biomass to glucosamine. The glucosamine thus obtained is then separated from the reaction solution, resulting in a yield of glucosamine from the total chitin content of the fungal biomass source used that is greater than 50%.

V. UNLAWFUL AND UNFAIR ACTS OF THE RESPONDENTS

A. Specific Instances of Importation and Sale

1. NFT

37. On information and belief, NFT manufactures non-shellfish glucosamine outside the United States, marketed by NFT as Vegan D-Glucosamine HCL and Vegan D-Glucosamine sulfate (2KCL), which NFT then imports, sells for importation, and/or sells in the United States after importation, and which infringes at least one claim of the '433 patent in violation of, *inter alia*, 19 U.S.C. § 1337(a)(1)(B)(i).

38. NFT's non-shellfish glucosamine product is intended for sale in the United States. NFT advertises and sells its non-shellfish glucosamine on its website. Attached as Exhibit 7 are excerpts from NFT's website, claiming that NFT manufactures its non-shellfish glucosamine in China, with an output of between 30 and 50 metric tons ("MT") per month. According to NFT, its non-shellfish glucosamine is produced solely for export mainly to the United States, Canada, Europe, and Southeast Asia. Declaration of Cargill Investigator ("Investigator Decl.") (Confidential Exhibit 8).

39. As described in the Declaration of William Gruber ("Gruber Decl."), attached as Confidential Exhibit 9, Bai Jianguo, owner and general manager of NFT, acknowledged during a meeting with Mr. Gruber that NFT produced 1 to 3 metric tons ("MT") of non-shellfish glucosamine at the facilities of Jiangsu Nantong Ruili Chemical Co., Ltd. ("Ruili") in Nantong, Jiangsu, China. NFT admitted that, in producing this non-shellfish glucosamine, it is practicing the method used by Cargill to produce Regenasure® Glucosamine, as claimed by the '433 patent. Confidential Exhibit 9 (Gruber Decl.).

40. Mr. Bai explained that NFT exports glucosamine products through a broker-distributor network in the United States, which includes DNP International, Inc. ("DNP"), TSI Health Sciences, Inc., and Tiancheng International, Inc., among others. Mr. Bai stated that NFT imported a portion of the non-shellfish glucosamine produced at Ruili's facility in 25 kilogram drums to DNP and Tiancheng USA in the United States to be distributed as samples at no charge to U.S. consumers in order to establish NFT's presence for this product in the U.S. marketplace. Confidential Exhibit 9 (Gruber Decl.).

41. Cargill's investigator purchased a 25 kg. drum of non-shellfish glucosamine from DNP in the United States in March 2008. The label affixed to that drum was identical to the photograph of NFT's "D-Vegan Glucosamine HCL" on its website, except that the label on the DNP drum deletes the statement "Manufactured by: Nantong Foreign Trade Medicines and Health Products Co., Ltd." *See* Exhibit 10.

42. Finally, DNP informed Cargill by email that it purchased non-shellfish glucosamine in the United States from Tiancheng USA. Exhibit 11. In response, counsel for Cargill contacted Tiancheng USA by letter on July 17, 2008. Exhibit 12. Tiancheng USA acknowledged not only that it sold non-shellfish glucosamine to DNP, but that Tiancheng's supplier of this non-shellfish glucosamine was NFT in China. Exhibit 13.

43. By importing samples of non-shellfish glucosamine to the United States from China, and based on other evidence including that described above concerning NFT's supply of non-shellfish glucosamine to the United States, NFT has satisfied the importation standard under Section 337.

2. DNP

44. On information and belief, DNP imports, distributes, and/or sells non-shellfish derived glucosamine in the United States after importation, which infringes at least one claim of the '433 patent in violation of, *inter alia*, 19 U.S.C. § 1337(a)(1)(B)(i).

45. DNP sells non-shellfish glucosamine after importation into the United States. DNP advertises and sells its "Fermentation Grade Glucosamine HCL and Glucosamine Sulfate Potassium" on its website, which DNP promotes as a nutritional supplement and describes as being produced from corn fermentation. DNP's website also stresses that it imports such nutritional supplement products for sale in the United States. Portions of DNP's website, along with additional information concerning DNP, are attached as Exhibit 14.

46. As described in the Investigator Declaration, attached as Confidential Exhibit 8, Cargill arranged to purchase from DNP in the United States a 25-kg. drum of DNP's non-shellfish "Fermentation Glucosamine HCL." DNP acknowledged prior to the purchase that the product's country of origin is China. Cargill received the glucosamine together with a packing slip/invoice and Certificate of Analysis ("COA"). The COA confirms that the product purchased by Cargill originated in China. Confidential Exhibit 8(C) (Investigator Decl.). Photographs of the 25 kg. drum containing the non-shellfish glucosamine purchased from DNP are attached as Exhibit 10.

47. The evidence demonstrates that NFT is the source in China of DNP's non-shellfish glucosamine. First, as noted above, DNP informed Cargill by email that it purchased non-shellfish glucosamine in the United States from Tiancheng USA. Exhibit 11. Tiancheng USA acknowledged both that it sold non-shellfish glucosamine to DNP and that Tiancheng's supplier of this non-shellfish glucosamine was NFT in China. Exhibit 13. Second, the label

affixed to the 25 kg. drum containing the product exactly matches the photograph of NFT's "D-Vegan Glucosamine HCL" on its website, except that the label on the DNP drum deletes the statement "Manufactured by: Nantong Foreign Trade Medicines and Health Products Co., Ltd." Exhibit 10. Third, as described above, Bai Jianguo, NFT's owner and general manager, stated that NFT imported a portion of the 1-3 MT of non-shellfish glucosamine produced at Ruili's facility in Nantong in 25 kilogram drums to DNP in the United States.

48. Accordingly, on information and belief, the non-shellfish glucosamine sold by DNP in the United States was imported from NFT in China.

3. Tiancheng (USA)

49. On information and belief, Tiancheng (USA) imports, distributes, and/or sells non-shellfish glucosamine in the United States after importation, which infringes claims 1-10 of the '433 patent in violation of, *inter alia*, 19 U.S.C. § 1337(a)(1)(B)(i).

50. As described above, DNP informed Cargill by email that it purchased non-shellfish glucosamine in the United States from Tiancheng USA. Exhibit 11. Tiancheng USA acknowledged both that it sold non-shellfish glucosamine to DNP and that Tiancheng's supplier of this non-shellfish glucosamine was NFT in China. Exhibit 13. NFT indicated that it has exported glucosamine products through a broker-distributor network in the United States, which includes DNP and Tiancheng, among others. Confidential Exhibit 9 (Gruber Decl.).

4. Hygieia and TSI

51. On information and belief, Hygieia manufactures non-shellfish glucosamine outside the United States, marketed by Hygieia as GlucosaGreen® glucosamine, which Hygieia then imports, sells for importation, and/or sells in the United States after importation, and which

infringes at least one claim of the '433 patent in violation of, *inter alia*, 19 U.S.C. § 1337(a)(1)(B)(i).

52. Hygieia advertises and sells its "GlucosaGreen®" non-shellfish glucosamine via its website. Portions of Hygieia's website, along with other information concerning Hygieia, are attached as Exhibit 15. Hygieia has registered its GlucosaGreen® brand as a trademark in the United States. Exhibit 16.

53. On further information and belief, Hygieia is affiliated with TSI (USA) and TSI Health Sciences ("TSI"), the parent company of TSI (USA). Indeed, Hygieia and TSI have constructed a complex web of affiliated production and sales facilities in China, the United States, and elsewhere designed, in part, to facilitate the importation and sale by TSI (USA) of GlucosaGreen® glucosamine into the United States, which infringes Cargill's '433 patent. Attached as Exhibit 17 are portions of TSI's website. Attached as Exhibit 18 is an ownership chart and other corporate information depicting the affiliation between Hygieia, TSI and TSI (USA).

54. On information and belief, TSI (USA) imports, distributes, and/or sells non-shellfish derived glucosamine in the United States after importation, including GlucosaGreen® glucosamine purchased from Hygieia in China, which infringes at least one claim of the '433 patent in violation of, *inter alia*, 19 U.S.C. § 1337(a)(1)(B)(i).

55. TSI and Hygieia have confirmed that TSI obtains its non-shellfish glucosamine from Hygieia in China. Cargill contacted TSI by letter on November 27, 2007, concerning TSI (USA)'s sale of non-shellfish glucosamine in the United States. Exhibit 19. Counsel for TSI responded in a letter dated January 11, 2008, that "TSI is the exclusive licensee for marketing, distribution and sales of the GlucosaGreen® product in the United States. Exhibit 20. The

licensor and manufacturer is Hygieia Health Co., Ltd., a Chinese company." Counsel for TSI made similar representations in a subsequent letter, dated April 17, 2008. Exhibit 21. Thereafter, counsel for Hygieia also wrote to Cargill and acknowledged that Hygieia produces glucosamine from non-shellfish sources. Exhibit 22.

56. As described in the Investigator Declaration, attached as Confidential Exhibit 8, Cargill has obtained samples of Hygieia and TSI's GlucosaGreen® glucosamine products that TSI (USA) advertises and offers for sale in the United States on its website. TSI (USA) stated in response to the inquiry of Cargill's investigator that the product is available for purchase in the United States, but that, as of March 2008, it was not yet stocked in TSI (USA)'s U.S. warehouse. TSI (USA) stated that the product could be imported directly from China to the United States, from its factory outside of Shanghai. TSI (USA) quoted a price for its Chinese glucosamine HCL product of $20 per kilogram with a minimum purchase requirement of 25 kilos. Confidential Exhibit 8 (Investigator Decl.).

57. TSI (USA) then shipped Cargill's investigator 100 gram samples of both D-Glucosamine HCL USP and D-Glucosamine Sulfate 2KCL USP, as well as a TSI corporate brochure. Confidential Exhibit 8(D) (Investigator Decl.). Based on information and belief, the glucosamine samples provided to Cargill by TSI (USA) are Hygieia's GlucosaGreen® product, produced in China, sold by Hygieia for importation into the United States, and imported by TSI (USA) for sale in the United States. Significantly, in the cover letter accompanying the samples, TSI described the products, respectively, as "our non-shellfish GlucosaGreen Hcl" and "non-shellfish GlucosaGreen 2KCL." *Id.* In addition, TSI claims on its website to be the "exclusive marketer and distributor of GlucosaGreen™" and promotes GlucosaGreen® glucosamine as the

"World's Most Comprehensive Line of Vegetarian & Vegan Glucosamine HCl and Sulfates." Exhibit 17.

58. Further, the two non-shellfish glucosamine samples obtained by Cargill from TSI (USA) were accompanied by separate Certificates of Analysis, both of which have a fax stamp indicating that they were faxed on November 11, 2007, from "TSI China" to "Montana." Confidential Exhibit 8(D) (Investigator Decl.).

59. On information and belief, TSI (China) and Hygieia's affiliate, Hygieia Health, are related and/or jointly owned companies. Both companies share an office in Shanghai. Exhibit 23. In addition, TSI (USA) and Hygieia share an office in Montana. Exhibit 24. Hygieia also prepared the two COAs received by Cargill with the TSI glucosamine samples and certified that Hygieia had produced the non-shellfish glucosamine in question. Confidential Exhibit 8(D) (Investigator Decl.). Moreover, the "QA/QC Manager" of Hygieia approved the COAs by signing and dating both documents. *Id.* The two COAs also state that GlucosaGreen® is a trademark of Hygieia. Finally, Hygieia's website identifier and address in Shanghai appear at the bottom of both COAs. *Id.*

60. Accordingly, on information and belief, Hygieia produced the non-shellfish GlucosaGreen® glucosamine products provided to Cargill by TSI (USA). Moreover, on information and belief, Hygieia and TSI (USA), its affiliated party, acted together to then import the infringing GlucosaGreen® non-shellfish glucosamine for sale in the United States. By importing these samples of non-shellfish glucosamine to the United States from China, and then providing the samples to Cargill, Hygieia and TSI (USA) satisfied the importation standard under Section 337.

5. ENI

61. On information and belief, ENI imports, distributes, and/or sells non-shellfish glucosamine in the United States after importation, which ENI markets as GreenGrown® glucosamine, and which infringes claims 1-10 of the '433 patent in violation of, *inter alia*, 19 U.S.C. § 1337(a)(1)(B)(i).

62. ENI advertises and sells its GreenGrown® glucosamine in both HCL and sulfate forms on its website, which ENI promotes as being produced using "a proprietary process of corn fermentation." Portions of ENI's website, along with other information concerning ENI, are attached as Exhibit 25. ENI has registered its GreenGrown® brand as a trademark in the United States. Exhibit 26.

63. As described in the Investigator Declaration, attached as Confidential Exhibit 8, Cargill arranged in March 2008 to purchase from ENI in the United States a 25-kg. drum of ENI's GreenGrown® non-shellfish glucosamine. ENI acknowledged prior to the purchase that the product is manufactured in China, but ships from ENI's Sunnyvale, California warehouse. Confidential Exhibit 8 (Investigator Decl.). After placing an order by telephone to purchase the GreenGrown® non-shellfish glucosamine from ENI, Cargill's investigator received the product together with a Certificate of Analysis. *Id.*

64. Photographs of the 25 kg. drum containing the non-shellfish glucosamine purchased from ENI are attached as Exhibit 27. The drum states that the product was "Made in China" and is "Exclusively distributed by Ethical Naturals, Inc." *Id.* However, ENI refused to disclose the identity of its Chinese manufacturer to Cargill, and despite reasonable efforts, Cargill has thus far been unable otherwise to obtain this information.

B. Patent Infringement

1. The Chemistry and Reaction Kinetics of Glucosamine Conversion from Fungal Biomass

65. Cargill has conducted an extensive investigation of the glucosamine products manufactured by the named respondents. That investigation has included the retention of investigators, the testing of products manufactured by the named respondents, direct inquiry of the named respondents, and retention of experts to evaluate information about the processes used by the named respondents. That investigation has demonstrated facts strongly suggesting that the respondents manufacture glucosamine using a process that infringes Cargill's '433 patent.

66. *First,* Cargill has tested the products manufactured by each of the named respondents. Those tests demonstrate the presence of citric acid residue in all of the respondents' products, which is consistent with the manufacture of glucosamine using Cargill's process. Samples of glucosamine derived from shellfish typically contain no measurable amounts of citric acid because citric acid is not typically found in shellfish. Consequently, the presence of measurable amounts of citric acid in a given sample of glucosamine strongly suggests that the glucosamine was obtained from fungal biomass used in citric acid fermentation. *See* Confidential Exhibit 2 (Bohlmann Decl.). This is because the citric acid found in fungal-derived glucosamine is not naturally found in, and so is not a natural component of, the fungal biomass. Rather, the citric acid found in fungal-derived glucosamine samples is a co-product of an industrial process, called citric acid fermentation, in which the fungal biomass is used to produce citric acid. Citric acid fermentation is usually carried out by fungal organisms, such as *Aspergillus niger.* Because the chitin in fungal organisms is naturally found intertwined with complex carbohydrates called glucans, acid hydrolysis is required to convert fungal chitin to glucosamine.

67. The production of glucosamine from fungal biomass on a commercial scale entails high production costs, including (i) variable costs, such as the use of acids (like hydrochloric acid, in the hydrolysis reaction) and the costly disposal of those acids; and (ii) fixed costs, including acid corrosive-resistant plant equipment. *See* Confidential Exhibit 2 (Bohlmann Decl.). Given the technical complexity of the chemistry and the high variable and fixed costs involved in obtaining glucosamine from fungal chitin, it is very difficult to attain yields of glucosamine on a commercially viable scale. *See id.* Cargill scientists have conducted extensive experimentation and trial runs over the course of more than two years to arrive at a commercially viable process of producing glucosamine from fungal chitin, as claimed in the '433 patent. *See id.*

68. Although the presence of citric acid cannot disclose the specific acid concentration or temperature used in obtaining glucosamine from the fungal biomass used, Cargill has spent a substantial amount of time testing the hydrolysis of fungal biomass with various acid types, at various acid concentrations and various temperatures and for various periods of time. Based on the results of these numerous experiments and trials, Cargill believes that there is no commercially feasible means of manufacturing glucosamine from fungal chitin using acid hydrolysis which does not use the process claimed in the '433 patent. Thus, there is a substantial likelihood that the glucosamine products made and/or imported and sold by the respondents were made using the process disclosed in the '433 patent.

69. *Second*, Cargill has made extensive efforts to determine the process actually used by each of the respondents. That investigation generally confirmed that there is no other commercially feasible process for converting fungal biomass into glucosamine. Where Cargill was able to learn the process employed by a respondent (e.g., NFT), it was confirmed that the

respondent in fact used Cargill's patented process. Where Cargill has obtained some limited information about the process purportedly used by the other respondents, an analysis of those processes discloses that the processes purportedly used would be economically inefficient. This analysis strongly reinforces the substantial likelihood that the respondents use the process disclosed in the '433 patent.

70. **NFT:** For example, during Cargill's investigation, NFT admitted that its process infringes upon the process employed by Cargill.

71. **Hygieia:** As part of its investigation, Cargill reviewed a patent application recently filed by Hygieia for the manufacture of vegan glucosamine. That patent application discloses a process of using acid hydrolysis to convert fungal biomass to glucosamine, which employs nearly all the steps involved in Cargill's '433 patent. Although that application claims to use a reaction time of less than 4 hours, based on our expert analysis, it is unlikely that Hygieia actually limits its reaction period to less than 4 hours. Cargill requested additional information from Hygieia about the process it employs, and Hygieia refused to provide any detailed information concerning that process.

72. **ENI**: As part of its investigation, Cargill requested that ENI provide certain information concerning the process that it uses to manufacture vegan glucosamine. Although ENI has provided some information (subject to a confidentiality agreement) concerning the process it purportedly uses, an analysis of that purported process suggests that it would not be commercially feasible, raising the strong inference that ENI is not in fact using that process. Cargill has requested additional information from ENI (such as an inspection of the manufacturing facility), which ENI has refused to provide without imposing unreasonable requirements on Cargll.

73. Based on the evidence demonstrating the substantial likelihood that the respondents are using Cargill's patented process, and based on the substantial investigation conducted by Cargill, Cargill would be entitled to a presumption under 35 U.S.C. § 295 that NFT, Hygieia and ENI use a process that infringes on Cargill's '433 patent.

2. NFT, DNP and Tiancheng USA

74. On information and belief, NFT infringes at least one claim of the '433 patent with certain NFT products that are manufactured, imported into the United States, sold for importation, and/or sold after importation. NFT distributes that product in the United States through DNP and Tiancheng USA.

75. As described in paragraphs 44-48 above, in March 2008, Cargill's investigators purchased a 25 kg. drum of infringing non-shellfish glucosamine from DNP in the United States. *See* Confidential Exhibit 8 (Investigator Decl.). A sample of this non-shellfish glucosamine is submitted with this Complaint as Physical Exhibit A. Covance analyzed a sample of this non-shellfish glucosamine for the presence of citric acid residues, which was found to contain citric acid residues in the amount of 4.28 mcg/g. *See* Declaration of Darryl Sullivan, Exhibit 28 (Sullivan Decl.) and Exhibit 28(M). The presence of citric acid residues in the sample of glucosamine obtained from DNP strongly supports the conclusion that DNP's non-shellfish glucosamine is derived from a process in which fungal biomass used in citric acid fermentation is converted to glucosamine through acid hydrolysis.

76. DNP informed Cargill that it purchased non-shellfish glucosamine in the United States from Tiancheng USA. Exhibit 11. In addition, NFT acknowledged exporting non-shellfish glucosamine to Tiancheng USA. Confidential Exhibit 9 (Gruber Decl.). Counsel for Cargill contacted Tiancheng USA by letter on July 17, 2008. Exhibit 12. Tiancheng USA

acknowledged importing non-shellfish glucosamine from NFT in China, which Tiancheng USA sold to DNP. Exhibit 13. Thus, Tiancheng USA has acknowledged both that it is a distributor of non-shellfish glucosamine manufactured by or on behalf of NFT, and that it has distributed non-shellfish glucosamine obtained from NFT to DNP.

77. NFT has admitted to Cargill that the manufacturing process it uses infringes at least certain claims of Cargill's '433 patent. *See* Confidential Exhibit 9 (Gruber Decl.).

78. A claim chart applying independent claim 1 to a representative infringing sample of NFT's glucosamine (obtained from DNP) is attached to this Complaint as Exhibit 29. Further discovery may reveal that additional claims of the '433 patent are infringed by NFT's accused product and/or that other NFT products infringe the claims of the '433 patent.

3. Hygieia and TSI

79. On information and belief, both Hygieia and its affiliated party, TSI, infringe at least one claim of the '433 patent with certain Hygieia and TSI products that are manufactured, sold for importation, imported into the United States, and/or sold after importation.

80. As described in paragraphs 51-60 above, in March 2008, Cargill's investigators obtained from TSI (USA) in the United States samples of infringing GlucosaGreen® glucosamine that were manufactured in China and imported into the United States by Hygieia and TSI. *See* Confidential Exhibit 8 (Investigator Decl.). A portion of one of these samples of this non-shellfish glucosamine is submitted with this Complaint as Physical Exhibit B. Covance subsequently analyzed these samples for the presence of citric acid residues. *See* Exhibit 28 (Sullivan Decl.). Results of that analysis show that Hygieia and TSI's non-shellfish GlucosaGreen® glucosamine samples contain citric acid residues of 1.14 and .940 mcg/g, respectively. *See* Exhibit 28 and Exhibits 28(H) and (I).

81. Given this evidence, there is a strong likelihood that Hygieia and TSI's GlucosaGreen® glucosamine is derived from fungal biomass. Because there are no economically feasible alternatives to obtaining glucosamine from fungal biomass using acid hydrolysis other than by practicing the methods claimed in the '433 patent, *see* Confidential Exhibit 2 (Bohlmann Decl.), this evidence also demonstrates that Hygieia and TSI infringe the '433 patent.

82. Hygieia has submitted a patent application that discloses a process for manufacturing non-shellfish glucosamine that is nearly identical to the process in Cargill's '433 patent, except that Hygieia's patent application claims to react the chitin in the acid hydrolysis for three hours or less. Exhibit 30. An expert retained by Cargill has evaluated that patent application. Based on that analysis, it appears that the process followed by Hygieia likely does infringe Cargill's '433 patent. *See* Declaration of Frank H. Verhoff ("Verhoff Decl.") (Confidential Exhibit 31). This is because, though the patent application discloses a process in which the Biomass is reacted in acid for three hours, this does not appear to account for the time needed to heat and cool the acid mixture. *Id.* Once those time periods are included, it is likely that the process disclosed in Hygieia's patent application would infringe on Cargill's '433 patent.

83. Further, based on an economic analysis of the process employed by Hygieia, Cargill's expert believes that the process would not be commercially viable, because the cost of production would exceed the market price for vegan glucosamine. Verhoff Decl. (Confidential Exhibit 31). Based on this analysis, it appears likely that Hygieia may not be using its disclosed process, and may instead be using Cargill's process.

84. Cargill has asked Hygieia to disclose detailed information about the process that it uses so that Cargill can determine whether that process infringes Cargill's '433 patent, but

Hygieia has refused to do so. As a result, Cargill would be entitled to a presumption under 35 U.S.C. § 295 that Hygieia's process infringes on Cargill's '433 patent.

85. A claim chart that applies independent claim 1 of the '433 patent to the infringing Hygieia and TSI GlucosaGreen® glucosamine is attached to this Complaint as Exhibit 32. Further discovery may reveal that additional claims of the '433 patent are infringed by these accused products and that other Hygieia and/or TSI products infringe the claims of the '433 patent.

4. ENI

86. ENI infringes claims 1 to 10 of the '433 patent with certain ENI products that are manufactured, imported into the United States, sold for importation, and/or sold after importation.

87. As explained in paragraphs 61-64 above, in March 2008, Cargill's investigators purchased a 25 kg. drum of infringing GreenGrown® glucosamine from ENI in the United States. *See* Confidential Exhibit 8 (Investigator Decl.). A sample of this non-shellfish is submitted with this Complaint as Physical Exhibit C. Covance subsequently tested a sample of this GreenGrown® glucosamine for citric acid residues. *See* Exhibit 28 (Sullivan Decl.). Results of that analysis show that ENI's non-shellfish glucosamine contains .227 mcg/g citric acid residues. *See* Exhibit 28 (Sullivan Decl.) and Exhibit L to Sullivan Decl.

88. Given this evidence, there is a strong likelihood that ENI's non-shellfish glucosamine is derived from fungal biomass. Because there are no economically feasible alternatives to obtaining glucosamine from fungal biomass using acid hydrolysis other than by practicing the methods claimed in the '433 patent, *see* Confidential Exhibit 2 (Bohlmann Decl.), this evidence also demonstrates that ENI infringes the '433 patent.

89. In a confidential submission to Cargill's counsel, ENI has asserted that it uses a process that differs from that in Cargill's '433 patent. Cargill is not at liberty to disclose the contents of that submission. However, Cargill has provided the documents submitted by ENI to an outside expert. Based on his review of those documents, this expert believes that it is likely that the process disclosed would not be commercially feasible. Declaration of Charles Damschen ("Damschen Decl.") (Confidential Exhibit 33). As a result, the expert believes that ENI may be using a process different from that which was disclosed to Cargill.

90. Cargill has asked ENI to permit a tour of ENI's manufacturing facility and to provide Cargill with other information, which ENI has refused to provide without imposing unreasonable requirements on Cargll.

91. A claim chart that applies independent claim 1 of the '433 patent to the infringing ENI non-shellfish glucosamine is attached to this Complaint as Exhibit 34. Further discovery may reveal that additional claims of the '433 patent are infringed by these accused products and that other ENI products infringe the claims of the '433 patent.

VI. HTSUS Classification

92. Upon information and belief, the infringing imported non-shellfish glucosamine is classified under 2932.99, 2932.99.90, 2932.99.90.10, and/or 2932.99.90.90 of the Harmonized Tariff Schedule of the United States.

VII. THE DOMESTIC INDUSTRY

A. Technical Prong

93. Complainant Cargill's Regenasure® Glucosamine practices the '433 patent. Cargill manufactures Regenasure® Glucosamine at its facility in Eddyville, Iowa. Attached to this Complaint as Exhibit 2 is the declaration of John Bohlmann, setting forth a description of the

process used to manufacture Cargill's Regenasure® Glucosamine as well as the physical properties of Regenasure® Glucosamine. A claim chart applying a representative claim of the '433 patent to Cargill's Regenasure® Glucosamine is attached to this Complaint as Confidential Exhibit 34. A sample of Regenasure® Glucosamine is submitted herewith as Physical Exhibit D. Copies of brochures and other information from Cargill's website are attached as Exhibit 4.

B. Economic Prong

94. As defined by Section 337(a)(3), a domestic industry exists with respect to Cargill's Regenasure® Glucosamine that practices the claims of the '433 patent. Cargill has made significant investment in plant and equipment to develop and produce Regenasure® Glucosamine. *See* Burnett Decl. (Confidential Exhibit 3). Cargill employs a substantial amount of labor and capital in the United States for the engineering, research, design, and development of Cargill's Regenasure® Glucosamine embodying the claims of the '433 patent. *Id.*

95. Complainant Cargill's production facility in Eddyville, Iowa manufactures Regenasure® Glucosamine that exploits the '433 patent. The Burnett Declaration, Confidential Exhibit 3, sets forth for these facilities the area in square feet dedicated to the manufacture of Regenasure® Glucosamine. Complainant Cargill has also made significant investment in land, building, and equipment used to manufacture the Regenasure® Glucosamine at its production facility in Eddyville, Iowa. These costs are also set forth in the Burnett Declaration, Confidential Exhibit 3.

96. Complainant Cargill currently employs in the United States a number of persons involved in the domestic manufacturing and marketing of Regenasure® Glucosamine that exploits the '433 patent. The Burnett Declaration, Confidential Exhibit 3, sets forth the number of such employees and the total cost of salaries and benefits paid to these employees. Cargill has

also spent substantial time and sums of money in conducting the research and development necessary to develop Regenasure® Glucosamine and bring it to market. *See* Confidential Exhibit 3 (Burnett Decl.).

97. Cargill makes a substantial investment in the exploitation of its '433 patent in the United States. Cargill's advertising expenses for Regenasure® Glucosamine, together with its costs and expenses associated with the sale of Regenasure® Glucosamine, are set forth in the Burnett Declaration at Confidential Exhibit 3. Cargill's total revenues (total sales) in the United States for Regenasure® Glucosamine during 2007 are also contained in Confidential Exhibit 3.

VIII. RELATED LITIGATION

98. Contemporaneously with the filing of this action, Cargill will file a complaint in the United States District Court for the District of New Jersey naming the respondents as defendants in that action.

99. The '433 patent has not been the subject of any other United States court or agency litigation.

IX. GENERAL EXCLUSION ORDER

100. There is a widespread pattern of violation of Section 337, and it is difficult to identify all the sources of infringing non-shellfish glucosamine and products containing same.

101. Several entities in China are known to manufacture non-shellfish glucosamine, which Cargill has identified in this Complaint. Other entities in China are known to have permitted their facilities to be used in the production of non-shellfish glucosamine and to have expressed interest in producing non-shellfish glucosamine. As described in the Gruber Declaration, attached as Confidential Exhibit 9, Bai Jianguo, owner and general manager of NFT, stated that NFT produced 1 to 3 MT of non-shellfish glucosamine at the facilities of Ruili

in Nantong, Jiangsu, China, using Cargill's method for producing Regenasure® Glucosamine, as described in the '433 patent. Cargill's investigators also visited Ruili's facilities. Confidential Exhibit 8 (Investigator Decl.). According to Wang Jian, Ruili's general manager, Ruili sells non-shellfish (corn) glucosamine. Mr. Wang stated that Ruili previously had a cooperative relationship with others to produce this non-shellfish glucosamine and has plans to manufacture the product on its own at a factory that is under construction. *Id.*

102. In addition, ENI refused to disclose the identity of its Chinese manufacturer to Cargill, and despite reasonable efforts, Cargill has thus far been unable otherwise to obtain this information.

103. Upon information and belief, other entities are capable of shifting, at minimum expense, all or a substantial amount of their production of shellfish-derived glucosamine or other nutritional supplement products to non-shellfish glucosamine using the method described in the '433 patent.

104. Business conditions exist in the United States such that foreign manufacturers other than the named respondents may enter the market with infringing non-shellfish glucosamine and products containing same. On information and belief, Cargill is aware that demand in the United States for such products has increased substantially over the last several years and is continuing to increase.

105. There is also available in China and elsewhere an essentially unlimited supply of vegetarian sources, such as fungal biomass, for manufacturing non-shellfish glucosamine. In addition, labor costs are a significant part of the overall cost of production of non-shellfish glucosamine, and labor costs in China are much lower than in the United States. As a result,

there is a significant likelihood that more infringers will enter this market if a general exclusion order is not entered.

106. Entry into the market for non-shellfish glucosamine is relatively easy using the method described in the '433 patent. There are a large number of manufacturers in China who have the capacity to convert existing manufacturing facilities to the manufacture of non-shellfish glucosamine. The cost to do so, particularly for those companies that already have shellfish-derived glucosamine manufacturing capability, is not high. The cost of entry, even with respect to building new facilities, is not high, particularly in light of the large and increasing demand for infringing non-shellfish glucosamine. On information and belief, the startup costs for manufacturing substantial quantities of infringing non-shellfish glucosamine using the method described in the '433 patent is relatively modest.

107. Marketing and distribution networks for non-shellfish glucosamine are available for foreign manufacturers. Many large distributors exist in the United States who can and already do handle shellfish-derived glucosamine and other nutritional supplement products. Distributors that buy from Cargill have regularly been solicited to buy competing, infringing non-shellfish glucosamine from other manufacturers and distributors.

108. In addition, infringing non-shellfish glucosamine, including those of Respondents, are regularly offered for sale and sold via the internet. In addition to Respondents' websites, shellfish glucosamine and other nutritional supplements are offered for sale and sold via the websites of distributors and retailers of all nature of products.

109. Overseas suppliers and potential suppliers are numerous. U.S. demand is robust and increasing. Thus, within a short timeframe, new distribution channels can be established and

operating to import infringing non-shellfish glucosamine into the United States. For the foregoing reasons, a general exclusion order is necessary to protect Cargill's patent rights.

X. RELIEF

110. WHEREFORE, by reason of the foregoing, Complainant Cargill requests that the United States International Trade Commission:

a. Institute an immediate investigation pursuant to Section 337(b)(1) of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337(b)(1), with respect to violations of that section based upon the unlawful importation into the United States, the sale for importation, and/or the sale within the United States after importation of Respondents' non-shellfish derived glucosamine products that infringe U.S. Patent No. 7,049,433;

b. Render a determination that the importation, sale for importation, and/or sale within the United States after importation of infringing non-shellfish glucosamine and products containing same constitutes one or more violations of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337;

c. Issue a general exclusion order pursuant to Section 337(d) of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337(d), permanently excluding from entry into the United States all non-shellfish glucosamine and products containing same that infringe one or more claims of the '433 patent;

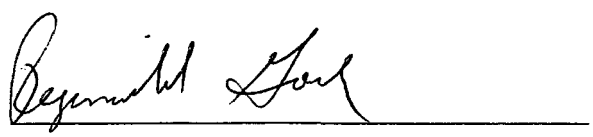
d. In the alternative, issue a limited exclusion order pursuant to Section 337(d) of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337(d), permanently excluding from entry into the United States all non-shellfish derived glucosamine and products containing same sold for importation or imported by or on behalf of each named Respondent and its affiliates that infringe one or more claims of the '433 patent;

e. Issue a cease and desist order, pursuant to Section 337(f) of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337(f), permanently prohibiting each named Respondent and its affiliates having domestic inventories to cease and desist from importing, marketing, demonstrating, sampling, selling, offering for sale (including via the internet or electronic mail), advertising (including via the internet or electronic mail), distributing or soliciting within the United States any non-shellfish glucosamine and products containing same that infringe one or more claims of the '433 patent; and

f. Issue such other and further relief as the Commission deems just and proper based on the facts determined by the investigation and under the authority of the Commission.

Dated: January 27, 2009

Respectfully submitted,



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VERIFICATION OF COMPLAINT

I, Jack Staloch, am Vice President of Cargill Corn Milling North America, Director BioTDC, for Cargill, Incorporated ("Cargill") and am duly authorized to execute this complaint on behalf of Cargill. I have read the complaint and am aware of its contents. To the best of my knowledge, information, and belief, formed after an inquiry reasonable under the circumstances, I hereby certify as follows:

1. The complaint is not being presented for any improper purpose, such as to harass or cause unnecessary delay or needless increase in the cost of the investigation;

2. The claims and other legal contentions in the complaint are warranted by existing law or by a nonfrivolous argument for the extension, modification, or reversal of existing law or the establishment of new law; and

3. The allegations and other factual contentions in the complaint have evidentiary support or, if specifically so identified, are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on January 27, 2009.

Jack Staloch

Jack Staloch
Vice President of Cargill Corn Milling North America
Director BioTDC