

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MOTIF FOODWORKS, INC.,
Petitioner,

v.

IMPOSSIBLE FOODS, INC.,
Patent Owner.

Case No. IPR2023-00206
Patent No. 9,943,096

EXPERT DECLARATION OF PROFESSOR MICHAEL C. QIAN, PH.D.

TABLE OF CONTENTS

	<u>Page</u>
I. Qualifications and Background	1
A. Education and Experience	1
B. Bases for Opinions and Materials Considered	3
C. Scope of Work	3
II. Legal Standards	4
III. Person of Ordinary Skill in the Art	6
IV. Summary of Opinions	7
V. The '096 Patent	8
A. Challenged Claims of the '096 Patent and Claim Construction	8
1. “food flavor additive composition”	14
2. “a compound selected from cysteine, cystine, thiamine, methionine, and mixtures of two or more thereof”	15
VI. Background	15
A. Plant-Based Meat Products	15
B. Meat Aroma	17
C. Off-Flavors and Aromas	19
VII. The '096 Patent Claims are Novel and Non-Obvious	19
A. Ground 1: Claims 1-5, 7-9, 23 and 24 are Not Anticipated by Brown (EX1012)	20
1. Claim 1 of the '096 Patent is Not Anticipated by Brown	20
2. Claims 2-5, 7-9 and 23-24 Are Not Anticipated by Brown	27
B. Ground 2A: Claims 1-12, 14-17, and 20-24 Are Not Obvious Over Giacino and Brown	32
1. Claim 1 is Not Obvious Over the Combination of Giacino and Brown	33
2. Claim 10 is Not Obvious Over Giacino and Brown	41
3. Claims 2-9, 11-12, 14-17, and 20-24 are Not Obvious Over Giacino and Brown	42

TABLE OF CONTENTS
(continued)

	<u>Page</u>
C. Ground 2B: Claims 18-19 are Not Obvious Over Giacino, Brown and MacLeod	42
D. Ground 3A: Claims 1-2, 4-7, 9-12, 14-15, and 20-24 are Not Obvious Over Giacino, Conrad and Crane	42
1. Crane is not analogous art.....	43
2. No reason to combine Giacino, Conrad, and Crane with a reasonable expectation of success.....	45
3. Claim 10.....	48
E. Ground 3B-3D: Claims 3, 8, 16, 17 and 18-19 are Not Obvious Over Giacino, Conrad and Crane, and Further In View Of Proulx, Perret or MacLeod	49
F. Ground 4A: Claims 1-7, 9-12, 14-16, and 20-24 are Not Obvious Over Giacino, Proulx and Conrad	50
1. Claim 10.....	51
2. Claims 2-7, 9, 11-12, 14-16, and 20-24.....	52
G. Grounds 4B-4C: Claims 8, 17, and 18-19 are Not Obvious Over Giacino, Proulx and Conrad, and Further In View Of Perret or MacLeod.....	52
VIII. Conclusion	54
IX. Appendix A.....	55

I, Michael C. Qian, Ph.D., declare as follows:

1. Counsel for Impossible Foods, Inc. (“Impossible”) retained me to provide my opinion regarding U.S. Patent No. 9,943,096 (“the ’096 patent,” EX1001), the subject patent of *inter partes* review IPR2023-00206 filed by Motif Foodworks, Inc. (“Motif”). My opinions in this expert declaration support Impossible’s position that all challenged claims of the ’096 patent are valid as novel and non-obvious over the cited references.

I. QUALIFICATIONS AND BACKGROUND

A. Education and Experience

2. I earned a Bachelor of Science in Chemistry from Wuhan University in 1982, and completed a Masters of Science in Food Science at the University of Illinois at Urbana-Champaign in 1989. I earned a Ph.D. in Food Science from the University of Minnesota under the supervision of Dr. Gary Reineccius in 2000. Before joining Oregon State University (OSU), I worked in the food science industry for ten years in various positions. I have been at the Department of Food Science and Technology since 2001, with teaching and graduate student responsibilities as a Professor at OSU, as well as my research in food and flavor chemistry. I am currently on sabbatical from OSU, giving research talks and collaborating with colleagues in the food science field in China.

3. My research at Oregon State University involves both the basic understanding and practical application of flavor chemistry. Over the course of my

tenure at Oregon State University, I have received numerous research grants, awards, and contracts from federal and state agencies, commodity groups, and private industries to support my flavor chemistry research program. I have devoted much of my research program to helping the industry innovate and/or solve flavor-related challenges. Through my research and scholarship, I have contributed to the understanding of the flavor chemistry of many types of foods, including in dairy products such as cheese, whey powder, and whey protein concentrate, berry fruits, wine, beer, coffee, collagen products, and other food products. For my scholarship activities, I received the Distinguished Lipid and Flavor Science Award from the Institute of Food Technologists (IFT) and the Excellence in Flavor Science Award from the Flavor Extract and Manufacturing Association (FEMA).

4. I have co-edited 5 flavor chemistry-related books and authored over 100 referenced journal articles. I have been leading numerous projects related to food flavor chemistry, including as an editor in the 2011 American Chemical Society book of sulfur compounds in food “Volatile Sulfur Compounds in Food” (American Chemical Society, DOI: 10.1021/bk-2011-1068, <http://pubs.acs.org/isbn/9780841226166>). I am an Advisory Committee Member of the Journal of Agricultural and Food Chemistry, an associate editor for the journal Molecules: Flavor and Fragrance section, and an associate editor for the Journal of Distilled Science.

5. I am a frequent invited lecturer at national and international flavor conferences and symposia. I actively promote the field of flavor science through the development and organizing of both domestic and international flavor symposia and conferences, and through my other professional activities. I was the initiator and the Chair of the 1st, 2nd, and 3rd International Flavor and Fragrance Conferences (IFFC). I have held various officer positions in the Agricultural and Food Chemistry Division of the American Chemical Society, including the Chair position of the division in 2014. I was elected as a Fellow of the American Chemical Society in 2019, and a Fellow of the American Chemical Society-Agricultural and Food Chemistry Division in 2014.

6. For a more detailed listing of my credentials and publications, please see my *curriculum vitae*, attached as EX2031.

B. Bases for Opinions and Materials Considered

7. I considered the references cited in Appendix A, in addition to my experience, education, and training, in providing the opinions contained herein.

C. Scope of Work

8. I have been retained by Impossible as a technical expert in this matter to provide various opinions regarding the '096 patent. I receive \$250.00 per hour for my services. No part of my compensation is dependent upon my opinions given or the outcome of this case.

II. LEGAL STANDARDS

9. For my opinions in this declaration, I understand that it requires applying various legal principles. As I am not an attorney, I have been informed by counsel for Impossible about various legal principles that involve my analysis. I have used my understanding of those principles in forming my opinions. I summarize those principles as I understand them below.

10. For example, I understand that Motif bears the burden of proving unpatentability in this proceeding by a preponderance of the evidence. I am informed by counsel that this preponderance of the evidence standard means that Motif must show that unpatentability is more probable than not.

11. I understand that review and consideration of the claims should be viewed from the perspective of a person of ordinary skill in the art (“POSA”) at the time of invention. (I discuss the POSA standard that I have applied in my analysis in more detail at ¶17). I understand that from this perspective, a claim should be given its ordinary and customary meaning to a POSA. As part of this analysis, I understand I must also look to any prior claim construction determination that has been made in a civil action or a court proceeding, so long as the prior claim construction was properly entered into the record. Counsel for Impossible has informed me that a claim construction order was entered by the District Court of Delaware in litigation that includes the ’096 patent, and I have reviewed the order

which was issued by the district court on August 15, 2023, which includes the construction of certain claim terms, including claim terms relevant to the '096 patent.

12. I have been asked by counsel to consider the question of anticipation, namely, whether the claims cover something that is new or novel. I understand that the concept of anticipation requires that each and every element of a challenged claim is present in or otherwise taught by a single reference. I also understand that an anticipatory reference does not need to explicitly describe each element because anticipation can occur when a claimed limitation is necessarily inherent or otherwise implicit in the relevant reference. I understand that inherency of a result or characteristic is not found if that result or characteristic may occur or be present in the prior art. Instead, I understand that the inherent result or characteristic must necessarily flow from the disclosure of the cited art.

13. I have been asked to consider the question of obviousness/non-obviousness. Again, I understand that this analysis must be from the perspective of the POSA, and whether the ordinary artisan would consider any differences between the prior art and what is claimed to have been obvious. To make this assessment, I understand that the concept of patent obviousness involves four factual inquiries: (1) the scope and content of the prior art; (2) the differences

between the claimed invention and the prior art; (3) the level of ordinary skill in the art; and (4) secondary considerations of non-obviousness.

14. I have been further instructed by counsel that one cannot use the challenged patent as a guide to select from prior art elements, or otherwise engage in hindsight. Rather, I understand that my analysis should consider what a person of ordinary skill in the art knew, and what the art taught, suggested, or motivated the POSA to further pursue, and to differentiate between steps that were routinely done (such as in response to known problems, steps or obstacles), and those which, for example, may have represented a different way of solving existing or known problems.

15. I have been advised that any obviousness rationale for modifying or combining prior art must include a showing that a POSA would have had a reasonable expectation of success.

III. PERSON OF ORDINARY SKILL IN THE ART

16. As above, I understand that the analysis is to be conducted from the perspective of a POSA at the time of the invention.

17. I understand that in the Institution Decision, the Patent Trial and Appeal Board (the “Board”) applied Petitioner’s standard for a POSA. Paper No. 23 (Institution Decision), 15. For purposes of my analysis, I have applied this standard to a person who at least has “a Master of Science degree or Ph.D. in food

science or at least three years of experience working as a food scientist” and “could also be part of a team of food scientists, including flavor chemists.” Institution Decision, 15 (citing Pet. 5).

IV. SUMMARY OF OPINIONS

18. In my opinion, Brown (EX1012) does not anticipate claims 1-5, 7-9, 23 and 24 of the '096 patent. *See* Section VII.A.

19. In my opinion, claims 1-12, 14-17, and 20-24 are not obvious in view of the combination of Giacino (EX1015) and Brown. *See* Section VII.B. In my opinion, claims 18-19 are not obvious in view of the combination of Giacino, Brown, and MacLeod (EX1024). *See* Section VII.C.

20. In my opinion, claims 1-2, 4-7, 9-12, 14-15, 20-24 are not obvious in view of the combination of Giacino, Conrad (EX1013), and Crane (EX1014). *See* Section VII.D. In my opinion, claims 3 and 16 are not obvious in view of the combination of Giacino, Conrad, Crane, and Proulx (EX1019). *See* Section VII.E. In my opinion, claims 8 and 17 are not obvious in view of the combination of Giacino, Conrad, Crane, and Perret (EX1020). *See id.* In my opinion, claims 18-19 are not obvious in view of the combination of Giacino, Conrad, Crane, and MacLeod. *See id.*

21. In my opinion, claims 1-7, 9-12, 14-16, 20-24 are not obvious in view of the combination of Giacino, Proulx, and Conrad. *See* Section VII.F. In my

opinion, claims 8 and 17 are not obvious in view of the combination of Giacino, Proulx, Conrad, and Perret. *See* Section VII.G. In my opinion, claims 18-19 are not obvious in view of the combination of Giacino, Proulx, Conrad, and MacLeod. *See id.*

V. THE '096 PATENT

22. I have read the '096 patent, which is titled “Methods and Compositions for Affecting the Flavor and Aroma Profile of Consumables,” and its claims.

23. I am familiar with the time period when this patent was filed, which I understand from the cover of the '096 patent claims priority to January 11, 2013.¹

A. Challenged Claims of the '096 Patent and Claim Construction

24. I understand that Motif is challenging claims 1-12 and 14-24 of the '096 patent.

25. Claim 1, which is an independent claim in the '096 patent, recites: “A food flavor additive composition comprising:

¹ I understand that Motif has challenged the priority claims of the '096 patent in its Petition for *Inter Partes* Review. My opinions are not dependent upon whether Motif's position is correct. As I discuss below, the Brown reference does not anticipate the challenged claims, and the combination of Brown and Giacino does not render these claims obvious. *See* Sections VII.A.-VII.G.

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.”

26. Claim 10, which is a second independent claim in the '096 patent, recites: “A food flavor additive composition prepared by a process of:

a) combining an isolated heme-containing protein; a compound selected from glucose, ribose, 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 the 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).”

27. Claims 2-9 and 23-24 depend from claim 1, and claims 11-22 all
ultimately depend from claim 10. The dependent claims recite additional aspects of
the claims, including specific heme-containing proteins, additional components of
the claimed food flavor additive composition as well as other aspects, and are
summarized in Table 1 (below).

Table 1. '096 Dependent Claims

No.	Claim
2	The food flavor additive composition of claim 1, wherein the heme-containing protein is selected from the group consisting of a androglobin, a cytoglobin, a globin E, a globin X, a globin Y, a hemoglobin, a myoglobin, a leghemoglobin, an erythrocrucorin, a beta hemoglobin, an alpha hemoglobin, a protoglobin, a cyanoglobin, a cytoglobin, a histoglobin, a neuroglobins, a chlorocruorin, a truncated hemoglobin, a truncated 2/2 globin, and a hemoglobin 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.
4	The food flavor additive composition of claim 1, wherein the food flavor additive composition is a powder or a liquid composition.
5	The food flavor additive composition of claim 1, wherein the heme-containing protein is a plant, a yeast or filamentous fungi, or bacterial heme-containing protein.
6	The food flavor additive composition of claim 1, further comprising one or more of an extract or hydrolysate selected from a vegetable protein hydrolysate, a soy protein hydrolysate, a yeast extract, a yeast protein hydrolysate, and an algal protein hydrolysate.
7	The food flavor additive composition of claim 1, further comprising one or more of a compound selected from alanine, arginine, asparagine, aspartate, glutamic acid, glutamine, glycine, histidine, isoleucine, leucine, lysine, phenylalanine, proline, threonine, tryptophan, tyrosine, valine, maltodextrin, thiamine, IMP, GMP, lactic acid, and creatine.
8	The food flavor additive composition of claim 1, further comprising one or more of an oil selected from coconut oil, mango oil, sunflower oil, cottonseed oil, safflower oil, rice bran oil, cocoa butter, palm fruit oil, palm oil, soybean oil, canola oil, corn oil, sesame oil, walnut oil, flaxseed, jojoba oil, castor, grapeseed oil, peanut oil, olive oil, algal oil, and oil from bacteria or fungi.
9	The food flavor additive composition of claim 1, further comprising one or more of albumin or a globulin.
11	A food flavor additive composition of claim 10, wherein the food flavoring

	wherein the food flavoring additive composition further comprises a compound selected from the group consisting of 2-methyl-furan, bis(2-methyl-3-furyl)disulfide, 2-pentyl-furan, 3,3'-dithiobis-2-methyl-furan, 2,5-dimethyl-pyrazine, 2-methyl-3-furanthiol, bis(2-methyl-4,5-dihydro-3-furyl) disulfide, dihydro-3-(2H)-thiophenone, 5-methyl-2-thiophenecarboxaldehyde, 3-methyl-2-thiophenecarboxaldehyde, 2-methyl-thiazole, dimethyl sulfide, decanal, 5-ethyl-dihydro-2(3H)-furanone, dihydro-5-pentyl-2(3H)-furanone, 2-octanone, 3,5-octadien-2-one, p-Cresol, and hexanoic acid.
12	The food flavor additive composition of claim 11, wherein the compound is detectable in the headspace above the heme flavor reaction mixture during the heating of step b) or in the headspace above the food flavoring additive composition after the heating of step b).
13	The food flavor additive composition of claim 10, where the process further comprises removing the heme-containing protein from the food flavoring additive composition after the heating in step b) of the heme flavor reaction mixture.
14	The food flavor additive composition of claim 10, wherein the heme-containing protein is present in an amount between about 0.01% and about 5% by weight in the heme flavor reaction mixture.
15	The food flavor additive composition of claim 10, wherein the heme-containing protein is selected from the group consisting of an androglobin, a cytoglobin, a globin E, a globin X, a globin Y, a hemoglobin, a myoglobin, a leghemoglobin, an erythrocrucorin, a beta hemoglobin, an alpha hemoglobin, a protoglobin, a cyanoglobin, a cytoglobin, a histoglobin, a neuroglobins, a chlorocruorin, a truncated hemoglobin, a truncated 2/2 globin, and a hemoglobin 3.
16	The food flavor additive composition of claim 10, wherein the heme-containing protein comprises an amino acid sequence having at least 80% sequence identity to a polypeptide set forth in SEQ ID NOs: 1-26.
17	The food flavor additive composition of claim 10, wherein the heme flavor reaction mixture further comprises one or more oils selected from coconut oil, mango oil, sunflower oil, cottonseed oil, safflower oil, rice bran oil, cocoa butter, palm fruit oil, palm oil, soybean oil, canola oil, corn oil, sesame oil, walnut oil, flaxseed, jojoba oil, castor, grapeseed oil, peanut oil, olive oil, algal oil, and oil from bacteria or fungi.

18	The food flavor additive composition of claim 10, further comprising an ingredient selected from an emulsifier and a gelling agent.
19	The food flavor additive composition of claim 10, the process further comprising adding an emulsifier and a gelling agent to the heme flavor reaction mixture prior to the heating of step b).
20	The food flavor additive composition of claim 10, wherein the heme flavor reaction mixture is an aqueous solution.
21	The food flavor additive composition of claim 10, wherein the heme flavor reaction mixture is an oil-based mixture.
22	The food flavor additive composition of claim 10, further comprising one or more of an extract or hydrolysate selected from a vegetable protein hydrolysate, a soy protein hydrolysate, a yeast extract, a yeast protein hydrolysate, and an algal protein hydrolysate, and or a globulin.
23	A process for imparting a meaty flavor and/or meaty aroma to a consumable food product, comprising: adding to the consumable food product a food flavor additive composition of claim 1; and heating the consumable food product after the adding step.
24	The food flavor additive composition of claim 1, in the form of a soup, stew base, a bouillon powder, bouillon cube, flavor packets or seasoning packet.

28. I understand that the claim terms of the '096 patent are to be given their plain and ordinary meaning, *i.e.*, the meaning that the terms would have had to the ordinarily skilled artisan at the time of the invention. I understand that the relevant timeframe is January 11, 2013, the earliest claimed provisional application filing date on the face of the patent.²

² As noted above, I understand that Motif has challenged the priority claims of the '096 patent in its Petition for *Inter Partes* Review. As I explain further below,

29. I understand from counsel that this analysis focuses on intrinsic evidence, including how the claim term is used in the claims, specification, and prosecution history. I also understand that dictionaries or other extrinsic sources may assist in determining the plain and ordinary meaning but cannot override a meaning that is unambiguous from the intrinsic evidence. I have followed these principles in my analysis throughout this declaration.

1. “food flavor additive composition”

30. I understand from counsel that Impossible sued Motif for patent infringement (the “Litigation”), and that in the Litigation, Motif asserted that the term “food flavor additive composition” should be construed to mean “a composition that modulates a food product’s flavor and/or aroma when added to the food product,” and “must be distinct from the food product itself.” EX2016(order), 17. I understand that the district court agreed with Motif and concluded that “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 recited compounds are present in the end food product.” EX2016(order), 18 (referencing claim 1 of

my opinions are not dependent upon whether the priority claims of the ’096 patent are correct. *See* Sections VII.A.-VII.G.

the '096 patent reciting a “food flavor additive composition compris[ing] compounds from each of three groups of compounds”).

31. As I explained above, it is my understanding that I should apply the district court’s construction of this claim term to my analysis below. *See* ¶11.

2. “a compound selected from cysteine, cystine, thiamine, methionine, and mixtures of two or more thereof”

32. I further understand from counsel that Motif in the Litigation asserted that the term “compound” should be construed to exclude “much larger compositions that comprise sulfur-containing compounds as part of their building blocks,” such as plant proteins. EX2016(order), 8 (alterations omitted). I understand that the district court agreed and concluded that “the ‘sulfur compound’ limitation must be satisfied by a compound that is present separately from a protein.” EX2016(order), 9.

VI. BACKGROUND

A. Plant-Based Meat Products

33. While plant-based burgers or similar products have been available for decades, these products were “marketed and sold to vegetarians” and not intended to appeal to the vast majority of non-vegetarian consumers who eat and crave real meat products. *See* EX2002(Goldfine), 4. As the '096 patent recognized, that “[c]urrent plant-based meat substitutes have largely failed to cause a shift to a vegetarian diet,” owing to the “fail[ure] to replicate the experience of cooking and

eating meat.” *See* EX1001(’096 patent) 1:46-49. For example, prior plant-based substitute products contrasted with animal-based meat products by providing “a texture and mouthfeel that [we]re more homogenous than that of equivalent meat products.” *Id.*, 1:50-52. Also absent was the ability of these plant-based substitutes to “replicate aromas, flavors, and other key features associated with cooking meat.” *Id.*, 1:52-55. While prior plant-based substitute products appealed to an established vegetarian/vegan base, these products “failed to appeal to the larger consumer segment accustomed to eating meat.” *Id.*, 1:55-59.

34. One of the challenges with plant-based meat-substitute products is the successful reproduction of the meat-eating experience with these products: the aromas and flavors associated with preparing and eating meat products are essential for providing the experience necessary to satisfy meat-eating consumers. *See* EX2002(Goldfine), 4. The ’096 patent is directed towards filling this gap by providing “methods and compositions for modulating the flavor and/or aroma profile of” plant-based food products. *Id.*, 1:66-2:3. With the flavor additive compositions disclosed in the ’096 patent, plant-based food products can be made “to give the cooked consumable food product a particular meaty taste and smell” and “hav[e] a cooked flavor and/or aroma profile that is more meat like.” *Id.*, 2:66-3:14, 19:3-20; EX2002(Goldfine) (“The Impossible Burger bleeds, sizzles and tastes just like meat....”). The compositions described in the ’096 patent can

be free of animal products, adding to its desirability and ability to improve the meat flavor of plant-based food products. *See* EX1001('096 patent), Abstract.

B. Meat Aroma

35. Petitioner's rationale relies on the assumption that a Maillard reaction occurs in Giacino to produce a meat-associated aroma. *See, e.g.*, Pet., 34 (Ground 2A). However, meat associated aromas are not limited to the Maillard reaction. *See, e.g.*, EX1024(MacLeod), 367-368; EX1005, ¶¶34-36; ¶¶36-40. Furthermore, compounds produced via the Maillard reaction contribute both positively as well as adversely to flavor profiles. *See* EX1136(Whistler), 103; EX1151(Ames), 150 ("Foods stored at room temperature may develop off-flavours due to the Maillard reaction"); *id.*, 152 ("Problems arise [when dried and concentrated foods are stored] due to the development of yellow colours and off-odours"). The Maillard reaction is not limited to meat aromas. Example products of the Maillard reaction include the volatile aroma constituents in chocolate, coffee, toasted cereal grains, wheat bread crust, popcorn, roasted nuts, and meats. *See* EX1039(McGorin), 225.

36. The formation and identity of volatile aroma compounds via the Maillard reaction is sensitive to compositional and processing conditions such as temperature and time (EX1033(Reineccius), 106-107), the system composition/matrix (*id.*, 108-109), water (*id.*, 109), pH (*id.*, 109), and salt (*id.*, 110). *See also* EX1151(Ames), 150-151. For example, for thermal reactions

between ribose and cysteine, the pH and ratio of ribose to cysteine affect the overall odor, which can range from meat-like to a rubbery, sulfury odor. *See* EX1045(Hofmann), 2189.

37. The presence or absence of lipids and water in a matrix can influence the formation of volatile compounds via the Maillard reaction. *See* EX1033(Reineccius), 121-122; EX1129(Mottram), 986; EX1017(Mottram), 421 (“phospholipids exert a quenching effect on the quantities of heterocyclic compounds formed in the Maillard reaction”). For example, Table 1 of EX1129(Mottram) at 986, reproduced partially below, shows varying concentrations, from not detected to very large, of volatile compounds depending on the presence or absence of phospholipid and water.

compound	LRI ^b	relative concentration ^c					method of identification ^d
		water absent		water present			
		C + R	C + R + L	C + R	C + R + L	C alone	
5-methylthiazole ^e	846	tr	—	tr	—	+	MS
2,4-dimethylthiazole ^e	892	tr	—	tr	—	—	MS + LRI
4,5-dimethylthiazole	933	tr	—	tr	—	tr	MS + LRI
5-ethylthiazole ^e	940	+	tr	—	—	tr	MS
2-propylthiazole ^e	981	tr	—	—	—	tr	MS
trimethylthiazole	1000	+	+	+	+	+	MS + LRI
5-ethyl-2-methylthiazole	1015	+++	++	+	++	+	MS
5-ethyl-4-methylthiazole	1039	tr	—	tr	tr	tr	MS + LRI
2,5-dimethyl-4-ethylthiazole ^e	1066	+	tr	+	+	—	MS + LRI
4-ethyl-5-methylthiazole	1068	tr	—	tr	—	—	MS
2,4-dimethyl-5-ethylthiazole	1078	+	+	+	+	—	MS + LRI
4,5-dimethyl-2-ethylthiazole ^e	1105	tr	tr	—	tr	—	MS + LRI
4,5-dimethyl-2-propylthiazole ^e	1180	tr	+	tr	tr	tr	MS + LRI
4(or 5)-ethyl-2-propylthiazole ^e	1190	+	+	tr	+	+	ms

38. Another important source of aroma compounds is lipid oxidation. Lipid oxidation includes autoxidation, which is often iron catalyzed, and thermally

induced lipid oxidation. EX1024(MacLeod), 389. The products of autoxidation, which form without heating and give off-flavors, differ from the products of thermal lipid oxidation, which can form desirable meaty aromas. *See id.*; EX1033(Reineccius), 119-120; EX1028(Calkins), 64, 75-76.

C. Off-Flavors and Aromas

39. Off-flavors are sensory attributes that are often significant detractors to food quality. *See* EX1039(McGorin), 237. Such off-flavors can be generated from nonenzymatic browning, chemical reactions between food constituents, enzymatic pathways, and lipid autoxidation at room temperature. *See id.*

40. Warmed-over flavors (WOF), which give rancid or stale flavors, are developed from the oxidation of cooked meat, including lipid oxidation. EX1048(Pearson), 287; EX1024(MacLeod), 393. Iron is a known catalyst of oxidation that causes WOF. EX1048(Pearson), 288. Myoglobin, as a source of iron, is readily broken down during the cooking process to release iron, and thus also catalyzes WOF. *Id.*, 290

VII. THE '096 PATENT CLAIMS ARE NOVEL AND NON-OBVIOUS

41. The '096 patent provides “methods and compositions for modulating the flavor and/or aroma profile of consumable products,” including plant-based food products. EX1001('096 patent), 1:66-2:3. By adding such compositions, plant-based food products can be made “to give the cooked consumable food product a particular meaty taste and smell” and “hav[e] a cooked flavor and/or

aroma profile that is more meat like.” *Id.*, 2:66-3:14, 19:3-20; EX2002(Goldfine) (“The Impossible Burger bleeds, sizzles and tastes just like meat....”). The compositions described can be formulated to be free of animal products, thus adding to its desirability and ability to improve the meat flavor of plant-based food products. *See* EX1001(’096 patent), Abstract.

A. Ground 1: Claims 1-5, 7-9, 23 and 24 are Not Anticipated by Brown (EX1012)

1. Claim 1 of the ’096 Patent is Not Anticipated by Brown

42. The elements of claim 1 are shown in Table 2 below.

Table 2. ’096 Patent Claim 1 Limitations

Element	Claim Limitation
1[pre]	A food flavor additive composition comprising:
1[a]	a) an isolated heme-containing protein;
1[b]	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
1[c]	c) a compound selected from cysteine, cystine, thiamine, methionine, and mixtures of two or more thereof;
1[d]	wherein the flavor additive composition contains no animal products; and

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

- a) Brown does not disclose a “food flavor additive composition” as recited in claim 1

43. Petitioner asserts that Brown anticipates claim 1 of the '096 patent because it discloses a food flavor additive composition as claimed in the form of a “muscle replica” that “contains[s] pea flour (which includes cysteine, methionine, and thiamine), glucose, sunflower oil, and isolated soy leghemoglobin (‘heme-containing protein’).” Pet., 20 (citing EX1012(Brown), [00364]). I disagree that Petitioner has shown that Brown discloses a food flavor additive composition as recited in claim 1 for two reasons. First, Petitioner has not shown that Brown’s “muscle replica” is a food flavor additive composition as that term is understood in the art. Second, Petitioner has not shown that the muscle replica of paragraph [00364] of Brown includes “an isolated heme-containing protein” as recited in the claim.

- i) Brown’s muscle replica of paragraph [0364] is not a “food flavor additive composition”

44. As I noted above in ¶30, based on the claim construction order, the district court found that “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 recited compounds are present in the end food product.” EX2016(order), 18 (referencing claim 1 of the '096 patent reciting a “food flavor additive composition compris[ing] compounds from each of three groups of compounds”).

45. It is my opinion that a “food flavor additive composition” is a composition that is *added* to a food product for the purpose of imparting flavor; it is not a food product itself. This position is consistent with the use of the term “flavor” in the art. *See, e.g.*, 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)”).

46. Consistent with this understanding, food flavor additive compositions were generally understood in the art to be concentrated products so as to minimize dilution of the food product to which the food flavor additive composition is added. For example, a food flavor additive composition could be a seasoning package that is added in minimum quantities to a food product, without substantial change to the matrix of the food product. *See, e.g.*, EX1020(Perret), 1:20-34 (describing the preparation of a concentrated beef flavoring by hydrolyzing and concentrating a large quantity of beef tissue into a relatively small quantity of concentrated extract); EX1015(Giacino), 7:15-28 (providing preferable amounts of liquid flavor compositions at 0.1 to 1 weight percent of a food product, and preferably 5 to 10 weight percent flavor composition of a dry food product).

47. While Petitioner relies on Brown’s “muscle replica” as a food flavor additive composition, Brown explains that a muscle replica “replicates or approximates key features of animal skeletal muscle”, for example, the “physical

organization of skeletal muscle.” EX1012(Brown), [00305], [00244]. Brown states that the muscle replica may be combined into a meat substitute product at 40-90% of the product by weight. *Id.*, [00191]. Therefore, in view of the claim construction order and my understanding of a food flavor additive composition, it is my opinion that Petitioner has not shown that the muscle replica of [00364] of Brown would have been understood to be a “food flavor additive composition” because the muscle replica is physically organized as a *food product* that replicates key features of muscle, and it is present as a significant component (up to 90%) of a meat substitute, rather than as a concentrated flavor additive.

- ii) Brown’s muscle replica of paragraph [0364] does not comprise “an isolated heme-containing protein”

48. In addition, Petitioner asserts that “Brown’s muscle replica is a ‘food flavor additive composition’” as claimed because it “contains[s] pea flour (which includes cysteine, methionine, and thiamine), glucose, sunflower oil, and isolated soy leghemoglobin (‘heme-containing protein’).” Pet., 20 (citing EX1012(Brown), [00364]). Petitioner’s assertion, however, is not consistent with the muscle replica described in paragraph [00364] of Brown. In my opinion, paragraph [00364] of Brown describes a *meat replica* that contains a muscle replica having pea flour, sunflower oil, and glucose, which is then cooked with leghemoglobin to form the meat replica. Thus, paragraph [00364] of Brown does not describe a “muscle

replica” that contains “an isolated heme-containing protein” as recited in claim 1. Moreover, because the meat replica of paragraph [00364] would have been understood to be a food product itself, it is not a “food flavor additive composition.”

49. Specifically, Brown describes, as “[e]vidence 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...reduced leghemoglobin (LHb)....” EX1012(Brown), [00364]. Thus, in this paragraph, Brown distinguishes the muscle replica, which includes pea flour, sunflower oil, and glucose, from leghemoglobin, which is added as a separate ingredient to be cooked with the muscle replica to generate the “meat replica” of paragraph [00364]. I note that Brown makes this same distinction later in the paragraph when detailing “a composition of aligned GCMS profiles...of other identical muscle-replica samples cooked in the presence of leghemoglobin.” *Id.*

50. Thus, in my opinion, a POSA would have understood that the “muscle replica” described in paragraph [00364] does not include leghemoglobin, and instead, it is the “muscle replica” comprising pea flour, sunflower oil, and glucose, together with leghemoglobin that represents a meat replica—*i.e.*, an end food product.

51. In addition, the “meat replica” of Brown at [00364] is also not a “food flavor additive” that is added to a food product to impart flavor because it represents a final food product that is consumed. Petitioner has not shown that Brown suggests that the composition made in paragraph [00364] is added to another end food product. Moreover, Brown describes that meat replicas are consumables that can replace animal based foods, *e.g.*, meat products such as ground beef. EX1012(Brown), [00272].

- b) Brown’s pea flour is not “a compound selected from cysteine, cystine, thiamine, methionine, and mixtures of two or more thereof”

52. I understand that Petitioner premises its anticipation ground based on Brown by “map[ping] ‘a compound selected from cysteine ...’ and a compound selected from alanine ...” to “pea flour, which contains proteins having the claimed sugar and sulfur compounds.” Pet., 12. I also understand that Motif in the Litigation asserted that the term “compound” should be construed to exclude “much larger compositions that comprise sulfur-containing compounds as part of their building blocks,” such as plant proteins. EX2016(order), 8. And I further understand that the district court found that “the ‘sulfur compound’ limitation must be satisfied by a compound that is present separately from a protein.” *Id.*, 9. Thus, in view of the claim construction order, the “compound selected from cysteine. . .” limitation cannot be satisfied by “proteins having the claimed...sulfur

compounds,” which Petitioner maps to the claimed compound limitation. For this reason, Petitioner has not shown that Brown discloses “a compound selected from cysteine, cystine, thiamine, methionine, and mixtures of two or more thereof.”

2. Claims 2-5, 7-9 and 23-24 Are Not Anticipated by Brown

53. Claims 2-5, 7-9 and 23-24 depend from claim 1. I understand that these dependent claims include all limitations of claim 1. As explained above, the Petitioner fails to establish that Brown anticipates claim 1. The dependent claims are not anticipated for at least the same reasons as claim 1. *See ¶¶42-52.*

a) Claims 4 and 24

54. Claim 4 depends from claim 1 and further recites “the food flavor additive composition is a powder or a liquid composition.” Claim 24 depends from claim 1 and further recites that the food flavor additive composition is “in the form of a soup, stew base, a bouillon powder, bouillon cube, flavor packets or seasoning packet.”

55. Regarding claim 4, Petitioner asserts “Brown discloses a food-flavor additive composition that is a powder” because Brown discloses that “[t]he muscle replica ‘can be optionally dried at room temperature overnight, then ground to a fine powder (<60 mesh) using a Braun food grinder,’” which a POSA would allegedly understand as a “bouillon powder.” Pet., 24 (emphasis omitted) (citing EX1012(Brown), [00311]). I do not agree with Petitioner’s characterization of

Brown. A POSA would not have understood the powder described in paragraph [00311] to be a muscle replica because a powder does not replicate muscle. Instead, a POSA would have understood the powder to represent a sample collected for the purposes of testing characteristics of the composition, such as pH, or, at best, an intermediary product of the extrusion method described for making a muscle replica. In either case, a POSA would not have understood the powder described in paragraph [00311] to be a “muscle replica” as that term is understood in Brown.

56. As an initial matter, a powder does not replicate muscle. First, the cited paragraph [00311] relates to “methods for making a muscle replica.” *Id.*, [00310]. The “muscle replica” can be formed “into asymmetric fibers” (or “spun fibers” or “extruded fibers”) “prior to incorporation into the consumable,” which can “replicate muscle fibers.” *Id.* That muscle replicas replicate muscle is consistent with Brown generally. *See, e.g.*, EX1012(Brown), [00305] (“replicates or approximates key features of animal skeletal muscle...[s]uch a composition will be labeled herein as ‘muscle replica’”). A powder, on the other hand, *does not replicate muscle*. Thus, as a general matter, because a “powder” does not replicate muscle, the “powder” referenced in paragraph [00311] of Brown would not have been understood by a POSA to be a muscle replica.

57. Second, the powder referenced in [00311] of Brown would have been understood to represent a testing sample, rather than the muscle replica itself. Specifically, in that paragraph, Brown describes a particular method of extrusion to form “the final product” of a muscle replica. *See* EX1012(Brown), [00311] (“In some embodiments extrusion can be conducted using an MPF19 twin-screw extruder (APV Baker, Grand Rapids, Mich.) with cooling die. The cooling die can cool the extrudate prior to return of the extrudate to atmospheric pressure, thus substantially inhibiting expansion or puffing of the final product.”).

58. After the final product is extruded, “[o]bservations can be made on color, opacity, structure, and texture for each collected sample.” *Id.* Brown goes on to state that “[c]ollected samples can be optionally dried at room temperature overnight, then ground to a fine powder (<60 mesh) using a Braun food grinder” and “[t]he pH of samples can be measured in duplicate using 10% (w/v) slurries of powdered sample in distilled water.” *Id.*

59. Thus, rather than representing the “final product” of muscle replica intended for “incorporation into the consumable” (made by, *e.g.*, extrusion as described in paragraphs [00310]-[00311]), a POSA would have understood that the powder merely represents a testing sample for measuring characteristics of the extruded products, *e.g.*, for quality assurance purposes—for example, to test its pH “using 10% (w/v) slurries of powdered sample in distilled water.”

60. Third, even if Brown may be said to describe a powder in connection with a method of making a muscle replica, a POSA would not have understood that powder to represent the muscle replica itself and instead would have viewed it as an intermediary product in the process of making a muscle replica. As I noted above, Brown describes methods of producing muscle replicas, *e.g.*, by forming “asymmetric fibers” that can “replicate muscle fibers.” EX1012(Brown), [00310] (stating further that the fibers may also be “spun fibers” or “extruded fibers”). Brown references methods of extrusion for producing such fibers, including US20120093994 (EX2010), which at paragraph [0007] indicates that while a powder is formed during extrusion, “[b]efore being used in or as an edible food application, such an extruded protein [the] product must be rehydrated with water.” Thus, although a powder may be formed as an intermediate during extrusion to form muscle replica fibers, the muscle replica is not itself a powder.

61. For the same reasons discussed above with respect to claim 4, Petitioner fails to establish that Brown anticipates claim 24.

b) Claim 23

62. Claim 23 depends from claim 1 and recites “[a] process for imparting a meaty flavor and/or meaty aroma to a consumable food product.” The process comprises “adding to the consumable food product a food flavor additive

composition of claim 1” and “heating the consumable food product after the adding step.”

63. Petitioner contends that Brown anticipates claim 23 because “[t]he composition is added to a meat substitute (‘consumable food product’) comprising other tissue replicas (fat, connective tissue)” and “[t]he meat substitute is then cooked.” Pet., 26. I disagree with this contention because Brown does not disclose that the composition of paragraph [00364] is thereafter added to a meat substitute that is then cooked. Instead, Petitioner points to other paragraphs in Brown that are not directed to the composition described in paragraph [00364]. *See, e.g.*, EX1012, [0035]-[0042] (discussing indicators that indicates cooking progression), [00189], [00191] (general discussion of “some embodiments” of a meat substitute product as containing muscle, fat tissue, and connective tissue replicas), [00272] (discussion of general appearance of consumable products), [00270], [00412] (discussing ground beef patty of Figure 17 having muscle tissue analog compositions of paragraphs [00396]-[00403]).

64. As I noted above, the composition described in Brown’s paragraph [00364] is cooked to form a meat replica, which Brown utilizes this term interchangeably with “meat substitute”, as do the Petition materials. *See, e.g.*, EX1003(Tarté), ¶60 (“meat ‘replicas’—also called ‘analog’ or ‘substitutes’—”); *id.*, ¶80 (Dr. Tarté referencing the meat replica of par. 364 as a “meat substitute”).

Petitioner does not explain why a POSA would understand that the already-cooked meat replica product of paragraph [00364] of Brown would have been subsequently added to another meat substitute and cooked again.

B. Ground 2A: Claims 1-12, 14-17, and 20-24 Are Not Obvious Over Giacino and Brown

65. For Ground 2A, Petitioner contends that “Giacino discloses every limitation of the independent claims except ‘an isolated heme-containing protein’ (which is taught by Brown).” Pet., 26. Petitioner contends that the compositions of Giacino “include well-known meat flavor precursors,” *including* cysteine, thiamine, and ribose, xylose, and hydrolyzed vegetable proteins, which, when heated, produce “meaty flavor.” *Id.*, 26-27. However, Petitioner fails to specifically identify any particular composition from Giacino that meets the limitations of claim 1. Instead Petitioner only makes disparate and general ingredients from distinct disclosures in Giacino. *See, e.g.*, EX1003(Tarté), ¶¶175, 226, 235-236, 210, 228; EX2032(Tarté deposition), 48:14-49:14. However, the identity and amount of each ingredient in a composition, as well as the matrix of the composition, may affect whether certain reactions will occur upon heating the composition, and what volatile aroma compounds, if any, would be produced. *See, e.g.*, EX1024(MacLeod), 367-368; EX1005, ¶¶34-36; ¶¶36-40. In addition, Giacino does not mention anything about heme-containing proteins.

66. Petitioner further contends that a POSA would have sought to also include leghemoglobin, as taught by Brown, to Giacino's compositions because it "would further Giacino's goal of providing a 'truer flavor' of meat" and "would only further contribute to the meaty aroma volatiles." Pet., 30, 34. However, the evidence supports that adding leghemoglobin to a composition would not "only further contribute to the meaty aroma volatiles" of Giacino's compositions, as discussed further below. See ¶¶67-80. However, Petitioner has not established why a POSA would combine Giacino and Brown as described further below.

1. Claim 1 is Not Obvious Over the Combination of Giacino and Brown

- a) The combination of Giacino and Brown does not necessarily "result in the production of at least two volatile compounds which have a meat-associated aroma"

67. Petitioner asserts that "[a] POSITA would understand that heating Giacino's composition, which includes cysteine, thiamine, and ribose, induces a Maillard reaction that produces a myriad of volatiles (at least two) known to have a meat-associated aroma." Pet., 34 (citing EX1003(Tarté), ¶210). I note that Giacino does not expressly disclose "the production of at least two volatile compounds which have a meat-associated aroma" when its products are heated nor does it explicitly reference a Maillard reaction. Thus, I understand that Petitioner's assertion is based on the assumption that "Giacino's composition, which includes cysteine, thiamine, and ribose," inherently (or necessarily) will produce a Maillard

reaction when heated, even in the presence of the leghemoglobin of Brown, that would lead to the production of “at least two volatile compounds which have a meat-associated aroma”. *See* ¶12.

68. First, Petitioner’s assertion that “Giacino’s composition, which includes cysteine, thiamine, and ribose,” without more specificity, is insufficient to show that a Maillard reaction will occur and, even if it did, that it would lead to the production of “at least two volatile compounds which have a meat-associated aroma.” As Petitioner’s evidence shows, and I described above (*see* ¶¶35-40), the specific ingredients contained in a composition and other factors will dictate what types of reactions occur and whether volatiles having a meat-associated aroma will be produced. *See* ¶37 (partially reproducing EX1129, 986 (Table 1)) (showing varying concentrations, from not detected to very large, of volatile compounds depending on the relative presence of cysteine, ribose, phospholipid, and water). Moreover, with respect to the Maillard reaction specifically, the reaction is known to produce other aromas not associated with meat. *See* ¶35.

69. Petitioner, however, does not identify the composition of Giacino that would be heated. In fact, Petitioner does not address that Giacino itself contemplates the inclusion of ingredients that go beyond cysteine, thiamine, and ribose. For example, Giacino explains that its meaty flavor is the result of heating thiamine *and taurine* as the reactive components. *See, e.g.*, EX1015(Giacino),

1:12-15, 1:60-65, 2:8-13; EX1043(Dreher), 3097 (disclosing thiamine degradation). Petitioner does not address this necessary reactive component of Giacino and its impact on the Maillard reaction (and resulting volatiles) that Petitioner alleges will occur from cysteine, thiamine, and ribose in the composition. Therefore, Petitioner has not shown that the mere presence of cysteine, ribose, and thiamine (together with the necessary taurine) in a heated composition necessarily means that “at least two volatile compounds which have a meat-associated aroma” would be produced.

70. Moreover, Petitioner references numerous potential ingredients, including saccharide materials, thiamine, cysteine, cystine, vegetable protein hydrolysate, albumin or a globulin, and gum arabic, that Petitioner asserts may be 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 acids or other components of the composition to alter the identity of the aroma compounds. *See id.* With respect to the identity of the aroma compounds, aroma compounds may contribute positively or adversely to flavor, *e.g.*, the products of a

Maillard reaction may have meat-like or rubbery and sulfury odors. *See* ¶36.

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.

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.

b) Petitioner identifies no good reason to combine Giacino and Brown

72. Petitioner asserts that based on Brown’s teachings that “adding leghemoglobin to a meat flavoring composition, such as a muscle replica, that already comprises known meat flavor precursors” (referencing glucose, and thiamine, cystine, and methionine from pea flour), a POSA “would have been motivated to add leghemoglobin to a flavoring composition, such as Giacino’s, that already includes flavor precursors (e.g., sulfur compounds and reducing sugars) to provide a cooked meat aroma and flavor.” Pet., 29, 30, footnote 9; *see also* EX1003(Tarté), ¶184 (“Hence, a POSITA would reasonably expect the same

catalyzation to take place when adding leghemoglobin to Giacino's compositions to produce volatiles associated with cooked meat.""). For the reasons set forth below, I disagree that a POSA would have been motivated to combine Giacino and Brown.

73. First, while Petitioner asserts that "a POSITA would reasonably expect the same catalyzation to take place when adding leghemoglobin to Giacino's compositions," Petitioner fails to establish what alleged "catalyzation" reaction occurs in Brown that presumably would also occur in Giacino. *See* Tarté deposition, 23:3-24. I note that neither Giacino nor Brown discuss that a Maillard reaction is the reactive component underlying the production of meaty flavor or aroma in its compositions. *See* ¶35 (references cited including other possible 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.

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.

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 (flavor compositions can be incorporated at 0.05% to 15% percent by weight). In contrast, the Brown composition referenced by Petitioner is a *muscle replica*, which “approximates key features of animal skeletal muscle”, and includes pea flour, sunflower oil and glucose, and is not related to a food flavor additive composition. EX1012(Brown), [00364], [00305]. Therefore, Petitioner has not explained why a POSA working on a food flavor additive would have combined a meat replica with the concentrated flavoring composition of Giacino.

75. Lastly, Petitioner asserts that a POSA would understand that the modification of Giacino with the leghemoglobin of Brown “would only further contribute to the meaty aroma” in Giacino. Pet., 34, citing EX1003(Tarté), ¶212 (“A POSITA would understand that adding leghemoglobin to Giacino’s flavoring compositions would only further contribute to the meaty aroma and volatiles produced since Brown teaches that reacting leghemoglobin in the presence of vegetable proteins/amino acids (e.g., via pea flour) and glucose results in a ‘cooked meat’ aroma.”). Petitioner’s assertion is not supported because the only basis stated is Brown, which is a different composition from Giacino. Just because leghemoglobin contributed to flavor in the composition of Brown does not mean

that it would contribute in the same manner to the composition of Giacino. Furthermore, Petitioner's assertion does not consider that at the time of filing, a POSA would not have expected that the addition of a heme-containing protein, specifically leghemoglobin, to the composition of Giacino would "only further contribute to the meaty aroma" because it fails to consider the known potential for the development of off-flavors induced by heme.

76. The evidence in the prosecution record of related US 10,039,306 supports the unpredictable effect of heme proteins, such as leghemoglobin, on flavor and aroma. Citing to the Proulx Thesis (*see* EX1148('306 file history), 2715, citing to EX2003(Proulx Thesis)), Patent Owner emphasized that food products with heme could be adversely affected by off-flavors and rancidity, quoting Proulx's work as recognizing that "[f]ortification [with] iron has *a potential negative effect on organoleptic quality* of maize products, in that soluble forms of iron can cause *oxidative rancidity*.'" EX1148('306 file history), 2715. Patent Owner submitted numerous declarations, including by Dr. Keith R. Cadwallader, who stated:

This is a significant discovery since a person having ordinary skill in the art would not have anticipated that the inclusion of a heme protein would have any beneficial effect on flavor. In fact, iron, and specifically heme iron, has been most often associated with *causing*

deleterious off-odor consequences in foods and especially meat products.

77. *Id.*, 2715-2716 (emphasis added). Petitioner's own evidence in the record supports this. *See, e.g.*, EX1028(Calkins), 70 (“[H]eme iron has been thought to be a pro-oxidant that may influence meat flavor due to its reaction to produce radicals that can promote lipid oxidation in biological systems.”); EX1048(Pearson), Abstract (“WOF (Warmed-Over Flavor) is catalyzed by the non-heme iron released from meat pigments during cooking.”)

78. Petitioner asserts that “heme-containing proteins, such as hemoglobin and myoglobin, are naturally present in conventionally obtained meat, yet cooking conventionally obtained meat, which inevitably undergoes some amount of lipid oxidation, does not produce off-flavors.” Pet., 30, footnote 10. Petitioner's assertion is incorrect. In my experience, lipid oxidation in meat products produces off-flavors; for example, lipid oxidation in ground meat products were known to produce off-flavors. *See* EX1048(Pearson), 287. More importantly, Petitioner's assertion equates, without support, lipid oxidation within an actual meat product to lipid oxidation within a food flavor additive composition, when such products are completely different in terms of ingredients and matrix.

79. Petitioner's arguments also ignore that autoxidation can occur in food products without heat during storage, and such autoxidation can form undesirable aromas and flavors before consumption. *See*, ¶¶38-39 above.

80. In addition, lipid oxidation can occur after cooking, producing WOF. *See* ¶40. Petitioner asserts that “although heme-containing proteins can lead to lipid oxidation over time, a POSITA would understand that the food product is likely to be consumed shortly after cooking, before any undesirable lipid oxidation has had a chance to develop.” *Pet.*, 30, footnote 10 (emphasis omitted). I disagree as the assertion fails to account for the combination proposed. Giacino teaches that its compositions are heated to produce a meaty flavor and the compositions may be later added to a food product as a food flavor additive. *See* EX1015(Giacino), 1:60-72, 6:15-31. Petitioner did not consider that food flavor additives are expected to have a reasonable amount of shelf life so that the additives can be added to a food product. If a food flavor additive does not have a sufficient shelf life (because WOF has developed), the additive would be of limited commercial value as it would need to be utilized in a food product immediately after production.

2. Claim 10 is Not Obvious Over Giacino and Brown

81. For claim 10, Petitioner relies on the same reasoning for combining Giacino and Brown as it does for claim 1. *See* *Pet.*, 38-39 (incorporating claim 1

analysis). Thus, Petitioner fails to establish the obviousness of claim 10 for the same reasons discussed above with respect to claim 1. *See* ¶¶65-80.

3. Claims 2-9, 11-12, 14-17, and 20-24 are Not Obvious Over Giacino and Brown

82. Petitioner's Ground 2A also challenges claims 2-9, 11-12, 14-17, and 20-24 as allegedly obvious over Giacino and Brown. Pet., 14. Claims 2-9 and 23-24 depend from claim 1. Claims 11-12, 14-17, and 20-22 depend from claim 10. Thus, claims 2-9, 11-12, 14-17, and 20-24 are not obvious over Giacino and Brown for the same reasons identified above with respect to claims 1 and 10. *See* ¶¶65-80.

C. Ground 2B: Claims 18-19 are Not Obvious Over Giacino, Brown and MacLeod

83. Petitioner's Ground 2B challenges claims 18-19 as allegedly obvious over Giacino, Brown, and MacLeod (EX1024). Pet., 14. Claims 18-19 depend from claim 10. The addition of MacLeod as a reference does not alter the non-obviousness of claim 10, and thus dependent claims 18-19. *See* ¶¶65-80.

D. Ground 3A: Claims 1-2, 4-7, 9-12, 14-15, and 20-24 are Not Obvious Over Giacino, Conrad and Crane

84. Petitioner's Ground 3A challenges claims 1-2, 4-7, 9-12, 14-15, and 20-24 as allegedly obvious over the combination of Giacino, Conrad (EX1013), and Crane (EX1014). Pet., 14. As discussed below, the challenged claims are not obvious at least because Petitioner has not provided evidence showing that Crane

is analogous art, nor that a POSA would have been motivated to combine Giacino with Conrad, and then further with Crane.

1. Crane is not analogous art

85. I am informed by counsel that a reference qualifies as prior art for obviousness determination only when it is analogous to the claimed invention. I understand that a reference is analogous art when the reference is either (1) from the same field of endeavor as the patent, or (2) if not within the same field of endeavor, is reasonably pertinent to the particular problem with which the inventor is involved.

86. First, in my opinion, Crane is not “from the same field of endeavor” as the ’096 patent. The ’096 patent states that the field of its invention “relates to food products.” EX1001(’096 patent), 1:22-25. Petitioner also acknowledges that “[t]he ’096 patent claims are directed to food-flavor additive compositions that ‘modulate the flavor and/or aroma of consumable food products.’” Pet., 3. Crane, on the other hand, is expressly directed to “methods of producing recombinant functional heme-binding proteins...and methods of identifying agents that modulate the activity of heme-binding proteins.” EX1014(Crane), Abstract. Crane does not mention flavor additives or food products generally nor does it describe methods for preparing such additives and food products. Thus, I agree with the Board that Crane is not “from the same field of endeavor” as the ’096 patent,

because “the ’096 patent is directed to food products while Crane, on the other hand, relates to ‘methods for producing recombinant functional heme-binding proteins.” Institution Decision, 35.

87. Second, it is also my opinion that a POSA would not have found Crane “reasonably pertinent to the particular problem with which the inventor is involved.” As described in the ’096 patent, in my opinion, the problem solved by the inventors was to provide meat-like-food products that overcome the limitations of prior-art meat substitutes, “which largely fail to replicate the experience of cooking and eating meat,” “fail[] to cause a shift to a vegetarian diet,” and lack “appeal to the larger consumer segment accustomed to eating meat.”

EX1001(’096 patent), 1:46-62. Crane relates to generating heme-binding proteins with complete heme incorporation, which can be used as an oxygen carrier for blood transfusion, for use in screening assays, and production of bioethanol and chemical feedstocks for commercial use. *See* EX1014(Crane), [0003]-[0005], [0062], [0063], [0066]. I further agree with the Board that Crane is aimed at producing recombinant heme-binding proteins with complete heme incorporation for functional purposes such as improved “electron transfer, transport and storage of oxygen, production and sensing of nitric oxide, decomposition of reactive oxygen species, catalytic oxidation of substrates, signal transduction and control of gene expression.” Institution Decision, 36 (citing EX1014(Crane), [004, [0007])).

A POSA interested in replicating the experience of cooking meat would not have understood this to be reasonably pertinent to improving the flavor of food products, much less food products that replicate meat. Thus, I agree with the Board that Crane is not “reasonably pertinent” to the problem faced by the inventors of the ’096 patent.

2. No reason to combine Giacino, Conrad, and Crane with a reasonable expectation of success

88. Petitioner’s obviousness ground relies on combining Giacino with a blood fraction of Conrad (*see* Pet., 47), and then swapping that blood fraction with an entirely different component—a heme-containing protein produced recombinantly using the methods disclosed in Crane (*see id.*, 48-49).

89. First, it is my opinion that Petitioner fails to sufficiently explain why a POSA would have sought to incorporate the blood fraction of Conrad into a flavor additive composition like Giacino. Specifically, Giacino relates to “artificial meaty flavoring compositions,” which can be used to flavor food products. EX1015(Giacino), 1:19-20. In contrast, Conrad relates to a mixed meat product, where, due to the general expense of meat itself, “some” of the meat is replaced with a wheat product, which can include actual animal blood or a fraction of blood. EX1013(Conrad), 1:25-40. Thus, Conrad’s mixed meat product provides for a cheaper product made from actual meat and wheat having meat blood, with Conrad teaching that the flavor and color lost from extending the actual meat with wheat

can be compensated for by adding meat blood to the wheat. Given the distinct product and purpose of Conrad (i.e., the addition of meat blood to meat itself to compensate for dilution in flavor caused by the wheat extender), Petitioner does not explain why a POSA—who is starting not with meat, but with a concentrated flavor additive of Giacino having a flavor of meat—would dilute the flavor additive by adding an animal blood fraction and expect that blood fraction to impart a desirable flavor on Giacino’s flavor additive, which is made from a different compositional matrix.

90. Furthermore, it is also my opinion that Petitioner fails to sufficiently explain why a POSA would then take the Giacino flavoring composition modified with Conrad’s blood fraction, and substitute out the blood fraction with Crane’s recombinant heme-containing protein, with any expectation that the recombinant protein of Crane would impart the same flavor characteristics as the blood fraction of Conrad.

91. I understand that Petitioner asserts that a POSA would have substituted the blood fraction of Conrad for the recombinant heme-containing protein of Crane because Crane discloses “commercial applications” that would appeal to individuals who have concerns about consuming animal products. *See* Pet., 48. This argument is not supported. Just because Crane notes that its recombinant proteins have “commercial applications” does not necessarily mean

that its heme-containing proteins are suitable for inclusion in a food product, and that the proteins would impart the same flavor characteristics of the animal product (blood), from which the protein is natively found. As I noted above, Crane's focus is on producing recombinant heme-proteins with complete heme incorporation for improved functional purposes that are unrelated to food and food flavor. See ¶¶85-87.

92. Petitioner further argues that using Crane's recombinant heme proteins "would have also been a cost-effective option and would have produced the proteins with a high degree of purity." Pet., 48. This argument is also not supported. Crane does not state that the recombinant heme proteins are "a cost-effective option" relative to Conrad's blood. Crane's reference to its "simple and inexpensive method" is in comparison to *other recombinant production methods*. EX1014(Crane), [0004]-[0008], [0043], [0085]. Petitioner provides no evidence that a POSA would have understood the recombinantly-produced heme-proteins of Crane would somehow "lower[] costs" relative to the naturally-occurring, animal-obtained blood used in Conrad.

93. Petitioner further contends that a POSA would have been motivated to replace Conrad's animal blood with Crane's recombinant heme proteins and add it to Giacino's flavor compositions because it would improve the compositions' nutrition. See Pet., 48-49. However, neither Conrad nor Crane discuss any

nutritional benefit incurred from the consumption of animal blood or recombinant heme proteins. In addition, Giacino expresses no desire that its flavor additive compositions are intended to impart any nutritional benefit in the first place.

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)”); *see also* ¶¶44-47.

94. Lastly, as I explained above, heme-containing proteins were known to have detrimental effects to flavor, which undermines Petitioner’s assertions that a POSA would have been motivated to combine Giacino, Conrad, and Crane as proposed with the expectation that it would further improve the meat flavor of Giacino’s flavor additive. *See* ¶¶75-80.

3. Claim 10

95. For claim 10, Petitioner relies on the same reasoning for combining Giacino, Conrad and Crane as for claim 1. *See* Pet., 53 (incorporating claim 1 analysis). Thus, Petitioner fails to establish the obviousness of claim 10 for the same reasons discussed above with respect to claim 1. *See* ¶¶84-94.

4. Claims 2, 4-7, 9, 11-12, 14-15, and 20-24

96. Petitioner's Ground 3A also challenges claims 2, 4-7, 9, 11-12, 14-15, and 20-24 as allegedly being obvious over Giacino, Conrad, and Crane. Pet., 14. Claims 2, 4-7, 9, and 23-24 depend from claim 1. Claims 11-12, 14-15, and 20-22 depend from claim 10. Thus, claims 2, 4-7, 9, 11-12, 14-15, and 20-24 are not rendered obvious over Giacino, Conrad, and Crane for the same reasons identified above with respect to claims 1 and 10. *See* ¶¶84-94.

E. Ground 3B-3D: Claims 3, 8, 16, 17 and 18-19 are Not Obvious Over Giacino, Conrad and Crane, and Further In View Of Proulx, Perret or MacLeod

97. Petitioner's Ground 3B challenges claims 3 and 16 as allegedly obvious over Giacino, Conrad, Crane, and Proulx (EX1019). Pet., 14. Claims 3 and 16 depend from claims 1 and 10, respectively. Thus, claims 3 and 16 are not obvious over Giacino, Conrad, Crane, and Proulx for the same reasons identified above with respect to claims 1 and 10. The addition of Proulx as a reference does not alter the non-obviousness of claims 1 or 10, and thus dependent claims 3 and 16. *See* ¶¶84-94.

98. Petitioner's Ground 3C challenges claims 8 and 17 as allegedly obvious over Giacino, Conrad, Crane, and Perret (EX1020). Pet., 14. Claims 8 and 17 depend from claims 1 and 10, respectively. Thus, claims 8 and 17 are not obvious over Giacino, Conrad, Crane, and Perret for the same reasons identified above with respect to claims 1 and 10. The addition of Perret as a reference does

not alter the non-obviousness of claims 1 or 10, and thus dependent claims 3 and 16. *See* ¶¶84-94.

99. Petitioner’s Ground 3D challenges claims 18-19 as allegedly obvious over Giacino, Conrad, Crane, and MacLeod. Pet., 14. Claims 18-19 depend from claim 10. Thus, claims 18-19 are not obvious over Giacino, Conrad, Crane, and MacLeod for the same reasons identified above with respect to claim 10. The addition of MacLeod as a reference does not alter the non-obviousness of claims 1 or 10, and thus dependent claims 3 and 16. *See* ¶¶84-94.

F. Ground 4A: Claims 1-7, 9-12, 14-16, and 20-24 are Not Obvious Over Giacino, Proulx and Conrad

100. Petitioner’s Ground 4A swaps out Crane for Proulx and asserts the same rationale for combining the references as for the combination of Giacino, Conrad, and Crane in Ground 3A. Pet., 57-58. Specifically, Petitioner asserts that a POSA “would have been motivated to modify Giacino’s meaty flavoring compositions by adding an isolated heme-containing protein (*e.g.*, isolated leghemoglobin) to fortify the compositions’ with heme iron (as taught by Proulx) and enhance meaty flavor (as taught by Conrad)” in order to “encourage consumption by consumers who ordinarily enjoy consuming conventionally sourced meat.” *Id.* I disagree with Petitioner’s assertions.

101. First, regarding fortification, nothing in Giacino suggests that its flavor additives are intended to provide nutritional content to a food product.

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)”); *see also* ¶93.

102. Second, with respect to enhancing meaty flavor, for the reasons I discuss above (¶¶88-94), Petitioner does not explain why a POSA would expect that the addition of Conrad’s blood fraction, which Conrad teaches is added to compensate for lost flavor and color in meat extended with wheat, would only enhance meaty flavor in a different product having a different compositional matrix, i.e., the concentrated flavor additive of Giacino. Moreover, Petitioner does not explain why a POSA would then equate that same effect to extend to the soy leghemoglobin of Proulx—a *plant* heme-protein that is added to a tortilla product not for flavor purposes.

1. Claim 10

103. For independent claim 10, Petitioner relies on the same reasoning for combining Giacino, Proulx and Conrad it advances for claim 1. *See* Pet., 63 (incorporating claim 1 analysis). Thus, Petitioner fails to establish the obviousness of claim 10 for the same reasons discussed above with respect to claim 1. *See* ¶¶100-102.

2. Claims 2-7, 9, 11-12, 14-16, and 20-24

104. Petitioner's Ground 3A also challenges dependent claims 2-7, 9, 11-12, 14-16, and 20-24 as allegedly being obvious over Giacino, Proulx, and Conrad. Pet., 57. Claims 2-7, 9, and 23-24 depend from independent claim 1. Claims 11-12, 14-16, and 20-22 depend from independent claim 10. Thus, these claims are not rendered obvious over Giacino, Proulx, and Conrad for the same reasons identified above with respect to claims 1 and 10. *See* ¶¶100-102.

G. Grounds 4B-4C: Claims 8, 17, and 18-19 are Not Obvious Over Giacino, Proulx and Conrad, and Further In View Of Perret or MacLeod

105. Petitioner's Ground 4B challenges dependent claims 8 and 17 as allegedly obvious over Giacino, Proulx, Conrad, and Perret. Pet., 14. Claims 8 and 17 depend from independent claims 1 and 10, respectively. Thus, these claims are not obvious over Giacino, Proulx, Conrad, and Perret for the same reasons identified above with respect to claims 1 and 10. The addition of Perret as a reference does not alter the non-obviousness of claims 1 or 10, and thus dependent claims 8 and 17. *See* ¶¶100-102.

106. Petitioner's Ground 4C challenges dependent claims 18-19 as allegedly obvious over Giacino, Proulx, Crane, and MacLeod. Pet., 14. Claims 18-19 depend from independent claim 10. Thus, these claims are not obvious over Giacino, Proulx, Crane, and MacLeod for the same reasons identified above with respect to claim 10. The addition of MacLeod as a reference does not alter the

non-obviousness of claims 1 or 10, and thus dependent claims 18-19. *See* ¶¶100-102.

VIII. CONCLUSION

107. In signing this declaration, I understand that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I acknowledge that I may be subject to cross-examination in this case. If cross-examination is required of me, I will appear for cross-examination during the time allotted for cross-examination.

108. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that all of my statements are made with the knowledge that willful false statements are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: September 29, 2023

By: /Michael C. Qian/
Michael C. Qian, Ph.D.

IX. APPENDIX A

Exhibit No.	Description
EX1001	U.S. Patent No. 9,943,096
EX1003	Declaration of Rodrigo Tarté, Ph.D.
EX1005	Declaration of Robert McGorin, Ph.D.
EX1012	International Pub. No. WO 2013/010042 A1 to Brown et al. published January 17, 2013
EX1013	U.S. Patent No. 4,818,557 to Conrad, issued April 4, 1989
EX1014	U.S. Patent Publication No. 2011/0287467 A1 to Crane et al., published November 24, 2011
EX1015	U.S. Patent No. 3,519,437 to Giacino, issued July 7, 1970
EX1017	Mottram, Flavour Formation in Meat and Meat Products: A Review, 62 FOOD CHEM. 415-24 (1998)
EX1019	Proulx & Reddy, Iron Bioavailability of Hemoglobin from Soy Root Nodules Using a Caco-2 Cell Culture Model, 54 J. AGRIC. & FOOD CHEM. 1518-22 (2006)
EX1020	U.S. Patent No. 3,365,306 to Perret, issued January 23, 1968
EX1024	MacLeod et al., Natural and Simulated Meat Flavors (with Particular Reference to Beef), 14 CRITICAL REVIEWS IN FOOD SCI. & NUTRITION 309-437 (1981)
EX1026	Dwivedi & Brockman, Meat Flavor, 5 CRITICAL REVIEWS IN FOOD SCI. & NUTRITION 487-535 (1981)
EX1028	Calkins & Hodgen, A Fresh Look at Meat Flavor, 77 MEAT SCI. 63-80 (2007)
EX1033	Reineccius, FLAVOR CHEMISTRY AND TECHNOLOGY CH. 5 (2d ed. 2006)
EX1038	Manley, Process Flavors, in SOURCE BOOK OF FLAVORS 139-54 (G. Reineccius ed., 2d ed. 1999)
EX1039	McGorin, Character-Impact Flavor and Off-Flavor Compounds in Foods, in FLAVOR, FRAGRANCE, AND ODOR ANALYSIS 207-62 (R. Marsili ed., 2d ed. 2012)
EX1043	Dreher et al., GC–Olfactometric Characterization of Aroma Volatiles from the Thermal Degradation of

	Thiamin in Model Orange Juice, 51 J. AGRIC. FOOD CHEM. 3097-102 (2003)
EX1045	Hofmann & Schieberle, Evaluation of the Key Odorants in a Thermally Treated Solution of Ribose and Cysteine by Aroma Extract Dilution Techniques, 43 J. AGRIC. FOOD CHEM. 2187-2194 (1995)
EX1048	Pearson & Gray, Mechanism Responsible for Warmed-Over Flavor
EX1129	Mottram, Volatile Compounds from the Reaction of Cysteine, Ribose, and Phospholipid in Low-Moisture Systems, 43 J. AGRIC. FOOD CHEM. 984-88 (1995)
EX1136	Whistler & Daniel, Carbohydrates, in FOOD CHEMISTRY (O. Fennema, ed., 2d ed., revised and expanded, 1985)
EX1145	U.S. Provisional No. 61/908,634, filed November 25, 2013
EX1148	Prosecution History of U.S. Patent No. 10,039,306 to Vrljic et al.
EX1151	Ames, Control of the Maillard Reaction in Food Systems, 1 TRENDS IN FOOD SCI. & TECH. 150-54 (1990)
EX2002	Goldfine, “A brief history of Impossible Foods: how ‘bleeding’ plant-based burgers started a food industry trend,” The Business of Business, https://www.businessofbusiness.com/articles/impossible-foods-plant-based-burgers-milk-food-industry-trend-data/ , Last Accessed July 27, 2022
EX2003	Proulx, “Diversified strategies for improving iron bioavailability of maize” Ph.D. Thesis, Iowa State University, 2007
EX2010	U.S. Patent Publication No. 2012/0093994 to Hseih et al.
EX2016	Claim Construction Order, Impossible Foods Inc. v. Motif Foodworks, Inc., Case No. 1:22-cv-00311-WCB (D. Del. Aug. 15, 2023)
EX2031	Curriculum Vitae of Michael C. Qian, Ph.D.
EX2032	Tarté Deposition Transcript
Paper No. 2	Petition
Paper No. 23	Institution Decision