

Motif FoodWorks, Inc. v. Impossible Foods Inc.

IPR2023-00206

U.S. Patent No. 9,943,096

Petitioner's Demonstratives

Hearing: April 3, 2024

Grounds

Ground	Claim(s) challenged
1: Brown	1-5, 7-9, 23-24
2A: Giacino + Brown	1-12, 14-17, 20-24
2B: Giacino + Brown + MacLeod	18-19
3A: Giacino + Conrad + Crane	1-2, 4-7, 9-12, 14-15, 20-24
3B: Giacino + Conrad + Crane + Proulx	3, 16
3C: Giacino + Conrad + Crane + Perret	8, 17
3D: Giacino + Conrad + Crane + MacLeod	18-19
4A: Giacino + Proulx + Conrad	1-7, 9-12, 14-16, 20-24
4B: Giacino + Proulx + Conrad + Perret	8, 17
4C: Giacino + Proulx + Conrad + MacLeod	18-19

Presentation Roadmap

❖ '096 Patent and Claims

❖ Ground 2A: Giacino + Brown

- Giacino and Brown Disclose Claim Limitations
- Motivation to Combine and Reasonable Expectation of Success
- Patent Owner's Arguments Fail
 - PO's Three Inherency-Based Arguments Fail
 - Giacino Satisfies Two Volatiles Limitation Even If LegH Changes Aroma
 - Giacino's and Brown's Compositions Are Not "Completely Different"
 - Identical Reaction Chemistry Is Not Required
 - Lipid Oxidation Is Not a Concern
 - Patent Owner Mischaracterizes Dr. McGorrin's Statements

❖ Ground 4A: Giacino + Proulx + Conrad

❖ Dependent Claim 3

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❖ Ground 4A: Giacino + Proulx + Conrad

❖ Dependent Claim 3

'096 Patent Is Directed to Food Flavor Additive Compositions

Provided herein are methods and compositions for modulating the flavor and/or aroma profile of consumable food products, including animal- or non-animal (e.g., plant) based food products, or mixtures of animal- and non-animal-based food products. In some embodiments, the methods and

Ex. 1001, 1:66-2:3

'096 Claim 1

"Sugar Compound"
limitation

"Sulfur Compound"
limitation

"Two Volatile"
limitation

1. A food flavor additive composition comprising:
 - a) an isolated heme-containing protein;
 - b) a compound selected from glucose, ribose, fructose, lactose, xylose, arabinose, glucose-6-phosphate, maltose, maltodextrin, and galactose, and mixtures of two or more thereof; and
 - c) a compound selected from cysteine, cystine, thiamine, methionine, and mixtures of two or more thereof;wherein the flavor additive composition contains no animal products; and
- wherein cooking the food flavor additive composition results in the production of at least two volatile compounds which have a meat-associated aroma.

Presentation Roadmap

❖ '096 Patent and Claims

❖ Ground 2A: Giacino + Brown

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❖ Ground 4A: Giacino + Proulx + Conrad

❖ Dependent Claim 3

Giacino Discloses Meat-Flavored Additive Compositions

United States Patent Office

3,519,437

Patented July 7, 1970

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3,519,437

MEAT FLAVOR COMPOSITIONS

Christopher Giacino, Upper Nyack, N.Y., assignor to International Flavors & Fragrances Inc., New York, N.Y., a corporation of New York
No Drawing. Filed Feb. 6, 1967, Ser. No. 614,036
Int. Cl. A23L 1/22

U.S. Cl. 99-140

14 Claims

ABSTRACT OF THE DISCLOSURE

Flavor compositions are obtained from a reaction product between 2-aminoethane sulfonic acid and thiamine, and optional additional ingredients such as a source of amino acids. Sources of amino acids are illustrated by proteins, hydrolyzed proteins, free amino acids and the like.

This invention relates to novel artificial meaty flavoring compositions and to processes for preparing them. More specifically, it relates to novel compositions having meaty flavor characteristics such as beef, pork and poultry flavor, compositions from which they may be prepared, methods for preparing them and to novel food compositions containing them.

Food products enhanced with meat-like flavors are well-known and have long been used. There is considerable demand for meat-flavored products in which the actual meat such as beef, pork, chicken, turkey, duck and the like is not needed or is actually undesirable. For example, in the preparation of some soups, bouillons, broths and purees, the meat flavor is desired, but it is necessary to cook the food with the desired meat and then to remove the meat by straining or some similar operation to obtain the final product ready for use.

Additionally, where weight space or storage capability are a problem, e.g., when a convenience food is prepared, the presence of the actual meat may be undesirable because it will deteriorate in storage and spoil the food. Moreover, there are occasions when sterilizing or otherwise preserving the natural product is extremely deleterious to the flavor of the natural material and the desired natural flavor is lost. There are additionally those instances where the presence of the natural meat is desirable, but wherein because of cost factors, convenience or the like, consumer acceptance dictates in favor of enhancing the meat flavor already present. Artificial meat flavoring compositions would be eminently suited for this purpose if essentially true flavor reproduction and enhancement could be achieved. Prior attempts at preparing artificial meat flavor compositions have centered, to a large extent, around utilizing a spectrum of spices as in the case of attempting to simulate poultry flavor, or the use of meat extracts, in the case of beef flavor compositions. Such methods have not been entirely satisfactory, in that true flavor is generally not achieved in the case of spice formulations, whereas with extracts, cost and processing disadvantages are encountered.

It has now been discovered that when a pre-mix composition comprising 2-aminoethane sulfonic acid, also known as taurine, and thiamine is heated at an elevated temperature, there results a reaction mixture having a decided, marked meat flavor and which can be employed in a variety of ways. For example it can be used per se in a wide range of food stuffs, either as the dominant flavoring agent or as an aid in improving and enhancing existing flavor. It can serve as the basic flavor composition to which are added a variety of materials either before or after reaction or even re-reacted in the presence of such materials as hereinafter more specifically set forth. This invention contemplates, therefore, the

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novel flavor compositions produced therefrom, the novel composition used to prepare the flavor compositions, and the novel processes for making them. It contemplates also novel food products containing them.

As described above, the invention, in its broad aspect involves heating a mix composition comprising taurine and thiamine at an elevated temperature for a period of time whereby a meaty flavor is developed. It is to be noted that the pre-mix composition per se, possesses no meaty characteristics and hence the invention may be regarded as being in the discovery that taurine has the ability to impart these characteristics when employed as a reactive component.

The pre-mix composition will result in meaty flavor characteristics after heat treatment as long as both taurine and thiamine are present. In general, suitable pre-mix compositions will comprise from 0.025 to 90 weight percent taurine and from 0.025 to 50 weight percent thiamine, based on the total weight of the pre-mix composition. It is generally preferred to use 0.5 to 5 parts of taurine per part of thiamine, although values outside this range may be employed.

In practice, it is usually preferred to incorporate within the pre-mix composition a vehicle which includes materials such as water, edible oils or fats or the like to provide a medium for the reaction, in addition to other flavor adjuncts such as extenders, distribution agents and the like as will be described in more detail hereinafter. For ease of processing it is convenient to supply the vehicle in major amounts such that the pre-mix composition, based on the total weight thereof, comprises from 0.1 to 25, preferably 0.3 to 15 weight percent taurine and 0.1 to 15, preferably 0.3 to 10 weight percent thiamine. Lower or higher concentrations may be selected as desired since the characteristics of the composition may vary depending upon the nature and quantity of the vehicles employed.

Various other materials and ingredients can be incorporated into the compositions to provide a variety of flavor characteristics built upon the basic flavor of the taurine-thiamine reaction product. They can be added at any time, that is, before or after heat treatment, or at any stage in between. If added after the heat treatment they will thus be available for further reaction by the large food processor or the ultimate consumer. The nature and quality of such materials will vary depending on individual preferences. As noted, the basic reaction mixture is a composition which has a marked meat flavor and which can be utilized to develop meat flavors ranging from beef through pork to poultry such as chicken, turkey, duck and the like.

In general, development of a variety of flavors is achieved in separate compositions by providing in the pre-mix, or in the reacted composition, a quantity of a source of one or more amino acids such as one or more free amino acids, proteinaceous materials, such as proteins, polypeptides and the like in which the amino acids are bound, or the partial or complete hydrolyzates or autolysates thereof, or in which the amino acids are partially or completely free. By varying the type and proportion of amino acid bearing materials this variety is conveniently obtained. Generally, suitable results are obtained when the free amino acid, or mixture of free amino acids, or the proteinaceous material, or any combination of these are included preferably in the pre-mix, prior to reaction, but also in the reacted mix, at levels ranging up to about 50% by weight based on the total weight of the composition. In a preferred embodiment, wherein a vehicle or carrier is employed to aid in carrying out the reaction, the range is conveniently from 0.5 to about 35 percent by weight of the total composition. The actual amounts em-

3,519,437

Patented July 7, 1970

This invention relates to novel artificial meaty flavoring compositions and to processes for preparing them. More specifically, it relates to novel compositions having meaty flavor characteristics such as beef, pork and poultry flavor, compositions from which they may be prepared, methods for preparing them and to novel food compositions containing them.

Giacino, 1:19-25

Petition, 28; Ex. 1003, ¶171-72

Brown Is Impossible's Own Prior Art Publication

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(54) Title: METHODS AND COMPOSITIONS FOR CONSUMABLES

(57) Abstract: Provided herein are methods and compositions related to plant based meat substitutes which have properties similar to meat.

WO 2013/010042 A1

[00364] Evidence that the presence of leghemoglobin contributes favorably to aroma of meat replicas: A muscle replica comprising pea flour, sunflower oil, and glucose was heated for 10 minutes at 140C in the presence of either reduced leghemoglobin (LHb) or a mixture of iron (Fe3+), sodium and EDTA (EFS) in sealed containers carrying solid phase microextraction (SPME) fibers. These fibers contain polydimethylsiloxane (PDMS) which adsorbs volatile compounds for analysis by GC-MS. Analysis of GC-MS data from multiple replicas reveal consistent differences between the LHb and EFS samples. Non-limiting examples of compounds found exclusively or more abundantly in the LHb samples are: 2-octanone, 2-methyl furan, which are often associated with the aroma of cooked meat, and many other unidentified compounds. For example, Figure 1 shows a comparison of aligned GCMS profiles (in

Brown, [0364]

Impossible Alleged That Brown Provided §112 Support For Claims

For the '096 patent, Impossible will seek authorization with the Board to file a motion asking the Board to cede its jurisdiction so that Impossible can seek a certificate of correction from the Director. 37 C.F.R. § 1.323. When granted, Brown would fail to qualify as prior art under pre-AIA provisions, and thus

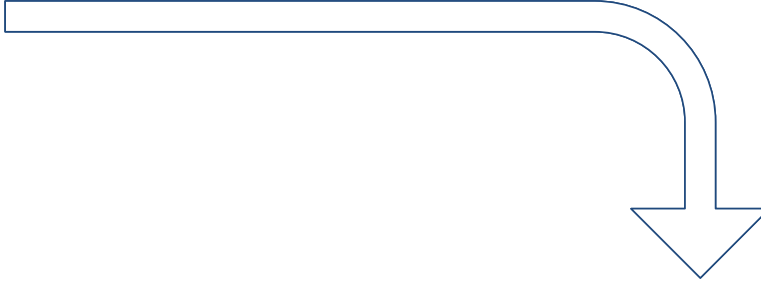
Paper 8 (POPR), 10 (Mar. 20, 2023)

1C in combination with Giacino, Ronai, and Rolan). Granting of a petition and request for a certificate of correction would disqualify Brown as prior art and thus provide a basis for rejecting these grounds, in addition to the merit-based arguments already outlined by Impossible in its preliminary responses. *See, e.g.,*

Paper 9 (PO's Motion for Leave), 9 (April 13, 2023)

Giacino Discloses a Food Flavor Additive Composition

1. A food flavor additive composition comprising:
a) an isolated heme-containing protein;
b) a compound selected from glucose, ribose, fructose, lactose, xylose, arabinose, glucose-6-phosphate, maltose, maltodextrin, and galactose, and mixtures of two or more thereof; and
c) a compound selected from cysteine, cystine, thiamine, methionine, and mixtures of two or more thereof;
wherein the flavor additive composition contains no animal products; and
wherein cooking the food flavor additive composition results in the production of at least two volatile compounds which have a meat-associated aroma.



This invention relates to novel artificial meaty flavoring compositions and to processes for preparing them. More specifically, it relates to novel compositions having meaty flavor characteristics such as beef, pork and poultry flavor, compositions from which they may be prepared, methods for preparing them and to novel food compositions containing them.

The flavor compositions of this invention can be used to flavor various foods, liquid or dry. They are con-

Giacino, 1:19-25, 7:15-16

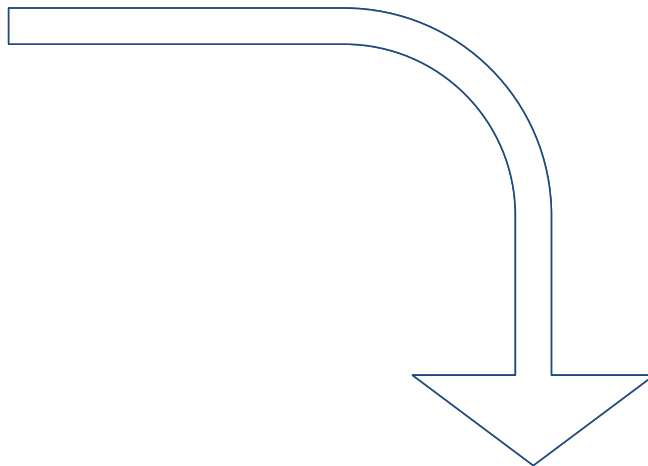
Brown Discloses an Isolated Heme Protein

1. A food flavor additive composition comprising:

a) an isolated heme-containing protein;

b) a compound selected from glucose, ribose, fructose, lactose, xylose, arabinose, glucose-6-phosphate, maltose, maltodextrin, and galactose, and mixtures of two or more thereof; and

c) a compound selected from cysteine, cystine, thiamine, methionine, and mixtures of two or more thereof; wherein the flavor additive composition contains no animal products; and wherein cooking the food flavor additive composition results in the production of at least two volatile compounds which have a meat-associated aroma.

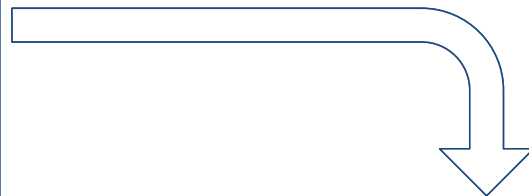


(for example root nodules from a pea plant, Figure 2). Figure 3 shows 100 mls of leghemoglobin solution isolated from 30 grams of pea root nodules. Leghemoglobins from different species are

Brown, [0376]

Giacino Discloses Claimed Sugar Compounds

1. A food flavor additive composition comprising:
 - a) an isolated heme-containing protein;
 - b) a compound selected from glucose, ribose, fructose, lactose, xylose, arabinose, glucose-6-phosphate, maltose, maltodextrin, and galactose, and mixtures of two or more thereof; and
 - c) a compound selected from cysteine, cystine, thiamine, methionine, and mixtures of two or more thereof;wherein the flavor additive composition contains no animal products; and wherein cooking the food flavor additive composition results in the production of at least two volatile compounds which have a meat-associated aroma.



tion, there may be added to the pre-mix a quantity of a saccharide material such as a mono saccharide or a polysaccharide exemplified by di- and trisaccharides. Ri-bose, surcrose, dextrose and xylose are illustrative of those which may be employed. The presence of the saccharides results in a reacted composition having somewhat more intense flavor characteristics. Care should

Giacino, 6:1-7

Giacino Discloses Claimed Sulfur Compounds

1. A food flavor additive composition comprising:
a) an isolated heme-containing protein;
b) a compound selected from glucose, ribose, fructose, lactose, xylose, arabinose, glucose-6-phosphate, maltose, maltodextrin, and galactose, and mixtures of two or more thereof; and
c) a compound selected from cysteine, cystine, thiamine, methionine, and mixtures of two or more thereof;
wherein the flavor additive composition contains no animal products; and
wherein cooking the food flavor additive composition results in the production of at least two volatile compounds which have a meat-associated aroma.



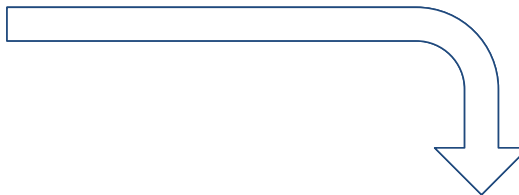
Particularly suitable are mixtures comprising:

0.1 to 15 and preferably 0.5 to 10 weight percent thiamine,
0.1 to 25 and preferably 0.5 to 25 weight percent taurine,
0 to 40 and preferably 0.5 to 35 weight percent hydrolysed protein,
0 to 5 and preferably 0 to 2.5 weight percent cysteine,
0 to 5 and preferably 0.1 to 2.5 weight percent glycine,
0 to 5 and preferably 0.1 to 2.5 weight percent glutamic acid,

Giacino, 5:1-10

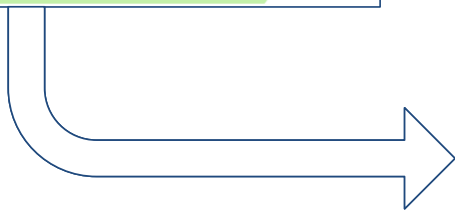
Giacino and Brown Satisfy the “No Animal Products” Limitation

1. A food flavor additive composition comprising:
- a) an isolated heme-containing protein;
 - b) a compound selected from glucose, ribose, fructose, lactose, xylose, arabinose, glucose-6-phosphate, maltose, maltodextrin, and galactose, and mixtures of two or more thereof; and
 - c) a compound selected from cysteine, cystine, thiamine, methionine, and mixtures of two or more thereof;
- wherein the flavor additive composition contains no animal products; and
- wherein cooking the food flavor additive composition results in the production of at least two volatile compounds which have a meat-associated aroma.



Giacino's Modified Comp.	Source
Thiamine	Yeast
Taurine	Synthetic
Vegetable Protein Hydrolysate	Plant
Cysteine	Synthetic
Ribose	Synthetic
Leghemoglobin	Plant

Giacino and Brown Satisfy the Two Volatiles Limitation

1. A food flavor additive composition comprising:
 - a) an isolated heme-containing protein;
 - b) a compound selected from glucose, ribose, fructose, lactose, xylose, arabinose, glucose-6-phosphate, maltose, maltodextrin, and galactose, and mixtures of two or more thereof; and
 - c) a compound selected from cysteine, cystine, thiamine, methionine, and mixtures of two or more thereof;wherein the flavor additive composition contains no animal products; and
wherein cooking the food flavor additive composition results in the production of at least two volatile compounds which have a meat-associated aroma.
- 

As described above, the invention, in its broad aspect involves heating a mix composition comprising taurine and thiamine at an elevated temperature for a period of time whereby a meaty flavor is developed. It is to be

The meat flavor of the compositions of the present invention is developed by heating the pre-mix compositions at an elevated temperature for a period of time. The time and temperature are interrelated, longer times being required at low temperatures for best flavor development and shorter times for higher temperatures. It is preferable to utilize temperatures of at least 200° F. in order to accomplish the reaction in a reasonable length of time. Generally, temperatures much above 420°

Both Parties Agree That Meaty “Flavor” Means Meaty “Aroma”



Dr. McGorrin:

passages.) Because aroma volatiles are predominant contributors to the flavor of food, flavor and aroma are highly linked. In flavor chemistry research, the terms “aroma” and “flavor” are often used interchangeably in recognition of the dominant contribution of aroma to total flavor.

Ex. 1005 (McGorrin), ¶127

Question: “... you agree with Dr. McGorrin’s statements here in [] paragraph [27]. Is that fair to say?”

Dr. Qian: “Yes, I agree.”

Ex. 1182, 41:11-22

Reply, 5

PO's Expert Admits That Giacino Satisfies Two Volatiles Limitation

PO's Expert:

Q. Is there anything about Giacino's teaching here that, when it says "a meaty flavor is developed," that leads you to believe that less than ten volatiles are being generated?

A. I do not believe so.

Q. You do not believe so?

A. I believe it will be more compounds generated.

Q. Than ten?

A. Right.

Ex. 1182, 49:5-14

Not Surprising That Giacino Produces Scores of Meaty Volatiles

Table 15 SOME VOLATILE REACTION PRODUCTS OF CYSTEINE/CYSTINE-RIBOSE ²⁰⁰	
Carbon disulfide	2,6-Diethyl-3-methylpyrazine
Hydrogen sulfide	2-Acetylpyrazine
Methanethiol	2-Acetyl-3-methylpyrazine
Ethanethiol	6,7-Dihydro-5H-cyclopentapyrazine
Propan-1-thiol	2-Methyl-6,7-dihydro-5H-cyclopentapyrazine
Acetaldehyde	2-Formylthiophen
Methylamine	3-Acetylthiophen
Propylamine	2-Formyl-5-methylthiophen
Pentylamine/ isopentylamine	2-Formyl-3-methylthiophen
Furfural	3-Acetyl-2-methylthiophen
Furfuryl alcohol	2-Acetyl-5-methylthiophen
2-Acetylfuran	5-Acetyl-2-methylthiophen
1 (2-Furyl)-2-propanone	Thieno[3,2- <i>b</i>] thiophen
<i>trans</i> -1,2-(2,2'-Difuryl)ethene	Thieno[3,4- <i>b</i>]thiophen
Pyrrole	3-Methyl-1,2,4-trithiane
2-Formyl-1-methylpyrrole	2-Methylthiazole
2-Acetylpyrrole	5-Ethylthiazole
1-Furfurylpyrrole	5-Ethyl-2-methylthiazole
2-Methylpyridine	2,4,5-Trimethylthiazole
5-Ethyl-2-methylpyridine	2,4-Dimethyl-5-ethylthiazole
Methylpyrazine	2-Acetylthiazole
Propylpyrazine	2-Propionylthiazole
Alkylpyrazine	2-Butyrylthiazole
2,5-Dimethylpyrazine	2-(2-Furyl)thiazole
2-Ethyl-6-methylpyrazine	

Ex. 1024 (MacLeod), 385

Petition, 34; Ex. 1003, ¶ 210-11

Brown's Leghemoglobin Contributes to Meaty Aroma/Volatiles

[00364] Evidence that the presence of leghemoglobin contributes favorably to aroma of meat replicas: A muscle replica comprising pea flour, sunflower oil, and glucose was heated for 10 minutes at 140C in the presence of either reduced leghemoglobin (LHb) or a mixture of iron (Fe³⁺), sodium and EDTA (EFS) in sealed containers carrying solid phase microextraction (SPME) fibers. These fibers contain polydimethylsiloxane (PDMS) which adsorbs volatile compounds for analysis by GC-MS. Analysis of GC-MS data from multiple replicas reveal consistent differences between the LHb and EFS samples. Non-limiting examples of compounds found exclusively or more abundantly in the LHb samples are: 2-octanone, 2-methyl furan, which are often associated with the aroma of cooked meat, and many other unidentified compounds. For example, Figure 1 shows a comparison of aligned GCMS profiles (in

Brown, [0364]

Presentation Roadmap

❖ '096 Patent and Claims

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❖ Ground 4A: Giacino + Proulx + Conrad

❖ Dependent Claim 3

Motivation to Combine Giacino and Brown

positions. Such methods have not been entirely satisfactory, in that true flavor is generally not achieved in the case of spice formulations, whereas with extracts, cost and processing disadvantages are encountered.

Giacino, 1:56-59

Various other materials and ingredients can be incorporated into the compositions to provide a variety of flavor characteristics built upon the basic flavor of the taurine-thiamine reaction product. They can be added at

Giacino, 2:38-41

Petition, 28; Ex. 1003, ¶171-72

Motivation to Combine Giacino and Brown

[00363] Some reactions that generate odorants released during cooking of meat can be catalyzed by iron, in particular the heme iron of myoglobin. Thus in some embodiments, some of the characteristic flavor and fragrance components are produced during the cooking process by chemical reactions catalyzed by iron. In some embodiments, some of the characteristic flavor and fragrance components are produced during the cooking process by chemical reactions catalyzed by heme. . In some embodiments, some of the characteristic flavor and fragrance components are produced during the cooking process by chemical reactions catalyzed by the heme iron in leghemoglobin. In some embodiments, some of the characteristic

Brown, [0363]

Motivation to Combine Giacino and Brown

[00364] Evidence that the presence of leghemoglobin contributes favorably to aroma of meat replicas: A muscle replica comprising pea flour, sunflower oil, and glucose was heated for 10 minutes at 140C in the presence of either reduced leghemoglobin (LHb) or a mixture of iron (Fe³⁺), sodium and EDTA (EFS) in sealed containers carrying solid phase microextraction (SPME) fibers. These fibers contain polydimethylsiloxane (PDMS) which adsorbs volatile compounds for analysis by GC-MS. Analysis of GC-MS data from multiple replicas reveal consistent differences between the LHb and EFS samples. Non-limiting examples of compounds found exclusively or more abundantly in the LHb samples are: 2-octanone, 2-methyl furan, which are often associated with the aroma of cooked meat, and many other unidentified compounds. For example, Figure 1 shows a comparison of aligned GCMS profiles (in

Brown, [0364]

Motivation to Combine Giacino and Brown



Dr. Tarté:

flavor. This would have motivated a POSITA to add leghemoglobin to Giacino's flavoring compositions to enhance those compositions' meaty flavor and aroma and achieve the enhanced volatile profile touted by Brown. This would also further Giacino's goal of providing the "true flavor" of meat. As I mention above, Giacino

Ex. 1003 (Tarté), ¶195

Reasonable Expectation of Success: Only Ordinary Skill Needed



Dr. Tarté:

compositions to produce volatiles associated with cooked meat. Moreover, nothing more than ordinary skill would have been required to obtain the soy leghemoglobin (which Brown describes in detail, *e.g.*, *see supra* Section XI.A.2), and mix it into Giacino's composition prior to heating.

Ex. 1003 (Tarté), ¶184

Petition, 30-31

Presentation Roadmap

❖ '096 Patent and Claims

❖ Ground 2A: Giacino + Brown

- Giacino and Brown Disclose Claim Limitations
- Motivation to Combine and Reasonable Expectation of Success
- Patent Owner's Arguments Fail
 - **PO's Three Inherency-Based Arguments Fail**
 - Giacino Satisfies Two Volatiles Limitation Even If LegH Changes Aroma
 - Giacino's and Brown's Compositions Are Not "Completely Different"
 - Identical Reaction Chemistry Is Not Required
 - Lipid Oxidation Is Not a Concern
 - Patent Owner Mischaracterizes Dr. McGorrin's Statements

❖ Ground 4A: Giacino + Proulx + Conrad

❖ Dependent Claim 3

Patent Owner Improperly Raises Petitioner's Burden to Inherency

establish obviousness. Petitioner's ground essentially rests on an inherent obviousness theory—that is, by including cysteine, thiamine, and ribose in a composition, it would necessarily result in the production of at least two volatile compounds associated with a meaty aroma upon heating. *See* Pet., 33-34.

POR, 25

achieving meaty flavor). However, given Petitioner's theory of its case—that including cysteine and ribose in Giacino's composition and further adding leghemoglobin from Brown will result in a meaty aroma—and given that Petitioner

POR, 27-28

PO's Failed Inherency Argument #1: Environmental Conditions

PO's Expert:

present in Giacino's composition. *See* ¶65. In addition, Petitioner's combination is further premised on adding leghemoglobin to Giacino's compositions. *See* Pet., 27. However, as I explained above, consistent with the Petition materials, for compositions having Maillard reaction precursors, the inclusion of additional ingredients can affect whether or not certain aroma compounds will be produced. *See* ¶¶35-40. For example, the additional ingredients may react with the amino

Ex. 2030, ¶70

PO's Failed Inherency Argument #1: Environmental Conditions

PO's Expert:

71. Given the above, it is my opinion that the Petition materials have not provided sufficient evidence to show that the Giacino composition (whatever that may be) when cooked necessarily “result[s] in the production of at least two volatile compounds which have a meat-associated aroma,” nor that such necessarily produced volatile compounds would still be present after the addition of the leghemoglobin of Brown.

Ex. 2030, ¶71

PO's Alleged Uncertainty Based on Environmental Conditions Legally Fails



“[C]ase law is clear that **obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success....** [A] rule of law equating unpredictability to patentability... would mean that any new [heme-containing composition]... would be separately patentable, simply because the formation and properties of each [composition] must be verified through testing. This cannot be the proper standard since the **expectation of success need only be reasonable, not absolute.**”

Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1364 (Fed. Cir. 2007)

Giacino Accounts for Environmental Conditions



Dr. McGorrin:

cooking times for its compositions. *See id.*, 6:15-23. Because Giacino teaches that its compositions produce a meaty aroma after undergoing a reaction when heated, a POSITA would understand that the reaction conditions taught in Giacino—*e.g.*, cooking temperature, cooking time, and matrix—permit the chemical reactions that produce volatiles which have a meat-associated aroma, including the Maillard reaction.

Ex. 1181, ¶22

POSITA Would Make Adjustments to Environmental Conditions



Dr. McGorrin:

44. *First*, a POSITA for the '096 patent would have certain relevant skill and training, as well as access to the knowledge of flavor chemists, all of which would inform any adjustments to the preparation of Giacino compositions modified to contain Brown's leghemoglobin, to the extent necessary to do so. I describe a POSITA's understanding in greater detail above.

Ex. 1181, ¶44

PO's Failed Inherency Argument #2: Testing/Particularity

Petitioner's indecisiveness and refusal to identify any specific composition makes the petition's conclusions speculative at best and prevents any meaningful opportunity of response to test those conclusions. As such, the petition's lack of

POR, 28

Claims Do Not Have the Level of Particularity PO Demands

1. A food flavor additive composition comprising:
 - a) an isolated heme-containing protein;
 - b) a compound selected from glucose, ribose, fructose, lactose, xylose, arabinose, glucose-6-phosphate, maltose, maltodextrin, and galactose, and mixtures of two or more thereof; and
 - c) a compound selected from cysteine, cystine, thiamine, methionine, and mixtures of two or more thereof;wherein the flavor additive composition contains no animal products; and
wherein cooking the food flavor additive composition results in the production of at least two volatile compounds which have a meat-associated aroma.

Petitioner Cites Giacino's Ingredients, Concentrations, Cooking Info

Particularly suitable are mixtures comprising:

0.1 to 15 and preferably 0.5 to 10 weight percent thiamine,
0.1 to 25 and preferably 0.5 to 25 weight percent taurine,
0 to 40 and preferably 0.5 to 35 weight percent hydrolysed
protein,
0 to 5 and preferably 0 to 2.5 weight percent cysteine,
0 to 5 and preferably 0.1 to 2.5 weight percent glycine,
0 to 5 and preferably 0.1 to 2.5 weight percent glutamic
acid,

Giacino, 5:1-10

In general, development of a variety of flavors is achieved in separate compositions by providing in the pre-mix, or in the reacted composition, a quantity of a source of one or more amino acids such as one or more free amino acids, proteinaceous materials, such as proteins, polypeptides and the like in which the amino acids are bound, or the partial or complete hydrolysates or autolysates thereof, or in which the amino acids are partially or completely free. By varying the type and proportion

Giacino, 2:53-60

reaction times. Accordingly, it is preferred to carry out the reaction at temperatures of from about 200° F. to about 420° F., until the desired flavor development is achieved. The heating periods may range from about one-quarter minute to about 6 hours depending upon the heating method used.

Giacino, 6:26-31

Petitioner Identifies Specific Compositions in Giacino

Giacino teaches, as one example, a meaty flavoring composition that includes thiamine, taurine, vegetable protein hydrolysate, cysteine, and a monosaccharide, such as ribose. *See* EX1015(Giacino), 2:5-8, 2:53-60, 3:23-25, 3:43-46, 5:1-10, 6:1-

Petition, 32

Giacino teaches that its flavoring compositions include albumins and globulins. EX1015(Giacino), 3:3-10 (“Among the proteins which may be used are

Petition, 37

Giacino Also Provides Specific Formulations

EXAMPLE I

The following ingredients are selected:

Ingredients:	Parts by weight
Fat (vegetable shortening) -----	622.67
Salt -----	321.65
Glutamic acid -----	5.14
L-cysteine hydrochloride -----	10.28
Glycine -----	5.14
Beta-alanine -----	1.28
Thiamine hydrochloride -----	10.28
Taurine -----	20.00
Mixture of disodium inosinate and disodium guanylate -----	3.34

Giacino, 7:40-54

EXAMPLE VI

Ingredient:	Parts by weight
L-cysteine hydrochloride -----	3.52
Hydrolyzed vegetable protein -----	154.70
Thiamine hydrochloride -----	3.52
Water -----	336.50
Taurine -----	10.00

Giacino, 9:70-10:8

PO's Failed Inherency Arg. #3: Dr. Tarté Is Not Unqualified

Q Right. And in Paragraph 212, you state that adding leghemoglobin would only further the flavor, correct?

A Yes.

Q And is that the only possible outcome of positive contribution to the meaty aroma?

A I don't know. I would defer to Dr. McGorrin on that. I would not have a good answer to that.

Q Okay. So you would defer to Dr. McGorrin as to whether it's possible that adding leghemoglobin would negatively impact the meaty aroma?

MR. MESSERIAN: Objection. Form.

THE WITNESS: Either negatively or in any other way. It's outside my area of expertise.

Brown Itself Supports Motivation to Combine Giacino and Brown



Board:

Petitioner's reason for modifying Giacino's artificial meaty flavoring composition with Brown's leghemoglobin is sufficient for purposes of institution because the benefits of including leghemoglobin in a meat flavoring composition are supported by Brown itself. Ex. 1012 (Brown) ¶ 364 (identifying leghemoglobin as a factor in producing volatile compounds associated with cooked meat). Moreover, the Petition proposes

Institution Dec., 28

Dr. McGorrin's Reply Declaration Does Not "Gap-fill"

Throughout his new declaration, Dr. McGorrin improperly presents Dr. Tarté's conclusory declaration testimony as a springboard to "gap-fill," for the first time, critical content missing from the petition materials—*e.g.*, how or why a POSA would have combined Giacino and Brown. *See, e.g.*, EX1181, ¶¶12, 14, 16-19, 29, 37-41, 43-45, 50, 52, 84, 92. Petitioner's reply and Dr. McGorrin's second

Sur-reply, 6

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❖ Ground 4A: Giacino + Proulx + Conrad

❖ Dependent Claim 3

PO's Expert Argues Aroma May Shift from "Desirable to Undesirable"

PO's Expert:

Therefore, when the composition of the matrix changes, the identity of the aroma compounds produced changes, and the aroma could shift from desirable to undesirable. *Id.* Additional factors that can affect aroma compound production and identity include temperature, time, water, pH, salt, and lipids. See ¶¶35-40.

Ex. 2030, ¶70

Reply, 21-22

But Claims 1-9 and 24 Do Not Require Any Type of Aroma

1. A food flavor additive composition comprising:

- a) an isolated heme-containing protein;
- b) a compound selected from glucose, ribose, fructose, lactose, xylose, arabinose, glucose-6-phosphate, maltose, maltodextrin, and galactose, and mixtures of two or more thereof; and
- c) a compound selected from cysteine, cystine, thiamine, methionine, and mixtures of two or more thereof;

wherein the flavor additive composition contains no animal products; and

wherein cooking the food flavor additive composition results in the production of at least two volatile compounds which have a meat-associated aroma.

10. A food flavor additive composition prepared by a process of:

- a) combining an isolated heme-containing protein; a compound selected from glucose, fructose, lactose, xylose, arabinose, glucose-6-phosphate, maltose and galactose, and mixtures of two or more thereof and a compound selected from cysteine, cystine, thiamine, methionine, and mixtures of two or more thereof, to form a heme flavor reaction mixture, and

- b) heating the heme flavor reaction mixture to at least 150° C. for at least 1 minute to result in a food flavor additive composition;

wherein the food flavoring additive composition contains no animal products; and

wherein the heme flavor reaction mixture has a meaty flavor and/or meaty aroma during the heating of step b) and the food flavoring additive composition has a meaty flavor and/or meaty aroma after the heating of step b).

Giacino Produces Meaty Volatiles Even If Leghemoglobin Changes Aroma



Dr. McGorin:

48. I disagree with Dr. Qian because a POSITA would recognize that Giacino teaches the production of volatiles which have a meat-associated aroma by heat-reacting Maillard precursors, as explained above. This would be obvious to a POSITA even if other ingredients in the composition, including leghemoglobin, reacted to produce additional volatile compounds or changed the overall aroma of the composition.

Ex. 1181, ¶48

Reply, 22

PO's Expert Also Expects Overlapping Volatiles Even If Aroma Changes

Q. Is it your understanding that no matter the end aroma, there are some volatile compounds that will be produced under both conditions that are going to be the same regardless?

* * *

A. Chemically, that's possible.

They could have many compounds in common.

* * *

leave it more generic and say, would you expect at least some compounds to be the same, even if the concentrations are different and the end aroma is different?

A. Yes.

Ex. 1182, 56:22-58:5

Reply, 22; Ex. 1181, ¶49.

Presentation Roadmap

❖ '096 Patent and Claims

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❖ Ground 4A: Giacino + Proulx + Conrad

❖ Dependent Claim 3

Giacino's and Brown's Compositions Are Not "Completely Different"

PO's Expert:

74. Second, the compositions of Brown and Giacino are completely different and Petitioner has failed to establish that a POSA would have expected that leghemoglobin would provide the same effect in the composition of Giacino.

Ex. 2030 (Qian), ¶74

Sur-reply:

Giacino and Brown do not share a single common ingredient.

Sur-reply, 13

Reply, 18-21; Ex. 1181, ¶¶40-41, 81-99

While Not Identical, Brown's and Giacino's Compositions Are Similar

Brown

Glucose
Sunflower Oil
Pea flour (i.e., plant proteins)

Giacino

Thiamine/taurine
Monosaccharide/ribose
Oil (optional)
"Proteinaceous Material"
(e.g., plant albumin/globulin,
vegetable protein hydrolysate,
cysteine)

Petition, 28-34 (citing Brown, [0364]; Giacino, 2:53-60, 3:23-25, 5:1-10, 6:1-7), 36-38 (citing Giacino, 2:23-26, 3:3-10); Reply, 18-21

PO's Contention That Giacino's Compositions Are "Concentrated" Fails

PO's Expert:

The compositions of Giacino are food flavor compositions having a *concentrated* amount of taurine, thiamine, and potentially other ingredients, that are diluted about 6 to 2,000 fold to flavor various foods. *See* EX1015(Giacino), 7:15-28

Ex. 2030, ¶74

Giacino Reacts Compositions in Unconcentrated Synthetic Meat

transfer-rate heat exchangers. Where the flavor composition of this invention is added to a food which is to be subsequently heated or cooked, the reaction time can be reduced, and in some of these cases, heating the pre-mix independently of the food can even be eliminated. That is the processor or the ultimate consumer in effect conducts the reaction.

Giacino, 6:71-7:2

cent. On the other hand, they can be admixed with carrier materials or with other flavoring ingredients or foodstuffs for incorporation into finished products, illustrative of which are the dry foods such as snacks, chips, synthetic meat fibres and the like. The compositions are conveniently

Giacino, 7:22-26

Leghemoglobin Is a Flavoring Agent, Not a Structural Component



Board:

compounds associated with cooked meat). Moreover, the Petition proposes to modify Giacino with the addition of Brown's leghemoglobin as a flavoring agent, not as a structural component of Brown's meat replica. Pet. 30 ("Based on Brown's teachings, a POSITA would have been motivated to add leghemoglobin to a flavoring composition, such as Giacino[] . . . to provide a cooked meat aroma and flavor.").

Institution Decision, 28

Presentation Roadmap

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❖ Ground 4A: Giacino + Proulx + Conrad

❖ Dependent Claim 3

Identical Reaction Chemistry Is Not Required

PO's Expert:

reactions that may produce meaty aromas). As I discussed above, Giacino instead teaches that its meaty flavor is based on taurine and thiamine. *See* ¶69. On the other hand, Brown discusses that its meaty aroma is based on the contribution of leghemoglobin. *See* EX1012(Brown), [00364]. Petitioner does not explain why a POSA would be motivated to combine Giacino, which relies on one type of reaction, with the leghemoglobin-based contribution of Brown.

Ex. 2030, ¶73

Claims Do Not Require Any Particular Reaction Chemistry

1. A food flavor additive composition comprising:
 - a) an isolated heme-containing protein;
 - b) a compound selected from glucose, ribose, fructose, lactose, xylose, arabinose, glucose-6-phosphate, maltose, maltodextrin, and galactose, and mixtures of two or more thereof; and
 - c) a compound selected from cysteine, cystine, thiamine, methionine, and mixtures of two or more thereof;wherein the flavor additive composition contains no animal products; and
wherein cooking the food flavor additive composition results in the production of at least two volatile compounds which have a meat-associated aroma.

Both Giacino and Brown Are Compatible With Maillard Chemistry



Dr. McGorrin:

1184 (Kato). Thus, contrary to Dr. Qian's apparent position that reaction chemistry would discourage a POSITA from combining Brown and Giacino, a POSITA would be aware from the explicit teachings of Brown itself that heme iron from leghemoglobin could catalyze Giacino's Maillard reaction-driven production of certain desirable volatiles.

Ex. 1181, ¶95

Different Reactions (Maillard, Strecker, etc.) Can Occur Simultaneously



Dr. McGorrin:

98. Giacino does not exclude the possibility that other chemical reactions will proceed when its compositions are heated, however. Indeed, consistent with Dr. Qian's testimony, a POSITA would understand that different reactions producing meaty aromas, such as Strecker and Maillard, can occur at the same time in the same composition when heated. Ex. 1182 (Qian Tr.), 49:8-51:23; 54:22-55:5 ([Q.] "And while these two reactions are taking place while you are heating a meat-flavored composition, could they both be contributing to meaty aroma?" [A:] "Both reaction, they could contribute to a meaty flavor if the condition is correct.").

Ex. 1181, ¶98

Presentation Roadmap

❖ '096 Patent and Claims

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❖ Ground 4A: Giacino + Proulx + Conrad

❖ Dependent Claim 3

Patent Owner's Lipid Oxidation Arguments Are Meritless

[00364] Evidence that the presence of leghemoglobin contributes favorably to aroma of meat replicas: A muscle replica comprising pea flour, sunflower oil, and glucose was heated for 10 minutes at 140C in the presence of either reduced leghemoglobin (LHb) or a mixture of iron (Fe³⁺), sodium and EDTA (EFS) in

Brown, [0364]

[00412] In a further test, the effect of cooking the ground beef replica patties was evaluated by grilling on a 350°F pan. A ground beef patty analog was made by combining 62% (wt/wt) muscle tissue analog (62% (wt/wt) “dark muscle analog” and 38% (wt/wt) “muscle analog”), 29% (wt/wt) fat tissue analog (from pea globulin and canola oil), 5% (wt/wt) connective tissue analog (Figure 17). The panel on the left shows the patty before cooking and the panel on the right shows the same patty after cooking for about 2 minutes. Observers described the aroma of the cooking ground beef replica as distinctly “beefy”.

Brown, [0412]

Claims Do Not Require Long Term Storage

1. A food flavor additive composition comprising:
 - a) an isolated heme-containing protein;
 - b) a compound selected from glucose, ribose, fructose, lactose, xylose, arabinose, glucose-6-phosphate, maltose, maltodextrin, and galactose, and mixtures of two or more thereof; and
 - c) a compound selected from cysteine, cystine, thiamine, methionine, and mixtures of two or more thereof;wherein the flavor additive composition contains no animal products; and
wherein cooking the food flavor additive composition results in the production of at least two volatile compounds which have a meat-associated aroma.

Antioxidants/Preservatives Would Reduce Risk of Lipid Oxidation



Dr. McGorin:

free and thus not be subject to lipid oxidation. Dr. Qian also fails to account for the availability of familiar preservatives that can prolong shelf life. Ex. 1005, ¶138.

Ex. 1181 (McGorin), ¶ 76

138. It is feasible to slow down lipid oxidation. For example, Maillard reaction products—contributed by heat-reacting the claimed sugars and sulfur compounds—can slow down lipid oxidation due to their antioxidant properties when cooked at high heat.

Ex. 1005 (McGorin), ¶ 138

Giacino's Compositions Do Not Require Lipids

It has been found, in preparing the reaction products of this invention, that the ingredients are desirably heated in a vehicle such as water, a triglyceride fat, natural fat, vegetable fat or the like. A triglyceride fat is preferred in the case of pork or poultry flavor compositions whereas water is preferred for beef formulations. The vehicle

Giacino, 5:22-27

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❖ Ground 4A: Giacino + Proulx + Conrad

❖ Dependent Claim 3

Patent Owner Mischaracterizes Dr. McGorrin's Prior Testimony

69. In contrast, the patents do not teach that plant proteins are Maillard reaction precursors. In fact, the patents teach that plant proteins can contribute to undesirable flavors and aromas. Specifically, the patents teach that plant proteins are associated with “planty” aromas and “off-flavors.” Ex. M9, '306 patent 13:52-56; 87:19-46; 87:63-88:9, Examples 16, 34. The patents

Ex. 2020, ¶69

Dr. McGorrin Was Referring to Disclosures in '306 Patent

In addition, as described herein, off-flavors or aromas (e.g., undesirable flavors or aromas) in isolated and/or purified components can be minimized by deodorizing with activated charcoal or by removing enzymes such as lipoxygenases (LOX), which can be present in trace amounts and which can convert unsaturated triacylglycerides (such as linoleic acid or linolenic acid) into smaller and more volatile molecules. LOX are naturally present in legumes such as peas, soybeans, and peanuts, as well as rice, potatoes, and olives. When legume flours are fractionated into separate protein fractions, LOX can act as undesirable “time-bombs” that can cause undesirable flavors or aromas on aging or storage. As shown in Example 34, compositions containing plant proteins (e.g., from ground plant seeds) can be subjected to purification to remove LOX using, for example, an affinity resin that binds to LOX and removes it from the protein sample. The affinity resin can be linoleic acid, linolenic acid,

Ex. 1157, 13:45-61

Patent Owner Mischaracterizes Dr. McGorrin's Prior Testimony

164. In fact, the combination of Maillard reactants and heme-containing protein with plant proteins and other components of a meat replica (e.g., lipids) could potentially lead to a non-“beef-like” volatile profile. As the '306 patent recognizes:

Mixed meat tissue replicas can increase the sense of flavors ... including ... multiple aromatic compounds associated with fruity/grean[sic] bean/metallic, nutty/green, peanut butter/musty, raw potato/roasted/earthy, vinegary, spicy/caramel/almond, creamy, sweet, fruity/stale beer, musty/nutty/coumarin/licorice/walnut/bread, coconut/woody/sweet, penetrating/sickening, minty, or toasty caramel aromas.

'306 patent, 49:12-19 (EX1157).

Ex. 1005, ¶164

Dr. McGorrin Was Referring to PO's Failure to Show Unexpected Results

162. Patent Owner did not test the effect of including heme-containing proteins in the more complicated milieu of the claimed “meat replica matrix.” Instead, Patent Owner’s experiments tested volatiles from precursors and leghemoglobin heat-reacted in isolation (Dr. Peterson refers to these experimental conditions as “aqueous thermal reactions”). This approach does not support finding a surprising aroma in the *claimed* context of a meat replica matrix or meat-like product, which contain other ingredients such as plant proteins.

Ex. 1005, ¶162

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❖ **Ground 4A: Giacino + Proulx + Conrad**

❖ Dependent Claim 3

Proulx Teaches Adding Heme Iron To Fortify Foods

Iron deficiency is a major nutritional problem, affecting over 2 billion people (1). Fortification of foods with iron has been a successful strategy for improving iron content of foods; however, the bioavailability of iron fortificants is often decreased due to the presence of inhibitors within the food matrix. Iron bioavailability is higher from heme iron sources because of lack of inhibition from chelating compounds including polyphenols and phytate and because of its intact absorption by pathways different than those of nonheme iron (2). Heme iron in the

Proulx, 1518

Giacino's Compositions Lack a Significant Source of Iron

Particularly suitable are mixtures comprising:

0.1 to 15 and preferably 0.5 to 10 weight percent thiamine,
0.1 to 25 and preferably 0.5 to 25 weight percent taurine,
0 to 40 and preferably 0.5 to 35 weight percent hydrolysed
protein,
0 to 5 and preferably 0 to 2.5 weight percent cysteine,
0 to 5 and preferably 0.1 to 2.5 weight percent glycine,
0 to 5 and preferably 0.1 to 2.5 weight percent glutamic
acid,

Giacino, 5:1-10

tion, there may be added to the pre-mix a quantity of
a saccharide material such as a mono saccharide or a
polysaccharide exemplified by di- and trisaccharides. Ri-
bose, sucrose, dextrose and xylose are illustrative of

Giacino, 6:1-7

Giacino's Compositions Are Added to Foods That Would Benefit from Iron

cent. On the other hand, they can be admixed with carrier materials or with other flavoring ingredients or foodstuffs for incorporation into finished products, illustrative of which are the dry foods such as snacks, chips, synthetic meat fibres and the like. The compositions are conveniently

Giacino, 7:22-26

Motivation to Combine Giacino and Proulx

410. In view of the foregoing, a POSITA would have been motivated to add isolated soy leghemoglobin (*e.g.*, LHb_A or LHb_D) as taught by Proulx into Giacino's meaty flavoring compositions to fortify the compositions with heme iron, which has a relatively high degree of bioavailability compared to non-heme iron. Doing so would allow the meaty flavoring compositions to better mimic the nutritional profile (*e.g.*, iron content) of conventionally sourced beef and encourage consumers to consume meat substitutes made with the fortified meaty flavoring compositions.

Ex. 1003 (Tarte), ¶, 410

Petitioner Clearly Articulated Two Independent Motivations to Combine

Hence, a POSITA would have been motivated to include soy leghemoglobin in Giacino's compositions for the additional (and separate) reason of improving their flavor profile. EX1003(Tarte), ¶¶396, 413. Accordingly, whether to fortify the composition with heme iron *and/or* to enhance meat flavor, a POSITA would have been motivated to add soy leghemoglobin to Giacino's compositions. *Id.*, ¶397.

Petition, 61

Reply, 22-23



“[I]f...a [POSITA] would recognize that [a technique] would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.”

KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 417 (2007)

PO's Contention That Flavor Additives Only Add Flavor is Wrong

Indeed, the evidence of record indicates that flavor additives are meant to impart flavor, rather than nutrition. EX1038(Manley), 139-140 (“The definition of a flavor captures the notion that it is a powerful material whose significant function is flavor and not nutrition or functionality (Food and Drug Administration 1990)”);

Ex. 2030 (Qian), ¶101

PO's Lone Evidentiary Support, Manley, Contradicts PO's Contention

There are specific ingredients used to make savory and dairy flavors that must be identified to the PMC during the formula review procedure. Table 5-13 indicates those ingredients that need to be acknowledged in a formula disclosure to the PMC. The basis of the disclosure is to indicate to the consumer the presence of any of the following materials: (1) materials of religious or ethnic interest (Kosher); (2) materials of health concern in terms of allergic activities (proteins); (3) materials that are personal aversions (MSG); and (4) materials that have water binding capabilities or make a significant nutritional contribution to the final food.

Ex. 1038 (Manley), 148-49

Reply, 26

PO Boasted the “Nutritive Value” of its *Flavoring* Composition

2.3.2 Purposes

The primary purpose of the characterizing component, soy leghemoglobin protein, in LegH Prep is to create a flavor impact in ground beef analogue products. In addition, soy leghemoglobin has a nutritive value as a source of iron, analogous to the role of myoglobin as an iron source in meat. Once cooked and digested, both soy leghemoglobin and animal-based myoglobin release identical heme B molecules into the digestive system (Annex 1). Studies using cell models of iron bioavailability have shown that the bioavailability of iron in soy leghemoglobin is equivalent to that of bovine myoglobin when in a food-like substrate (Proulx & Reddy, 2006). Thus, the use of LegH Prep in ground beef analogue products will enhance both the flavor and the dietary profile of those products (Carpenter & Mahoney, 1992).

Ex. 1052, 7

Use of Food Flavorings for Both Flavor and Nutritive Benefits Are Common

105. Nutritional yeast is a deactivated yeast product that is commonly sold as a powder or flakes. It is typically added to foods, such as cheese substitutes, condiments, and many other foods, for its nutritive benefits—it is rich in protein and B vitamins—as well as its distinctly umami flavor. *See, e.g.,* Ex. 1183 (Tomé), 487-

Ex. 1181, ¶105

PO's Response That Nutritive Ingredients Would Not Be Added Fails

rationale. *See* ID, 38. Indeed, as confirmed by the evidence, a POSA would not have viewed an ingredient's nutritional content alone as a motivation for modifying flavor additives like Giacino's. For instance, as noted in the POR, the

PO's Response That Nutritive Ingredients Would Not Be Added Fails

have nutritive benefits. Reply, 26-27. However, this does not support a finding that a POSA would have been motivated to add an ingredient to a flavor additive based on that ingredient's nutritional content alone. For example, Petitioner cites to “nutritional yeast, garlic, salt, and MSG” as examples of flavor additives that have nutritive benefits. *Id.*, 26. However, in each of these cases, the ingredient has a known, desirable *flavor* impact, therefore making them known as *flavor* additives. See EX1182, 105:8-13 (noting “[n]utritional yeast has a strong flavor

Sur-reply, 25

PO's Response That Nutritive Ingredients Would Not Be Added Fails

The same applies to Petitioner's citation to PO's GRAS notification (Reply, 27 (citing Pet., 60; EX1003, ¶394)), where PO described "[t]he *primary* purpose" of leghemoglobin in its products "is to create a flavor impact in ground beef analogue products," with its "nutritive value as a source of iron" being an additional benefit. EX1052, 7 (emphasis added). Thus, at best, Petitioner's evidence shows that, in the context of flavor additives, an ingredient's *flavor* is what is considered when seeking to add it to a given composition, with any nutritional value added by that ingredient being a bonus.⁵

Presentation Roadmap

❖ '096 Patent and Claims

❖ Ground 2A: Giacino + Brown

- Giacino and Brown Disclose Claim Limitations
- Motivation to Combine and Reasonable Expectation of Success
- Patent Owner's Arguments Fail
 - PO's Three Inherency-Based Arguments Fail
 - Giacino Satisfies Two Volatiles Limitation Even If LegH Changes Aroma
 - Giacino's and Brown's Compositions Are Not "Completely Different"
 - Identical Reaction Chemistry Is Not Required
 - Lipid Oxidation Is Not a Concern
 - Patent Owner Mischaracterizes Dr. McGorrin's Statements

❖ Ground 4A: Giacino + Proulx + Conrad

❖ **Dependent Claim 3**

Dependent Claim 3

3. The food flavor additive composition of claim 1, wherein the heme-containing protein comprises amino acid sequence having at least 80% sequence identity to a polypeptide set forth in SEQ ID NOs: 1-26.

SEQ ID NO. 4 Is Leghemoglobin from *Glycine Max* (i.e., Soy)

NO:3), a leghemoglobin such as that from *Glycine max* (SEQ ID NO:4), *Pisum sativum* (SEQ ID NO:16), or *Vigna*

Ex. 1001 ('096 Patent), 10:23-24

Brown and Proulx Both Use Leghemoglobin From Soy

Brown:

panel B) showing similarity of UV-VIS absorption profiles of two proteins. We purified soybean leghemoglobin from soybean root-nodules using here described protocol. Purified equine myoglobin was

Brown, [0377]

Proulx:

The objective of this study was to determine the iron bioavailability of crude soy root nodule extract (SRN) and two purified soy leghemoglobins and to compare their bioavailability with that of bovine hemoglobin (BHb) using the Caco-2 model. The

Proulx, 1518

Additional Points

Reaction-Based Meat Flavorings Have Been Known for Decades

Table 17
SOME G.B. AND U.S. "REACTION PRODUCTS" PATENTS

Table entry	Patent no., (year)	Assigned to or inventor(s)	Flavor	Reaction
1	G.B. 836,694 (1960)	Morton et al. ²⁵⁰	Meat	In general cysteine + additional amino acids (other than phenylalanine and methionine) or in a hydrolyzed protein form + a pentose or hexose
			Cooked pork	Cysteine + ribose
			Roasted beef	Cysteine + glutamic acid + β -alanine + glycine + ribose + glucose
			Roasted beef	A sulfur-containing polypeptide (e.g., glutathione) + ribose
			Cooked meat	Cysteine + casein hydrolysate or groundnut hydrolysate + glucose + xylose
			Roasted beef	Cysteine + defatted cod fish flesh or soybean protein hydrolysate + ribose
2	U.S. 2,934,435 (1960)	May and Neots ²⁵¹	Meat-like	An amino acid source (cysteine or cystine essential) + a pentose + a furan or 2-substituted furan, e.g., furfural
3	U.S. 2,934,436 (1960)	May et al. ²⁵²	Meat-like	Cysteine or cystine + glyceraldehyde
4	U.S. 2,934,437 (1960)	Morton et al. ²⁵³	Meat-like	Cysteine or cystine + a pentose or hexose or glyceraldehyde
5	U.S. 2,955,041 (1960)	Broderick et al. ²⁵⁴	Meat-like	2-Mercaptoethanol derivatives, e.g., mercaptoacetaldehyde, 2,5-dihydroxy-1,4-dithiane +

MacLeod (Ex. 1024), 400

Petition, 2; Ex. 1005, ¶76

McGorin Describes Glucose and Ribose

96. Each of these claimed-but-not-disclosed sugar and sulfur compounds has a unique chemical structure that is different from the compounds that are disclosed in the '816 Provisional. In my experience, chemical structure can be significant because it affects the compounds' chemical reactivity. For example, 5-carbon sugars (e.g., ribose) are more reactive in the Maillard reaction than 6-carbon sugars (e.g., glucose). Compounds with slower reactivity may be less successful at achieving the desired aroma profile with limited cooking time constraints.

Ex. 1005, ¶96

Dependent Claim 20

Q. Claim 20 (“heme flavor reaction mixture is an aqueous solution”)

Giacino discloses that its compositions may be an aqueous solution. EX1015(Giacino), 2:23-28 (“[I]t is ... preferred to incorporate ... a vehicle which includes ... *water* ... to provide a medium for the reaction”), 6:36-39 (“[B]eef flavor compositions involve[] refluxing an *aqueous* pre-mix.”); *see also id.*, 5:22-30, claim 12; EX1003(Tarte), ¶274.

Petition, 43

PO's Expert Agreed That Lipid Oxidation Was Not a Concern

Q. Okay. So lipid oxidation, at least for those compositions, wouldn't be a concern, right?

A. Lipids oxidation is not a concern; however, oxidation is a concern.

* * *

Q. In paragraphs 78, 79 and 80 of your declaration, you only discuss lipid oxidation, correct?

A. Yes, I only address the lipids oxidation issue.

Ex. 1182, 91:15-18, 92:1-5

Reacting Giacino's Compositions Within Foods Is Not a New Argument

279. Giacino also discloses that the consumable food product to which the meaty flavoring compositions are added may be cooked/heated. *See id.*, 6:71-7:2 (“Where the flavor composition of this invention is added to a food which is to be subsequently heated or cooked”). Moreover, a POSITA would have understood that at least with respect to some of the consumable food products to which Giacino’s compositions are added, such as soups, gravies, and synthetic meat fibres, the consumable food product would be heated after adding the meaty flavoring composition.

Ex. 1003 (Tarte), ¶ 279

Petition, 44

District Court's Food Flavor Additive Construction

Motif's proposed construction is plainly correct. As the specification of the '096 patent explains, a "flavor additive composition" is one that is "add[ed] to another consumable food product before, during, or after its cooking process." '096 patent, col. 3, ll. 32–37. That is, in order to be a "food flavor additive composition," the composition must be one that can be added to a food product to modulate the product's flavor and/or aroma. It is not sufficient that the three

Ex. 2016, 18