UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MOTIF FOODWORKS, INC.,

Petitioner,

v.

IMPOSSIBLE FOODS INC.,
Patent Owner.

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

"METHODS AND COMPOSITIONS FOR AFFECTING THE FLAVOR AND AROMA PROFILE OF CONSUMABLES"

Inter Partes Review No. 2023-00206

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,943,096 UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. §§ 42.100 *et seq*.

TABLE OF CONTENTS

Page

TABLE OF EXHIBITS viii
LIST OF CHALLENGED CLAIMS xviii
I. INTRODUCTION 1
II. STATE OF THE ART 1
A. Meat Flavor Chemistry 1
B. Simulated Meat Flavoring Compositions 2
C. Consumers' Concerns About Meat 2
D. Recombinant Technology 3
III. The '096 Patent 3
A. Background 3
B. Prosecution History 4
C. Person of Ordinary Skill in the Art 5
IV. PRIORITY DATE 5
V. CLAIM CONSTRUCTION 10
A. "contains no animal products" 10
B. "food flavor additive composition" 11
C. "a compound" 12
VI. STATEMENT OF RELIEF REQUESTED 13
A. Identification of Challenge (37 C.F.R. §§ 42.104(b)) 13
B. Ground of Challenge (37 C.F.R. § 42.204(b)(2)) 13
VII. SUMMARY OF PRIOR ART 14
A. "Brown" 14
B. "Giacino" 16
C. "Conrad" 16
D. "Crane" 16
E. "Proulx" 17
F. "Perret" 17

G. "MacLeod" 17

H. Cited Non-Patent References Are Printed Publications Publicly Available Before the Priority Date of the Challenged Claims 18

VIII. GROUND 1: BROWN (Anticipation) 20

A. Claim 1 20

1. Limitation 1[pre] ("food flavor additive composition") 20

2. Limitation 1[a] ("isolated heme-containing protein") 22

3. Limitation 1[b] ("[sugar] compound selected from…") 22

4. Limitation 1[c] ("[sulfur] compound selected from…") 22

5. Limitation 1[d] ("contains no animal products") 23

6. Limitation 1[e] ("at least two volatile compounds which have a meat-associated aroma") 23

B. Claim 2 ("heme-containing protein is selected from the group…") 24

C. Claim 3 ("amino acid sequence having…") 24

D. Claims 4, 24 ("is a powder or a liquid composition") 24

E. Claim 5 ("heme-containing protein is a plant…") 24

F. Claim 7 ("further comprising…a compound selected from…") 25

G. Claim 8 ("further comprising…an oil selected from…") 25

H. Claim 9 ("further comprising…[an] albumin or a globulin") 25

I. Claim 23 ("adding to the consumable food product a food flavor additive composition of claim 1; and heating [it]…") 25

IX. GROUNDS 2A-2B: GIACINO, BROWN, MACLEOD 26

A. Overview of Giacino and Brown 26

B. Claim 1 27

1. Limitation 1[pre] 27

2. Limitation 1[a] 28

3. Limitation 1[b] 31

4. Limitation 1[c] 31

5. Limitation 1[d] 32

6. Limitation 1[e] 33
C. Claims 2, 15 34
D. Claims 3, 16 34
E. Claims 4, 24 35
F. Claim 5 36
G. Claims 6, 22 ("further comprising…an extract of hydrolysate selected from…") 36
H. Claim 7 36
I. Claims 8, 17 36
J. Claims 9, 22 37
K. Claim 10 ("food flavor additive composition prepared by a process of…") 38
1. Limitations 10[pre], 10[a], 10[b], 10[c], 10[e] 38
2. Limitation 10[d] ("heating…to at least 150°C for at least 1 minute") 38
3. Limitations 10[f] ("meaty flavor and/or meaty aroma" "during … and … after the heating") 39
L. Claim 11 ("further comprises a compound selected from the group…") 39
M. Claim 12 ("compound is detectable in the headspace") 40
N. Claim 14 ("heme-containing protein is present in an amount…") 40
O. Claim 18 ("further comprising…an emulsifier [or] a gelling agent") 41
P. Claim 19 ("further comprising adding an emulsifier and a gelling agent…prior to the heating") 42
Q. Claim 20 ("heme flavor reaction mixture is an aqueous solution") 43
R. Claim 21 ("heme flavor reaction mixture is an oil-based mixture") 43
S. Claim 23 44

X. GROUNDS 3A-3D: GIACINO, CONRAD, CRANE, PROULX, PERRET, MACLEOD....44
A. Overview of Giacino, Conrad, and Crane....44
B. Claim 1....46
1. Limitation 1[pre], 1[b], 1[c]....46
2. Limitation 1[a]....46
3. Limitation 1[d]....50
4. Limitation 1[e]....50
C. Claims 2, 15....50
D. Claims 3, 16....51
E. Claims 4, 24....52
F. Claim 5....52
G. Claims 6-7, 9, 22....52
H. Claims 8, 17....52
I. Claim 10....53
1. Limitations 10[pre], 10[a], 10[b], 10[c], 10[e]....53
2. Limitation 10[d]....53
3. Limitations 10[f]....53
J. Claim 11....54
K. Claim 12....54
L. Claim 14....54
M. Claim 18....55
N. Claim 19....56
O. Claims 20-21....56
P. Claim 23....56
XI. GROUNDS 4A-4B: GIACINO, PROULX, CONRAD, PERRET, MACLEOD....57
A. Overview of Giacino, Proulx, and Conrad....57
B. Claim 1....58
1. Limitation 1[pre], 1[b], 1[c]....58

2. Limitation 1[a] 58
3. Limitation 1[d] 62
4. Limitation 1[e] 62
C. Claims 2, 15 62
D. Claims 3, 16 62
E. Claims 4, 24 63
F. Claim 5 63
G. Claims 6-7, 9, 22 63
H. Claims 8, 17 63
I. Claim 10 63
1. Limitations 10[pre], 10[a], 10[b], 10[c], 10[e] 63
2. Limitation 10[d] 64
3. Limitations 10[f] 64
J. Claim 11 64
K. Claim 12 64
L. Claim 14 65
M. Claims 18-19 65
N. Claims 20-21 65
O. Claim 23 65
XII. SECONDARY CONSIDERATIONS 66
A. No "Surprising" or "Unexpected" Results Support Patentability 66
B. PO's Volatiles Are Not Novel 67
C. A POSITA Would Not Be Discouraged from Adding a Heme Protein to a Meat Replica 68
D. Other Objective Indicia 69
1. No Long Felt But Unmet Need, Skepticism, or Failure of Others 69
2. No Nexus to Commercial Success 69
XIII. INSTITUTION WOULD BE EQUITABLE (§325(d)) 70

XIV. REQUIREMENTS FOR INTER PARTES REVIEW (37 C.F.R §§ 42.101, 42.104, and 42.108) 71

XV. CONCLUSION 71

XVI. MANDATORY NOTICES 72

A. Real Party-in-Interest (37 C.F.R. § 42.8(b)(1)) 72

B. Related Matters (37 C.F.R. § 42.8(b)(2)) 72

C. Lead and Back-Up Counsel (37 C.F.R. § 42.8(b)(3)) and Service Information (37 C.F.R. § 42.8(b)(3)-(4)) 72

D. Payment of Fees (37 C.F.R. § 42.15(a)) 73

TABLE OF AUTHORITIES

Page

Cases

Application of Ruschig,
379 F.2d 990 (C.C.P.A. 1967) 9

Ariad Pharms., Inc. v. Eli Lilly & Co.,
598 F.3d 1336 (Fed. Cir. 2010) 7

D Three Enterprises, LLC v. SunModo Corp.,
890 F.3d 1042 (Fed. Cir. 2018) 6

Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.,
800 F.3d 1375 (Fed. Cir. 2015) 6

KSR Intern. Co. v. Teleflex Inc.,
127 S. Ct. 1727 (U.S. 2007) 5

Statutes

35 U.S.C. §102(a)(1) 6

35 U.S.C. §102(b)(1) 15

35 U.S.C. §102(b)(1)(A) 15

35 U.S.C. §102(b)(1)(B) 15

35 U.S.C. §102(e) 6, 15

37 C.F.R. § 42.10(b) 72

37 C.F.R. § 42.15(a) 73

MPEP §2153.01(a) 15

MPEP 2136.04 15

Other Authorities

"*Iron Bioavailability of Hemoglobin from Soy Root Nodules Using a Caco-2 Cell Culture Model*" ("Proulx") was published on January 31, 2006 17

"*Natural and Simulated Meat Flavors (With Particular Reference to Beef)*," by Glesni MacLeod ("MacLeod") 17

Critical Reviews in Food Science and Nutrition on August 31, 1981 19

Journal of Agricultural and Food Chemistry on January 31, 2006 18

TABLE OF EXHIBITS

Exhibit No.	Description
EX1001	U.S. Patent No. 9,943,096
EX1002	Prosecution History of U.S. 9,943,096
EX1003	Declaration of Rodrigo Tarté, Ph.D.
EX1004	Curriculum vitae of Rodrigo Tarté, Ph.D.
EX1005	Declaration of Robert McGorrin, Ph.D.
EX1006	Curriculum vitae of Robert McGorrin, Ph.D.
EX1007	Declaration of Carl Batt, Ph.D.
EX1008	Curriculum vitae of Carl Batt, Ph.D.
EX1009	Declaration of Sylvia Hall-Ellis, Ph.D.
EX1010	Curriculum vitae of Sylvia Hall-Ellis, Ph.D.
EX1011	Exhibits to Declaration of Sylvia Hall-Ellis, 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

Exhibit No.	Description
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
EX1021	U.S. Patent Publication No. 2008/0268112 A1 to Rolan et al., published October 30, 2008
EX1022	U.S. Patent Publication No. 2008/0026128 A1 to Yamaguchi et al., published January 31, 2008
EX1024	MacLeod et al., *Natural and Simulated Meat Flavors (with Particular Reference to Beef)*, 14 CRITICAL REVIEWS IN FOOD SCI. & NUTRITION 309-437 (1981)
EX1025	U.S. Provisional No. 61/751,816, filed January 11, 2013
EX1026	Dwivedi & Brockman, *Meat Flavor*, 5 CRITICAL REVIEWS IN FOOD SCI. & NUTRITION 487-535 (1981)
EX1027	Pearson & Gillett, PROCESSED MEATS Ch. 3 (3d ed. 1996)
EX1028	Calkins & Hodgen, *A Fresh Look at Meat Flavor*, 77 MEAT SCI. 63-80 (2007)
EX1029	Williamson et al., *Red Meat in the Diet*, 30 NUTRITION BULLETIN 323-55 (2005)
EX1030	Garrocho-Villegas et al., *Plant Hemoglobins: What We Know A Six Decades after Their Discovery*, 398 GENE 78-85 (2007)
EX1031	McGorrin, *The Significance of Volatile Sulfur Compounds in Food Flavors*, *in* VOLATILE SULFUR COMPOUNDS IN FOOD 3-31 (Qian et al., eds., 2011)

Exhibit No.	Description
EX1032	Cerny & Davidek, *Formation of Aroma Compounds from Ribose and Cysteine during the Maillard Reaction*, 51 J. ARGRIC. FOOD CHEM. 2714-21 (2003)
EX1033	Reineccius, FLAVOR CHEMISTRY AND TECHNOLOGY CH. 5 (2d ed. 2006)
EX1034	Reineccius, FLAVOR CHEMISTRY AND TECHNOLOGY CH. 9 (2d ed. 2006)
EX1035	Verbeke & Viaene, *Ethical Challenges for Livestock Production: Meeting Consumer Concerns about Meat Safety and Animal Welfare*, 12 J. OF AGRIC. & ENV'T ETHICS 141-51 (2000)
EX1036	Pimentel & Pimentel, *Sustainability of Meat-Based and Plant-Based Diets and the Environment*, 78 AM. J. CLINICAL NUTRITION 660S-63S (2003)
EX1038	Manley, *Process Flavors*, *in* SOURCE BOOK OF FLAVORS 139-54 (G. Reineccius ed., 2d ed. 1999)
EX1039	McGorrin, *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)
EX1046	Goto et al., *Iron Fortification of Rice Seed by the Soybean Ferritin Gene*, 17 NATURE BIOTECH. 282-86 (1999)

Exhibit No.	Description
EX1047	Zhu & Cadwallader, *Streamlined Approach for Careful and Exhaustive Aroma Characterization of Aged Distilled Liquo*rs, 3 Food Chem.: X 100038 (2019)
EX1048	Pearson & Gray, *Mechanism Responsible for Warmed-Over Flavor in Cooked Meat*, *in* THE MAILLARD REACTION IN FOODS AND NUTRITION 287-300 (Waller & Feather eds., 1983)
EX1049	Hofmann & Schieberle, *Quantitative Model Studies on the Effectiveness of Different Precursor Systems in the Formation of the Intense Food Odorants 2-Furfurylthiol and 2-Methyl-3-furanthiol*, 46 J. AGRIC. FOOD CHEM. 235-41 (1998)
EX1050	Jahreis et al., *Legume Flours: Nutritionally Important Sources of Protein and Dietary Fiber*, 63 ERNÄHRUNGS UMSCHAU INT'L 36-42 (2016) (Original German)
EX1051	Hofmann et al., *Model Studies on the Oxidative Stability of Odor-Active Thiols Occurring in Food Flavors*, 44 J. AGRIC. FOOD CHEM. 251-55 (1996)
EX1052	GRAS Notice No. 737: GRAS Notification for Soy Leghemoglobin Protein Preparation Derived from Pichia Pastoris, submitted by Impossible Foods Inc. (Oct. 2, 2017), *available at* https://www.fda.gov/media/124351/download
EX1056	Klesk & Qian, *Aroma Extract Dilution Analysis of Cv. Marion (*Rubus spp. hyb*) and Cv. Evergreen (*R. laciniatus L.*) Blackberries*, 51 J. AGRIC. FOOD CHEM. 3436-41 (2003)
EX1057	Krumina-Zemture et al., *Amino Acid and Dietary Fibre Content of Pea an Buckwheat Flours*, RESEARCH FOR RURAL DEVELOPMENT 2016 VOL. 1, 84-90
EX1059	Jahreis et al., *Legume Flours: Nutritionally Important Sources of Protein and Dietary Fiber*, 63 ERNÄHRUNGS UMSCHAU INT'L 36-42 (2016) (English Version)

Exhibit No.	Description
EX1060	Marchand et al., *Possible Mechanism for Involvement of Cysteine in Aroma Production in Wine*, 50 J. AGRIC. & FOOD CHEM. 6160-64 (2002)
EX1064	Splivallo et al., *Bacteria Associated with Truffle-Fruiting Bodies Contribute to Truffle Aroma*, 17 ENV'T MICROBIOLOGY 2647-60 (2015)
EX1067	Meng & Cloutier, *Gelatin and Other Proteins for Microencapsulation*, *in* MICROENCAPSULATION IN THE FOOD INDUSTRY 227-39 (Gaonkar et al., eds., 2014)
EX1070	Karaca, *Nanostructured Proteins*, *in* FOOD STRUCTURE AND FUNCTIONALITY 181-200 (Galanakis ed., 2021)
EX1071	Flutto, *Pectin|Properties and Determination*, *in* ENCYCLOPEDIA OF FOOD SCIENCES & NUTRITION 4440-49 (2d ed. 2003)
EX1072	Green, *Headspace Analysis|Static*, *in* ENCYCLOPEDIA OF ANALYTICAL SCIENCE 229-36 (2d ed. 2005)
EX1073	Santana et al., *Evidence that the Plant Host Synthesizes the Heme Moiety of Leghemoglobin in Root Nodules*, 116 PLANT PHYSIOLOGY 1259-69 (1998)
EX1074	dos Santos & Grenha, *Polysaccharide Nanoparticles for Protein and Peptide Delivery: Exploring Less-Known Materials*, 98 Advances in Protein Chem. and Structural Biology 223-61 (2015)
EX1078	U.S. Patent No. 8,802,399 to Reutter-Maier et al., issued August 12, 2014
EX1079	U.S. Patent No. 6,218,168 to Leinfelder et al., issued April 17, 2001
EX1080	U.S. Patent No. 4,760,139 to Feniou et al., issued July 26, 1988
EX1081	U.S. Patent No. 8,609,890 to Hu, issued December 17, 2013

Exhibit No.	Description
EX1083	Buffo & Han, *Edible Films and Coatings from Plant Origin Proteins*, *in* FOOD SCIENCE & TECHNOLOGY, INNOVATIONS IN FOOD PACKAGING 277-300 (2005)
EX1084	Fellows, FOOD PROCESSING TECHNOLOGY: PRINCIPLES AND PRACTICE Ch. 6 (3d ed. 2009)
EX1085	WACKER CHEMIE AG, *Fermopure – Plant-Based L-cystine and L-cysteine* (2021), available at https://www.wacker.com/cms/en-us/products/brands/fermopure/fermopure.html
EX1087	Williams, *Nutritional Composition of Red Meat*, 64 NUTRITION & DIETETICS: J. OF THE DIETITIANS ASSOC. OF AUSTL. S113 (2007)
EX1089	Yebra-Biurrun, *Food and Nutritional Analysis|Sweeteners*, *in* ENCYCLOPEDIA OF ANALYTICAL SCIENCE (3d ed. 2013)
EX1093	Vauthey et al., *Structured Fluids as Microreactors for Flavor Formation by the Maillard Reaction*, 48 J. AGRIC. & FOOD CHEM. 4808-16 (2000)
EX1095	Withycombe & Mussinan, *Identification of 2-Methyl-3-Furanthiol in the Steam Distillate from Canned Tuna Fish*, 53 J. FOOD SCI. 658 (1988)
EX1096	Kerscher & Grosch, *Quantification of 2-Methyl-3-furanthiol, 2-Furfurylthiol, 3-Mercapto-2-pentanone, and 2-Mercapto-3-pentanone in Heated Meat*, 46 J. AGRIC. FOOD CHEM. 1954-58 (1958)
EX1098	Zyzak et al., *Investigation into the Sensorial and Analytical Differences of Traditional Hamburgers Versus the Plant-Based Analogues*, presentation at ACS Fall 2021, *available at* https://acs.digitellinc.com/acs/sessions/169689/view
EX1099	Mottram, *The Maillard Reaction: Source of Flavour in Thermally Processed Foods*, *in* FLAVOURS AND FRANGRANCES 269-83 (Berger ed., 2007)

Exhibit No.	Description
EX1100	Ulrich et al., *Investigation of the Boiled Potato Flavor by Human Sensory and Instrumental Methods*, 77 AM. J. POTATO RSCH. 111-17 (2000)
EX1101	Protein Sequence BLAST Results, *from* NAT'L LIBR. MED.: BLAST, https://blast.ncbi.nl.nih.gov/Blast.cgi
EX1106	*Peas, green, raw*, FoodData Central, U.S. DEP'T OF AGRIC., https://fdc.nal.usda.gov/fdc-app.html#/food-details/170419/nutrients
EX1107	*What Gives Meat its Color?*, EXPLORATORIUM: SCIENCE OF COOKING, https://www.exploratorium.edu/cooking/meat/INT-what-meat-color.html
EX1108	*Cystein,* PUBCHEM, https://pubchem.ncbi.nlm.nih.gov/compound/5862
EX1109	*Maltodextrin*, PUBCHEM, https://pubchem.ncbi.nlm.nih.gov/compound/Maltodextrin-dextrose-equivalent-10-15
EX1110	*Thiamine*, PUBCHEM, https://pubchem.ncbi.nlm.nih.gov/compound/1130
EX1111	*Ribose*, PUBCHEM, https://pubchem.ncbi.nlm.nih.gov/compound/D-Ribose
EX1112	*Sucrose*, PUBCHEM, https://pubchem.ncbi.nlm.nih.gov/compound/Sucrose
EX1113	*Organoleptic*, COLLINS, https://www.collinsdictionary.com/us/dictionary/english/organoleptic

Exhibit No.	Description
EX1114	*Sniffing Out which Plant-Based Burgers Smell the Most Like Real Beef*, AM. CHEM. SOC'Y, https://www.acs.org/content/acs/en/pressroom/newsreleases/2021/august/sniffing-out-which-plant-based-burgers-smell-the-most-like-real-beef.html
EX1115	d'Estries, *Science Reveals Which Plant-Based Burger Smells Closest to the Real Thing*, TREEHUGGER, https://www.treehugger.com/science-reveals-plant-based-burger-smells-5200260
EX1116	Second Amended Complaint for Damages and Injunctive Relief, *Impossible Foods Inc. v. Motif Foodworks, Inc.*, Case No. 1:22-cv-00311-CFC, D.I. 22 (D. Del. Sept. 7, 2022)
EX1118	Wang et al., *Reinvestigation of 2-acetylthiazole Formation Pathways in the Maillard Reaction*, 345 FOOD CHEM. 128761 (2021)
EX1119	Boelens & Gemert, *Volatile Character-Impact Sulfur Compounds and Their Sensory Properties*, 18 PERFURMER & FLAVORIST 29-39 (1993)
EX1120	Adam McQueen, *Beyond Meat vs. Impossible Foods: The Very Real Battle Between the Biggest 'Fake-Meat' Competitors*, KLUE, https://klue.com/blog/beyond-meat-vs-impossible-foods-the-very-real-battle-between-the-biggest-fake-meat-competitors
EX1121	Pat Brown, *Heme, Health, and the Plant-Based Diet*, IMPOSSIBLE, https://impossiblefoods.com/blog/heme-health-the-essentials
EX1122	Saha & Bhattacharya, *Hydrocolloids as Thickening and Gelling Agents in Food: A Critical Review*, 47 J. FOOD SCI. & TECH. 587-97 (2010)
EX1123	*Meat Consumption*, OECD (2022), https://data.oecd.org/agroutput/meat-consumption.htm

Exhibit No.	Description
EX1129	Mottram, *Volatile Compounds from the Reaction of Cysteine, Ribose, and Phospholipid in Low-Moisture Systems*, 43 J. AGRIC. FOOD CHEM. 984-88 (1995)
EX1130	Kang et al., *Gelation and Gel Properties of Soybean Glycinin in a Transglutaminase-Catalyzed System*, 42 J. AGRIC. FOOD CHEM. 159-65 (1994)
EX1131	Nio et al., *Gelation Mechanism of Protein Solution by Transglutaminase*, 50 AGRIC. & BIOLOGICAL CHEM. 851-55 (1986)
EX1132	U.S. Patent No. 4,153,738A to Ronai et al., issued May 8, 1979
EX1133	Hargrove et al., *Characterization of Recombinant Soybean Leghemoglobin a and Apolar Distal Histidine Mutants*, 266 J. MOLECULAR BIOLOGY 1032-42 (1997)
EX1134	Lund & Lorenz, *Influence of Time, Temperature, Moisture, Ingredients, and Processing Conditions on Starch Gelatinization*, 20 CRITICAL REVIEWS IN FOOD SCI. & NUTRITION 249-73 (2009)
EX1135	Nicola & Leach, *Structural Rearrangements Due to Ligand Binding and Haem Replacement in Myoglobin and Leghaemoglobins*, 78 EUROPEAN J. BIOCHEM. 133-40 (1977)
EX1136	Whistler & Daniel, *Carbohydrates*, *in* FOOD CHEMISTRY (O. Fennema, ed., 2d ed., revised and expanded, 1985)
EX1137	Batt et al., *Expression of Recombinant Bovine β-Lactoglobulin in* Escherichia coli, 54 AGRIC. & BIOLOGICAL CHEM. 949-55 (1990)
EX1138	Jamieson et al., *Cloning and Nucleotide Sequence of the Bovine β-Lactoglobulin Gene*, 61 GENE 85-90 (1987)
EX1139	Weed et al., *Is Hemoglobin an Essential Structural Component of Human Erythrocyte Membranes?*, 42 J. CLINICAL INVESTIGATION 581-88 (1963)

Exhibit No.	Description
EX1141	Evers et al., *Furan Substituted at the Three Position with Sulfur*, *in* PHENOLIC, SULFUR, AND NITROGEN COMPOUNDS IN FOOD FLAVORS SYMPOSIUM 184-93 (1976)
EX1145	U.S. Provisional No. 61/908,634, filed November 25, 2013
EX1146	*Sniffing Out which Plant-Based Burgers Smell the Most Like Real Beef* (Video), AM. CHEM. SOC'Y, *available at* https://www.youtube.com/watch?v=3W_0GqGnsN4&list=PPSV
EX1147	T.L. Stanley, *Impossible Foods Hires a Veteran of Apple Ads to Beef Up its Creative Marketing*, ADWEEK, https://www.adweek.com/brand-marketing/impossible-foods-hires-a-veteran-of-apple-ads-to-beef-up-its-creative-marketing/#:~:text=Impossible%20Foods%20Hires%20a%20Veteran%20of%20Apple%20Ads,record.%20Impossible%20By%20T.L.%20Stanley%20April%2013%2C%202021
EX1148	Prosecution History of U.S. Patent No. 10,039,306 to Vrljic et al.
EX1149	Prosecution History of U.S. Patent No. 11,013,250 to Vrljic et al.
EX1150	Prosecution History of U.S. Patent No. 11,224,241 to Fraser et al.
EX1151	Ames, *Control of the Maillard Reaction in Food Systems*, 1 TRENDS IN FOOD SCI. & TECH. 150-54 (1990)
EX1152	*Methionine*, PUBCHEM, https://pubchem.ncbi.nlm.nih.gov/compound/Methionine
EX1157	U.S. Patent No. 10,039,306 to Vrljic et al.
EX1158	U.S. Patent No. 11,013,250 to Vrljic et al.
EX1159	U.S. Patent No. 11,224,241 to Fraser et al.

LIST OF CHALLENGED CLAIMS

Claim 1	
Element No.	**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.
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 erythrocruorin, a beta hemoglobin, an alpha hemoglobin, a protoglobin, a cyanoglobin, a cytoglobin, a histaglobin, a neuroglobins, a chlorocruorin, a truncated hemoglobin, a truncated 2/2 globin, and a hemoglobin 3.	
Claim 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.	
Claim 4	
The food flavor additive composition of claim 1, wherein the food flavor additive composition is a powder or a liquid composition.	

Claim 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.	
Claim 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.	
Claim 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.	
Claim 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, com oil, sesame oil, walnut oil, flaxseed, jojoba oil, castor, grapeseed oil, peanut oil, olive oil, algal oil, and oil from bacteria or fungi.	
Claim 9	
The food flavor additive composition of claim 1, further comprising one or more of albumin or a globulin.	
Claim 10	
10[pre]	A food flavor additive composition prepared by a process of:
10[a]	a) combining an isolated heme-containing protein;

10[b]	a compound selected from glucose, ribose, fructose, lactose, xylose, arabinose, glucose-6-phosphate, maltose and galactose, and mixtures of two or more thereof; and
10[c]	a compound selected from cysteine, cystine, thiamine, methionine, and mixtures of two or more thereof, to form a heme flavor reaction mixture, and
10[d]	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;
10[e]	wherein the food flavoring additive composition contains no animal products; and
10[f]	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).

Claim 11

A food flavor additive composition of claim 10, 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-methy 1-2-thiophenecarboxaldehyde, 2-methy 1-thiazole, dimethyl sulfide, decanal, 5-ethyldihydro-2(3H)-furanone, dihydro-5-pentyl-2(3H)-furanone, 2-octanone, 3,5-octadien-2-one, p-Cresol, and hexanoic acid.

Claim 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).

Claim 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.
Claim 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 erythrocruorin, a beta hemoglobin, an alpha hemoglobin, a protoglobin, a cyanoglobin, a cytoglobin, a histaglobin, a neuroglobins, a chlorocruorin, a truncated hemoglobin, a truncated 2/2 globin, and a hemoglobin 3.
Claim 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.
Claim 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.
Claim 18
The food flavor additive composition of claim 10, further comprising an ingredient selected from an emulsifier and a gelling agent.
Claim 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).
Claim 20

The food flavor additive composition of claim 10, wherein the heme flavor reaction mixture is an aqueous solution.
Claim 21
The food flavor additive composition of claim 10, wherein the heme flavor reaction mixture is an oil-based mixture.
Claim 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.
Claim 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.
Claim 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.

I. INTRODUCTION

Motif FoodWorks, Inc. ("Petitioner") respectfully requests *inter partes* review of U.S. Patent No. 9,943,096 ("'096 patent"). Patent Owner ("PO"), Impossible Foods, Inc., sued Petitioner for patent infringement in the District of Delaware, Case No. 22-cv-00311, on March 9, 2022 ("the Litigation"). PO filed a first amended complaint on July 22, 2022 alleging infringement of the '096 patent. Petitioner seeks review of claims 1-12 and 14-24 of the '096 patent.

II. STATE OF THE ART

A. Meat Flavor Chemistry

Researchers have long recognized that the aroma of meat, such as beef, is associated with hundreds or thousands of individual volatile chemical compounds. EX1005(McGorrin), ¶¶27-42. To create the chemical compounds that produce meat flavor and aroma, other compounds termed "flavor precursors" may be chemically reacted using heat. *Id.*, ¶¶48-53. Precursors including sulfur compounds, such as cysteine, cystine, methionine, and thiamine, and reducing sugars, such as glucose, ribose, etc., have been known to be associated with meaty flavors/aromas. *See id.*

One well-known chemical reaction that plays a prominent role in meat flavor chemistry is the Maillard reaction. The Maillard reaction is a chemical reaction between amino acids and reducing sugars, and is in part responsible for the distinctive flavor/aroma of browned foods. *Id.*, ¶¶46-47, 54-55. The amount and

identity of the precursor compounds, cooking temperature, pH, cooking time, and moisture all impact the Maillard reaction. *Id.*, ¶¶56-61. Cysteine, cystine, methionine, and thiamine are all well-known reactants for the Maillard reaction. *Id.*, ¶¶62-71.

B. Simulated Meat Flavoring Compositions

Scores of patents have been issued for various simulated meat flavoring compositions, many of which include cysteine and a reducing sugar, such as glucose, arabinose, or ribose. *Id.*, ¶¶75-76. Compositions that have included thiamine and methionine are also well-known. *Id.*, ¶¶77-78.

That heme iron could also enhance meaty flavors/aromas was also well-documented in various publications. For example, as discussed in the grounds below, "Conrad" discloses that "[t]he addition of blood/hemoglobin further gives a desired taste improvement as it **improves the meat flavour** of the final product." EX1013 (Conrad), 4:14-16. "Brown" expressly touts that adding leghemoglobin to a flavor composition to be used in meat substitutes enhances the aroma of cooked meat. EX1012 (Brown), [00364]; EX1003(Tarte), ¶¶79-80.

C. Consumers' Concerns About Meat

Despite the popularity of meat, there is still a significant number of consumers that avoid meat and meat products in their diets for various reasons, including ethical, environmental, health, personal, and/or religious reasons. For example,

some consumers believe that meat is unhealthy, while others are concerned with the environmental impacts of industrial-scale animal husbandry, including the amount of land and water needed to raise and maintain animals. Yet other consumers believe that conventionally sourced meat is harmful to animal welfare. *See* EX1003(Tarte), Section VII.A-B.

D. Recombinant Technology

Scientists and researchers have long recognized the feasibility and value of using recombinant technologies to engineer proteins for use in food products. EX1007(Batt), ¶¶40-49. Indeed, it was well-known that heme-containing proteins, such as hemoglobin, myoglobin, and leghemoglobin, could be produced using recombinant technology. *Id.*, ¶¶28-32; EX1003(Tarte), Section VII.C.

III. The '096 Patent

A. Background

The '096 patent claims are directed to food-flavor additive compositions that "modulat[e] the **flavor** and/or **aroma** profile of consumable food products." EX1001, 1:59-2:10.[1] To that end, the '096 patent describes combining a "heme-containing protein" with "one or more flavor precursor molecules," such as cysteine, glucose, and ribose, to "provide a range of savory and meaty aromas and tastes…in a cooked consumable food product." *Id.*, 2:43-50.

[1] All emphasis added unless otherwise noted.

The use of flavor precursors including sulfur compounds (*e.g.*, cysteine, thiamine) and reducing sugars (*e.g.*, glucose, ribose) in Maillard reactions to provide meaty flavor and aroma was long known in the art. So too was the use of iron from hemoglobin proteins. *See supra* Section II.A, II.B.

B. Prosecution History

The '096 patent issued from U.S. Application No. 15/398,479 ("'479 application"). The '479 application was initially rejected as anticipated by references that disclosed the contents of *real* beef muscle tissue or blood. EX1002, 180-84.

To overcome the rejections, Applicant amended the claims to recite "wherein the flavor additive composition contains no animal products" (*id.*, 949 (Claim 31), 1178-79 (Claim 42)), and argued that the prior art references failed to satisfy this limitation because they included real beef/blood. *Id.*, 959-961.

The Examiner subsequently allowed the claims, stating that "the references do not disclose food flavor additive compositions that contain ***no*** animal products as presently claimed." *Id.*, 1180 (emphasis in original).

Although the reference "Proulx" (*see infra* Section VII.E) was not the basis of a rejection, the Examiner noted that "Proulx … [disclosed] that hemoglobin from soy root nodules … is a good source of bioavailable iron and can be used as a food fortificant, [but] there is no motivation to include the fortificant, in combination with

the claimed sugars and amino acids ***to produce meat associated flavors***." *Id.*[2] However, the Examiner appears to have reconsidered this conclusion in subsequent office actions issued for a child application to the '096 patent (App. No. 15/916,090) having substantially similar claims. *See* EX1003(Tarte), ¶¶42-47.

C. Person of Ordinary Skill in the Art

The '096 patent is directed to the art of food science and recombinant protein expression. A POSITA would have (i) a Bachelor of Science degree in food science, biology, chemistry, microbiology, or a related discipline, and (ii) a Master of Science degree or Ph.D. in food science or at least three years of experience working as a food scientist. A POSITA could also be part of a team of food scientists, including flavor chemists. EX1003(Tarte), Section V.A; EX1005(McGorrin), Section VI.A; EX1007(Batt), Section IV.A.

IV. PRIORITY DATE

The '479 application, which led to the '096 patent, was filed on January 4, 2017. It claims an earliest benefit of priority to U.S. Provisional No. 61/751,816 (the "'816 Provisional"), filed January 11, 2013. *See* EX1025. However, the Challenged Claims are not entitled to claim priority to the '816 Provisional because

[2] The Examiner's conclusion was in error. There is no requirement that a motivation to combine references must be the same subjective reason that motivated the inventors. *KSR Intern. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741–42 (U.S. 2007). Nor do the claims require any one particular compound, including the heme-containing protein, to contribute to the meaty flavor/aroma.

that application fails to adequately describe the full scope of the issued claims.[3] The next earliest priority date for the '096 patent is July 12, 2013, which is after the publication date of the "Brown" publication, relied on in Grounds 1-2.[4] Hence, if priority to the '816 Provisional is broken, Brown is prior art under 35 U.S.C. §102(a)(1) (*see infra* Section VII.A), otherwise it is prior art under pre-AIA 35 U.S.C. §102(e). Grounds 3 and 4 do not rely on Brown and are unaffected even if priority is not broken.

The '816 Provisional must reasonably convey that the named inventors "had possession of" the claimed subject matter as of the filing date.[5] This is a factual question and "requires an objective inquiry into the four corners of the specification from the perspective of" a POSITA. *D Three Enterprises, LLC v. SunModo Corp.*, 890 F.3d 1042, 1047 (Fed. Cir. 2018). Demonstrating adequate written description "requires a precise definition" of the invention. *Id.* "It is not sufficient … that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to the modifications that the inventor might have envisioned, but failed to disclose." *Id.* at 1050.

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[3] *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

[4] Application no. 13/941,211 (filed July 12, 2013) also fails to provide written description support for the Challenged Claims. However, Brown is prior art under §102(a)(1) even if the '211 application did provide support.

[5] *D Three*, 890 F.3d at 1047 (citation omitted).

Because it is the specification itself that must demonstrate possession, a description that merely renders the claimed invention *obvious* does not show possession of the invention for purposes of written description support. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010). The '816 Provisional fails to meet these standards for supporting the Challenged Claims.

First, the '816 Provisional does not disclose ***two*** of the sugar compounds recited in the claims: **glucose-6-phosphate** and **maltodextrin**. *See, e.g.,* EX1025, [00124]. It also does not disclose ***three*** of the recited sulfur compounds: **cystine**, **thiamine**, and **methionine**. *Id.*, [00217], [00254]-[00255].[6] Nor does it describe combining these claimed sugar and sulfur compounds with a heme protein in the context of methods of achieving a meat-associated aroma. EX1005(McGorrin), ¶¶94-96.

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. As Dr. McGorrin explains, chemical structure is 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.*,

[6] The '096 Provisional also claims priority to U.S. provisional app. no. 61/908,634, filed Nov. 25, 2013. Unlike the '816 Provisional, the later-filed '634 Provisional *does* expressly disclose glucose-6-phosphate, maltodextrin, cystine, thiamine, and methionine. *See* EX1145, 9-10 (Table 1).

glucose-6-phosphate). Compounds with slower reactivity may be less successful at achieving the desired aroma profile with limited cooking time constraints. Hence, the '816 Provisional's disclosure of a composition including ribose does not show possession of the claimed invention reciting glucose-6-phosphate. *Id.*, ¶¶94-97.

Second, the '816 Provisional does not disclose that a mixture of the specific sugar and sulfur compounds claimed, along with a heme protein, would "result in the production of at least two volatile compounds which have a meat-associated aroma" upon cooking, as claimed. Rather, the '816 Provisional's disclosure of adding heme protein into a food-flavor additive is general, and made almost entirely without reference to combinations with *specific* sugar or sulfur compounds. *See, e.g.*, EX1025, [0023], [0032], [00217], [00288], [00290]. In fact, only a *single* paragraph in the entire disclosure describes reacting certain heme-containing proteins (identified in Table 1) with specific compounds, and, even then, that disclosure is limited to only cysteine and glucose. *Id.*, [00255]. The '816 Provisional never discloses combining heme-containing proteins generally or certain heme-containing proteins with (1) any sugars except glucose or (2) any sulfur compounds except cysteine. And where the '816 Provisional does describe heat-reacting heme-containing protein with cysteine and glucose, the reaction is not described as producing a "meaty aroma." EX1005(McGorrin), ¶¶98-103.

This lack of disclosure is important because a POSITA would understand that

different combination(s) of the compounds recited in the Challenged Claims could produce aroma and flavor profiles that differ dramatically from the sole combination of certain heme-containing proteins, cysteine, and glucose disclosed in the '816 Provisional. For example, a POSITA would understand that the claimed sugar and sulfur compounds will chemically react differently in the Maillard reaction upon the claimed cooking of the food-flavor additive, and that the volatile products of the Maillard reaction depend on various factors such as temperature, pH, and the structural diversity of the precursor molecules that react to form volatiles. EX1005(McGorrin), ¶¶104-05.

This lack of disclosure is not remedied by the '816 Provisional's laundry list of potential generalized classes of components of the food-flavor additive, including "amino acids, fats, peptides, nucleotides, organic acids, sulfur compounds, sugars and other carbohydrates," that allegedly produce "the characteristic flavor and fragrance components" of meat. EX1025, [00254]; *see also id.*, [00217]. These passages fail to adequately describe the claimed sugar and sulfur compounds because generalized references to "sugars" and "sulfur compounds" do nothing to inform a POSITA that the named inventors were in possession of the full scope of the *specific* sugar and sulfur compounds and other recited elements in the Challenged Claims. *See Application of Ruschig*, 379 F.2d 990, 994 (C.C.P.A. 1967) ("Specific claims to single compounds require reasonably specific supporting disclosure."); *id.*

at 994-95 (application must provide "blaze marks" that single out a claimed species from a large genus of compounds); EX1005(McGorrin), ¶¶101-06, 112.

The '816 Provisional fails to provide blaze marks that identify the undisclosed sugar and sulfur compounds. For example, the '816 Provisional does not teach specific combinations of any heme-containing proteins with the undisclosed sugars and sulfur compounds. EX1005(McGorrin), ¶112.

Third, the '816 Provisional does not disclose the claimed combination of a genus of heme proteins, sugars, and sulfur compounds, ***without any animal products***, in the context of a food-flavor additive. The '816 Provisional discloses adding leghemoglobin and myoglobin to a "poultry composition" made with real chicken and evaluating for beef aroma. EX1025, [0044], [00256], [00407]-[00408]. However, this does not inform a POSITA that the named inventors were in possession of methods of imparting a meat-associated aroma to a food-flavor additive that "contains no animal products" by adding **any** combination of heme-containing protein, sugars, and sulfur compounds. EX1005(McGorrin), ¶¶107-08.

V. CLAIM CONSTRUCTION

A. "contains no animal products"

The challenged claims require that the food-flavor additive composition "contains no animal products." This limitation need not be construed for purposes of this proceeding.

However, in parallel litigation, PO asserts that "no animal products" covers bovine myoglobin, which is native to an animal (*Bos taurus* (cow)), even when produced in engineered yeast (a non-animal ***source***). EX1116(SAC), ¶¶32-36. If the Board adopts PO's infringement interpretation, Grounds 3A-3D presented herein are unaffected as they map "contains no animal products" to bovine hemoglobin produced recombinantly. If PO's interpretation is not adopted, these Grounds are unaffected because they alternatively map the term to leghemoglobin, a heme-containing protein native to plants. EX1003(Tarte), Section X.A.

B. "food flavor additive composition"

The term "food flavor additive composition" has a plain meaning and does not require construction for purposes of this proceeding. Specifically, a POSITA would understand its plain meaning as a composition that, when added to other consumable food products, modulates their flavor and/or aroma. EX1003(Tarte), ¶100.

PO also broadly contends in the Litigation that Petitioner's "**meat replica** products (including but not limited to its **burgers and sausage products)**," infringe the claimed "food flavor additive composition." EX1116(SAC), ¶¶35-36, 51. Thus, PO's interpretation of the term covers meat substitutes that are end products *directly* consumed by the consumer (not just additives to meat substitutes). While Ground 1 below (Brown) concerns a "muscle replica" that is *added* to a meat substitute (*i.e.*,

is not a meat substitute itself), to the extent Patent Owner argues that Brown's muscle replica is a meat substitute that is directly consumed, Patent Owner's interpretation would still treat such a meat substitute as a "food flavor additive composition." EX1003(Tarte), Section X.B.

C. "a compound"

The independent claims recite "***a compound*** selected from glucose …" and "***a compound*** selected from cysteine …." Dependent claim 7 similarly recites "***a compound*** selected from alanine …." The term "a compound" has a plain meaning and does not require construction for purposes of this proceeding. PO has implicitly taken the position in the Litigation that this term is not limited to ***free*** compounds of the claimed sugars and sulfur compounds (*i.e.*, compounds not chemically bound to the structure of another compound) because PO alleges that Petitioner's meat substitute products infringe the Challenged Claims even though Petitioner's products are not made using free cysteine, cystine, methionine, or thiamine. *See* EX1116(SAC), ¶¶36, 51; EX1003(Tarte), Section X.C. Hence, based on PO's interpretation of the term, Ground 1 maps "*a compound* selected from cysteine …" and "*a compound* selected from alanine …" to pea flour, which contains proteins having the claimed sugar and sulfur compounds. Even if PO's interpretation is not adopted, Grounds 2-4 are unaffected because they map these terms to free sugar and sulfur compounds.

VI. STATEMENT OF RELIEF REQUESTED

A. Identification of Challenge (37 C.F.R. §§ 42.104(b))

Petitioner requests *inter partes* review and cancellation of claims 1-12 and 14-24. Grounds 1 and 2 presume the '096 is not entitled to the '816 Provisional's filing date, and, consequently, advance invalidity arguments based on Brown as prior art under §102(a)(1). Ground 1 is also premised on PO's interpretation of the term "a compound" as not being limited to free compounds. *See supra* Section V.C. Ground 2 is unaffected by this term's construction as it already maps the claimed compounds to free compounds.

Grounds 3 and 4 apply regardless of whether priority to the '816 Provisional is broken. Specifically, Ground 3 maps the term "isolated heme-containing protein" to hemoglobin, including bovine hemoglobin and plant leghemoglobin, sourced from recombinant expression systems (as taught by Crane). To the extent, Patent Owner erroneously argues that a POSITA would not be motivated to modify Giacino to include such hemoglobin, Ground 4 maps the claimed isolated heme-containing protein to soy leghemoglobin sourced from soy root nodules (as taught by Proulx).

B. Ground of Challenge (37 C.F.R. § 42.204(b)(2))

No.	Claims	Ground for Challenge
1	1-5, 7-9, 23, 24	§102: Brown

No.	Claims	Ground for Challenge
2A	1-12, 14-17, 20-24	§103: Giacino, Brown
2B	18-19	§103: Giacino, Brown, MacLeod
3A	1-2, 4-7, 9-12, 14-15, 20-24	§103: Giacino, Conrad, Crane
3B	3, 16	§103: Giacino, Conrad, Crane, Proulx
3C	8, 17	§103: Giacino, Conrad, Crane, Perret
3D	18-19	§103: Giacino, Conrad, Crane, MacLeod
4A	1-7, 9-12, 14-16, 20-24	§103: Giacino, Proulx, Conrad
4B	8, 17	§103: Giacino, Proulx, Conrad, Perret
4C	18-19	§103: Giacino, Proulx, Conrad, MacLeod

VII. SUMMARY OF PRIOR ART

A. "Brown"

International Pub. WO/2013/010042 ("Brown") was filed on July 12, 2012 and claims priority to U.S. provisional 61/572,205, filed July 12, 2011. Brown was published on January 17, 2013. Brown is prior art under both AIA and pre-AIA provisions.

Under AIA: The '096 patent is not entitled to the filing date of provisional application 61/751,816, filed January 11, 2013. *See supra* Section IV. Thus, the effective filing date of the '096 patent is no earlier than July 12, 2013, which makes it subject to the AIA provisions.

Under the AIA, Brown is prior art at least under 35 U.S.C. §102(a)(1) because it was published on Jan. 17, 2013, which is before the '096 patent's earliest possible priority date (July 12, 2013). None of the exceptions under 35 U.S.C. §102(b)(1) apply. Brown is not a "disclosure … made by the inventor or joint inventor or by another who obtained the subject matter … from the inventor or a joint inventor." 35 U.S.C. §102(b)(1)(A). While Brown and the '096 patent share one inventor (Patrick Brown), none of the other inventors of Brown appear as inventors of the '096 patent, and thus Brown is not a disclosure "made by the inventor." *See* MPEP §2153.01(a). There is also no evidence that the subject matter of Brown was disclosed in an earlier publication by the inventors. 35 U.S.C. §102(b)(1)(B).

Under pre-AIA: To the extent the '096 patent is entitled to its earliest claimed effective filing date of January 11, 2013, then the '096 patent would be subject to pre-AIA provisions. Yet even under those provisions, Brown is still prior art under pre-AIA 35 U.S.C. §102(e) because it was filed "by another" before the '096 patent. *See* MPEP 2136.04.

Brown a "muscle replica" that together with fat and connective tissue replicas,

forms a "meat replica." The muscle replica comprises "pea flour, sunflower oil, and glucose" and is "heated for 10 minutes at 140C in the presence of…leghemoglobin (LHb)" to provide volatile compounds that "are often associated with the aroma of cooked meat." EX1012(Brown), [00364]; EX1003(Tarte), ¶¶79-81. Brown also teaches methods for isolating leghemoglobin and that heme can be used to generate meaty flavor/aroma. EX1003(Tarte), ¶¶81-83.

B. "Giacino"

U.S. Patent No. 3,519,437 ("Giacino") issued on July 7, 1970. Giacino discloses "artificial meaty flavoring compositions and … processes for preparing them." EX1015(Giacino), 1:19-20. Giacino's compositions include cysteine, ribose, thiamine, vegetable hydrolysate, and other common meat flavor precursors. EX1003(Tarte), ¶85.

C. "Conrad"

U.S. Patent No. 4,818,557 ("Conrad") issued on April 4, 1989. Conrad teaches "a meat replacement product to be used in mixed minced meat products, process for its preparation, and meat products comprising same, whereby the meat replacement product comprises the gluten protein and the bran fractions of whole cereal grain," and to which "a blood hemoglobin fraction can be added." EX1013(Conrad), Abstract; EX1003(Tarte), ¶¶86-87.

D. "Crane"

U.S. Patent Publication 2011/0287467 ("Crane") was published on November

24, 2011. Crane teaches "methods of producing recombinant functional heme-binding proteins with complete heme incorporation and purified preparations" thereof. EX1014(Crane), Abstract; EX1003(Tarte), ¶¶88-89.

E. "Proulx"

"*Iron Bioavailability of Hemoglobin from Soy Root Nodules Using a Caco-2 Cell Culture Model*" ("Proulx") was published on January 31, 2006. EX1009(Hall-Ellis), ¶¶64-65. Proulx teaches the use of plant-derived soy leghemoglobin to fortify non-animal food products. *See* EX1019(Proulx), Abstract. Proulx demonstrates that "the bioavailability of hemoglobin from soy root nodules [is] similar to that of heme iron from animal sources" and can "provide a unique alternative fortificant" and "improve the iron status of the population." *Id*., 1521; EX1003(Tarte), ¶¶92-94.

F. "Perret"

U.S. Patent No. 3,365,306 ("Perret") issued on January 23, 1968. Perret discloses "beef-flavored compositions" that include a "beef-flavored substance" made of cysteine/cystine and a reducing sugar (*e.g.*, glucose, ribose, etc.) along with other flavoring compounds. EX1020(Perret), 4:63-75, 5:52-57. Perret's compositions include "edible fat" such as safflower oil. *Id.*, 4:6-29. EX1003(Tarte), ¶¶90-91.

G. "MacLeod"

"*Natural and Simulated Meat Flavors (With Particular Reference to Beef)*," by Glesni MacLeod ("MacLeod") was published in 1981, decades before the '096

patent's priority date. EX1009(Hall-Ellis), ¶¶66-73. MacLeod describes the science behind meat flavors and aroma, including the various chemical reactions that select compounds can undergo to produce volatile compounds that are associated with a meaty aroma. EX1003(Tarte), ¶84.

H. Cited Non-Patent References Are Printed Publications Publicly Available Before the Priority Date of the Challenged Claims

Proulx and MacLeod are printed publication prior art. As set forth in EX1009, Proulx and MacLeod were disseminated or otherwise made available, including being cataloged and indexed by a library, such that a person interested in and ordinarily skilled in the relevant subject matter could locate them through the exercise of ordinary diligence at least as of January 31, 2006 and August 31, 1981, respectively.

For example, Ms. Hall-Ellis stated that she obtained a printout of Proulx from the Iowa State University digital repository, "a place where, if authentic, a copy of this document would likely be." EX1009(Hall-Ellis), ¶¶64-65. The repository indicates that Proulx was published in Volume 54, Issue 4 of the *Journal of Agricultural and Food Chemistry* on January 31, 2006. This journal was available through the National Library of Medicine and the National Agricultural Library. *Id.*, ¶64. Dr. Tarté stated that he is familiar with the Journal of Agricultural and Food Chemistry, and its publisher, the American Chemical Society ("ACS"). EX1003(Tarte), ¶92, n.6. The Journal of Agricultural and Food Chemistry is a

highly-reputable scientific journal within the field of food science. Dr. Tarté opined that in 2006, a POSITA would have considered the publication dates printed on the face of the journal and the paper itself to be a reliable indicator of its publication date. *Id.*

Ms. Hall-Ellis stated that MacLeod was published in the journal of *Critical Reviews in Food Science and Nutrition* on August 31, 1981, and that the University of Wisconsin–Madison Libraries has been receiving this journal since June 1980. *Id.*, ¶¶66-70. Ms. Hall-Ellis also opined that MacLeod was publicly available about August 31, 1981, because by that date it had been cataloged and indexed at the Library of Congress, made part of the OCLC bibliographic database, and received at the University of Wisconsin–Madison Libraries. *Id.*, ¶¶71-73. Additionally, Dr. Tarté stated that he is familiar with this journal, which is a highly-reputable scientific journal within the field of food science. EX1003(Tarte), ¶84, n.5. He opined that by 2013, a POSITA would have considered the publication dates provided on Taylor & Francis's website, the face of the journal, and the face of the paper itself to all be reliable indicators of its publication date. *Id.*

As further testified by Ms. Hall-Ellis, both Proulx and MacLeod are authentic copies that would have been available to a POSITA as of January 31, 2006 and August 31, 1981, respectively. EX1009¶¶65, 73.

VIII. GROUND 1: BROWN (Anticipation)

If the Board adopts PO's interpretation of "a compound" to not be limited to free compounds (*see supra* Section V.C), Brown **anticipates** claims 1-5, 7-9, and 23-24.

Brown discloses each and every limitation of independent claims 1 and 23. Brown teaches a muscle replica that contains pea flour (which includes cysteine, methionine, and thiamine), glucose, sunflower oil, and isolated soy leghemoglobin ("heme-containing protein"), and does not contain any animal products. EX1012(Brown), [00364]. As discussed below, Brown's muscle replica is a "food flavor additive composition" because it is added to a meat substitute that contains other tissue replicas to impart a cooked meat aroma. *Id.*, [00189], [00364]; *see infra* Section VIII.A.1. Brown also discloses that heating the composition releases at least two volatile compounds (2-octanone, 2-methyl furan) that have a meaty aroma. EX1012(Brown), [00364]; EX1003(Tarte), ¶¶106-165.

A. Claim 1

1. Limitation 1[pre] ("food flavor additive composition")

Brown provides an exemplary composition for a "muscle replica" comprising "pea flour, sunflower oil, and glucose" and that is "heated for 10 minutes at 140C in the presence of … leghemoglobin (LHb)" to provide volatile compounds that "are often associated with the aroma of cooked meat." EX1012(Brown), [00364]. This composition is added to "a meat substitute product," which also contains fat and

connective tissue replicas, and modulates the aroma/flavor of the meat substitute product by imparting an aroma of cooked meat. *Id.*, [00189], [00364].

The term "food flavor additive composition" in view of the '096 patent specification does not require any specific form and is, per its plain and ordinary meaning, a composition that, when added to a food product, modulates the food product's flavor and/or aroma. *See supra* Section V.B. The '096 patent's specification is consistent with this understanding. It explains that "[c]onsumable food products for use in the present disclosure can be flavor additive compositions, ***e.g., for addition to another consumable food product before, during, or after its cooking process***." EX1001, 3:32-35. The patent also discloses that it "can be used to ***modulate the flavor and/or aroma profile of a consumable food product***." *Id.*, 3:38-48. The specification does not place limits as to the ***form*** of the food flavor additive. *Id.*, 3:49-51 ("A flavor additive composition can be in the form, of ***but not limited to***, soup or stew bases, bouillon, e.g., powder or cubes, flavor packets, or seasoning packets or shakers."); EX1003(Tarte), ¶¶101, 111.

The Challenged Claims' use of the term is consistent. For example, claims 4 and 24 further narrow independent claim 1 to specify the form of the food flavor additive composition (*e.g.*, powder, liquid, soup, stew base, etc.), which support a POSITA's understanding that claim 1 does not require any specific form. EX1003(Tarte), ¶¶102, 112.

Based on this understanding, Brown's muscle replica is a "food flavor additive composition" because it is added to a food product (*e.g.*, "a meat substitute product"), and modulates the aroma/flavor of the meat substitute product by imparting an aroma of cooked meat. EX1003(Tarte), ¶¶103, 113.

2. Limitation 1[a] ("isolated heme-containing protein")

Brown discloses an exemplary composition that is prepared by mixing pea flour, sunflower oil, and glucose and then heating the mixture in the presence of ***leghemoglobin*** to provide volatile compounds that "are often associated with the aroma of cooked meat." EX1012(Brown), [00364]. A POSITA would have recognized that the leghemoglobin is "isolated" (to the extent the term has patentable weight) because Brown expressly teaches extracting soy leghemoglobin from plants or from recombinant expression systems. *Id.*, [00376]-[00377], [00380]-[00381]; EX1003(Tarte), ¶¶116-17.

3. Limitation 1[b] ("[sugar] compound selected from…")

Brown's composition includes glucose. EX1012(Brown), [00364]; EX1003(Tarte), ¶119.

4. Limitation 1[c] ("[sulfur] compound selected from…")

Brown's composition includes pea flour.[7] EX1012(Brown), [00364]. A

[7] To the extent "a compound" is interpreted to not be limited to free compounds, Brown's muscle replica, which contains pea flour, satisfies this limitation. *See supra* Section V.C.

POSITA would understand that pea flour contains cystine, thiamine, and methionine. EX1003(Tarte), ¶¶121-25; EX1050/EX1059(Jahreis), 39, Table 2 (1.4% cystine, 0.9% methionine), 41 (legumes include thiamine); EX1057(Krumina-Zemture), 86, Table 2 (0.15-0.16g methionine/100g); EX1106 (USDA), 3, 6-7.

5. Limitation 1[d] ("contains no animal products")

Brown's composition does not contain animal products because it contains only non-animal ingredients including sunflower oil, glucose, soy leghemoglobin, and pea flour. EX1012 (Brown), [00364]. A POSITA would understand that like sunflower oil, soy leghemoglobin, and pea flour, glucose is also conventionally derived from plant starches, such as from corn, wheat, and potato. EX1089(Yebra-Biurrun), 479; EX1003(Tarte), ¶¶127-131.

6. Limitation 1[e] ("at least two volatile compounds which have a meat-associated aroma")

Brown discloses that cooking its composition results in the production of at least two volatile compounds which have a meat-associated aroma (*e.g.*, 2-octanone, 2-methyl furan). EX1012(Brown), [00364]; EX1003(Tarte), ¶133. It was also well-known that heating a flavoring composition containing cystine and glucose, like Brown's composition, produces many volatile compounds that have a meaty aroma/flavor. *Id.*, ¶134; EX1005(McGorrin), Section V.B, V.D; EX1024(MacLeod), 313-356 (Table 1), 384 (Table 14).

B. Claim 2 ("heme-containing protein is selected from the group…")

Brown's composition includes leghemoglobin. EX1012(Brown), [00364]; EX1003(Tarte), ¶136.

C. Claim 3 ("amino acid sequence having…")

Brown's composition includes soy leghemoglobin (*see supra* Section VIII.A.2), which a POSITA would understand has an "amino acid sequence having at least 80% sequence identity to" the '096 patent's SEQ ID NO 4 that identifies the polypeptide of *Glycine max* leghemoglobin (*i.e.*, soy leghemoglobin). EX1001, 10:23-24, col. 43, Fig. 1; EX1003(Tarte), ¶138.

Moreover, Brown discloses that the heme-containing protein in its compositions can have "at least 98% homology to SEQ ID NO 1." EX1012(Brown), [0089]-[0091]. A POSITA would have recognized that SEQ ID NO 1 identified in Brown has about 92% homology with claimed SEQ ID NO 4 (leghemoglobin of *Glycine max*). EX1003(Tarte), ¶¶139-146.

D. Claims 4, 24 ("is a powder or a liquid composition")

Brown discloses a food-flavor additive composition that is a powder. EX1012(Brown), [00311] (The muscle replica "can be optionally dried at room temperature overnight, then ground to a **fine powder** (<60 mesh) using a Braun food grinder."). A POSITA would understand that such a powder is a "bouillon powder" since it has a cooked meat aroma. *See id.*, [00364]; EX1003(Tarte), ¶148.

E. Claim 5 ("heme-containing protein is a plant…")

Brown's composition contains a plant heme-containing protein (leghemoglobin). EX1012(Brown), [00364]; EX1003(Tarte), ¶¶150-51.

F. Claim 7 ("further comprising…a compound selected from…")

Brown's composition contains pea flour.[8] EX1012(Brown), [00364]. A POSITA would understand that pea flour includes alanine, arginine, asparagine, aspartate, glutamic acid, glutamine, glycine, histidine, isoleucine, leucine, lysine, phenylalanine, proline, threonine, tryptophan, tyrosine, valine, and thiamine. EX1003(Tarte), ¶¶153-57; EX1050/EX1059(Jahreis), 39 (Table 2), 41; EX1057(Krumina-Zemture), 85-86 (Table 2); *see generally* EX1106(USDA).

G. Claim 8 ("further comprising…an oil selected from…")

Brown's composition contains sunflower oil. EX1012(Brown), [00364]; EX1003(Tarte), ¶159.

H. Claim 9 ("further comprising…[an] albumin or a globulin")

Brown's composition includes pea flour. EX1012(Brown), [00364]. A POSITA would understand that pea flour contains globulin and albumin proteins. EX1003(Tarte), ¶¶161-62; EX1067(Meng), 235; EX1083(Buffo), 293; EX1070(Karaca), 196.

I. Claim 23 ("adding to the consumable food product a food flavor additive composition of claim 1; and heating [it]…")

Brown discloses adding its composition to a consumable food product and

[8] *See supra* n.7.

then heating the food product.

Brown's composition satisfies all limitations of claim 1. *See supra* Section VIII.A. The composition is added to a meat substitute ("consumable food product") comprising other tissue replicas (fat, connective tissue). EX1012(Brown), [00189], [00191]. The meat substitute is then cooked. *Id.*, [00270], [00412] ("[T]he ground beef replica patties w[ere] evaluated by grilling on a 350°F pan…. [T]he panel on the right [of Figure 17] shows the same patty after cooking for about 2 minutes."); *see also id.*, [0035]-[0042], (cooking a meat substitute), [00272]; EX1003(Tarte), ¶164.

IX. GROUNDS 2A-2B: GIACINO, BROWN, MACLEOD

Giacino and Brown render obvious claims 1-12, 14-17, and 20-24 (Ground 2A). Giacino, Brown, and MacLeod render obvious claims 18-19 (Ground 2B).

A. Overview of Giacino and Brown

Giacino discloses every limitation of the independent claims except "an isolated heme-containing protein" (which is taught by Brown). For example, Giacino discloses meaty flavoring compositions that are added to foods to impart a meaty flavor and aroma (*i.e.*, a "food flavor additive composition"). EX1003(Tarte), Section XII.A. The compositions include well-known meat flavor precursors including, for example, cysteine, thiamine, ribose, xylose, and hydrolyzed vegetable proteins. Giacino does not indicate that these compounds are sourced from animals.

Indeed, these compounds are routinely manufactured synthetically or obtained from plants. Giacino discloses that when the compositions are heated, they produce "meaty flavor." Relevant to independent claim 10, Giacino also discloses heating the compositions to at least 150°C for at least 1 minute. *See infra* Section IX.B, IX.K.

Brown discloses using plant heme-containing proteins (*e.g.*, leghemoglobin) in compositions to produce "the aroma of cooked meat." Such compositions include "muscle replicas" that are added to meat substitutes (along with other tissue replicas) to impart the cooked meat aroma. *See infra* Section IX.B.2; EX1003 (Tarte), Section XII.A. Accordingly, adding heme-containing protein (as taught by Brown) to Giacino's composition results in a modified composition that satisfies all limitations of the independent claims. EX1003(Tarte), ¶¶166-280.

B. Claim 1

1. Limitation 1[pre]

Giacino discloses the claimed "food flavor additive composition" as various "artificial meaty flavoring compositions" "having meaty flavor characteristics such as beef, pork and poultry flavor." EX1015(Giacino), 1:19-25. Giacino teaches "[t]he flavor compositions of this invention can be used to **flavor various foods**" including "gravies, sauces, soups, dressings" and "dry foods such as snacks, chips, synthetic meat fibres." *Id.*, 7:15-26; EX1003(Tarte), ¶187.

2. Limitation 1[a]

Giacino and Brown render obvious a food-flavor additive composition comprising an isolated heme-containing protein.

Giacino explains that "[t]here 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." EX1015(Giacino), 1:26-31. Giacino also laments that prior art meat flavor compositions lack the "true flavor" of meat. *Id.*, 1:51-59. Hence, a POSITA would have recognized that Giacino strives to create meaty flavoring compositions that fill this void and replicate the flavor and aroma of real meat as much as possible. EX1003(Tarte), ¶¶171, 190.

Moreover, a POSITA would have understood that Giacino was ripe for modifications that would enhance the meaty flavors and aromas of its flavoring compositions. Indeed, Giacino discloses that "[v]arious other materials and ingredients can be incorporated into the compositions to provide a variety of flavor characteristics" that build upon the "basic flavor" of its flavoring compositions. *Id.*, 2:38-41; EX1003(Tarte), ¶¶172, 191.

Brown teaches that heme iron found in meat catalyzes reactions that produce volatiles having a meaty aroma and flavor during the cooking of meat. EX1012(Brown), [00363]. Brown further teaches that this property of heme iron is similarly achieved when using other heme-containing proteins, such as soy

leghemoglobin, in reactions to produce the same "characteristic flavor and fragrance components" of cooked meat. *See id.* Exploiting this property, Brown teaches that adding leghemoglobin to a meat flavoring composition, such as a muscle replica, that already comprises known meat flavor precursors (*e.g.*, glucose and pea flour[9]), "contributes favorably to [the] aroma of" the composition and produces "the aroma of cooked meat." *Id.*, [00364]; EX1003(Tarte), ¶¶173, 192.

Brown further discloses that heating the composition containing leghemoglobin and flavor precursors generates volatile compounds associated with cooked meat that are "consistent[ly] differen[t]" than the volatiles produced by heating the same composition without leghemoglobin. EX1012(Brown), [00364]. According to Brown, volatile compounds, such as 2-octanone, 2-methyl furan, and "many other … compounds," were "found exclusively or more abundantly" in the leghemoglobin-containing composition versus the composition without leghemoglobin. *Id.* Brown teaches that these compounds are material because they "are often associated with the aroma of cooked meat." *Id.*; EX1003(Tarte), ¶¶174, 193.

Brown's soy leghemoglobin is an "isolated" (to the extent the term has patentable weight) heme-containing protein because it is extracted from soy root

[9] Pea flour contains well-known flavor precursors including thiamine, cystine, and methionine. *See supra* Section VIII.A.4; EX1005(McGorrin), Section V.B.

nodules or obtained using recombinant expression systems. *See* EX1012(Brown), [00376]-[00377], [00380]-[00381]; EX1003(Tarte), ¶194.

Based on Brown's teachings, a POSITA 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. A POSITA would have been motivated to make such a modification to capitalize on the express benefits touted by Brown that adding leghemoglobin has on the resulting volatile profile, especially since Giacino expressly invites incorporating additional ingredients to its compositions to modulate their flavor. This modification would further Giacino's goal of providing a "true[r] flavor" of meat. EX1003(Tarte), ¶¶175, 195.[10]

A POSITA would have had a reasonable expectation of success in combining

[10] Contrary to PO's arguments during prosecution, lipid oxidation would not discourage a POSITA from including a heme-containing protein in a food flavor additive composition. First, a POSITA would understand 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. Second, 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. Third, it was well-known in the art that oxidized lipids can contribute positively to meat flavor. Fourth, a POSITA would understand that potential lipid oxidation can be mitigated with the use of antioxidants. *See* EX1003(Tarte), Section XII.B.1; EX1005(McGorrin), Sections V.C, VIII.B.

Giacino's and Brown's teachings. Like Brown, Giacino's meaty flavoring compositions also include reducing sugars and sulfur compounds. *See infra* Section IX.B.3-4. Hence, a POSITA would reasonably expect the same catalyzation described in Brown to take place when adding leghemoglobin to Giacino's compositions to produce volatiles associated with cooked meat. Additionally, nothing more than ordinary skill would have been required to obtain Brown's soy leghemoglobin and mix it into Giacino's composition prior to heating. EX1003(Tarte), ¶¶184, 196.

Furthermore, initiating a Maillard reaction using flavor precursors was long known to produce desirable meaty flavors/aromas. *Id.*, ¶185; EX1005(McGorrin), Sections V.B, V.D. Hence, a POSITA would have known how to combine and heat flavor precursors, such as those taught in Giacino and Brown, to produce meat-associated volatiles.

3. Limitation 1[b]

Giacino discloses this limitation. Giacino teaches that a "saccharide material such as a mono saccharide [sic]," including "[r]ibose, surcrose [sic], dextrose, and xylose," is added to Giacino's flavoring compositions to provide "somewhat more intense flavor characteristics." EX1015(Giacino), 6:1-7; EX1003(Tarte), ¶199.

4. Limitation 1[c]

Giacino discloses this limitation. Giacino teaches that its flavoring

compositions include thiamine, cysteine, and/or cystine. EX1015(Giacino), 2:5-8 (thiamine), 2:14-16 (same), 3:43-46 (cysteine), 3:75-4:3 (same), 4:21-23 (cystine), 5:1-10 (thiamine and cysteine); EX1003(Tarte), ¶199.

5. Limitation 1[d]

Giacino's artificial meaty flavoring compositions do not contain animal products.

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, 6:1-4. Giacino further teaches that for the hydrolyzed protein ingredient, non-animal, vegetable hydrolysates "are preferred." *See id.*, 3:23-25. With respect to thiamine, Giacino expressly teaches that it is sourced from yeast. *Id.*, 5:68-70; EX1003(Tarte), ¶¶201-02.

As for cysteine, ribose, and taurine, Giacino does not teach or suggest that these compounds are sourced from previously live animals. Hence, a POSITA would understand that Giacino allows for—and indeed motivates—the use of cysteine, ribose, and taurine from non-animal sources. EX1003(Tarte), ¶203.

Indeed, it was well-known that cysteine could be obtained from non-animal sources, including synthetic cysteine made in recombinant microorganisms. *See generally* EX1085(Wacker); EX1078 (Reutter-Maier); EX1079(Leinfelder).

Similarly, it was well-known that taurine is derived synthetically from, for example, ethylene oxide or monoethanolamine. EX1081(Hu), 1:5-29. Ribose is also derived synthetically from xylose. EX1080(Feniou), 1:46-49; EX1003(Tarte), ¶204.

A POSITA would have been motivated to use non-animal sourced cysteine, taurine, and ribose to keep the meaty flavoring composition (and thus the food product to which it is ultimately added) free of animal products for those individuals that refrain from consuming animal products for health, environmental, ethical, or religious reasons. Using non-animal sourced cysteine, taurine, and ribose is also consistent with Giacino's teachings that "the actual meat such as beef, pork, chicken, turkey, duck … [can be] ***actually undesirable***" in the meaty flavoring composition. EX1015(Giacino), 1:27-30; EX1003(Tarte), ¶205.

Finally, adding leghemoglobin to Giacino's meaty flavoring composition would maintain the composition's "no animal products"-status because it is derived from plants. EX1003(Tarte), ¶206.

6. Limitation 1[e]

Giacino discloses that "[t]he 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." EX1015(Giacino), 6:15-17. The heating step causes a "reaction" that produces the meaty aroma and flavor. *Id.*, 6:20-23, 2:5-8; EX1003(Tarte), ¶¶208-09.

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. EX1003(Tarte), ¶210. For example, it was well-known in the art that heating ribose and cysteine produces at least two volatiles having a meat-associated aroma. The same is true with heating thiamine. *Id.*, ¶211; EX1005(McGorrin), Sections V.B, V.D.

A POSITA would understand that adding Brown's leghemoglobin would only further contribute to the meaty aroma volatiles because Brown's process reacts leghemoglobin with amino acids and sugars to achieve a "cooked meat" aroma. EX1003(Tarte), ¶212.

C. Claims 2, 15

Giacino and Brown render claims 2 and 15 obvious ("leghemoglobin").

As explained above, a POSITA would have been motivated to add soy ***leghemoglobin*** to Giacino's meaty flavoring compositions with a reasonable expectation of success as taught by Brown. *See supra* Section IX.B.2; EX1003(Tarte), ¶218.

D. Claims 3, 16

Giacino and Brown render claims 3 and 16 obvious because the modified meaty flavoring composition comprises soy leghemoglobin (*see supra* Section

IX.B.2), which has an "amino acid sequence having at least 80% sequence identity to" SEQ ID NO 4. Brown's SEQ ID NO 1 also has about 92% sequence identity with the '096 patent's SEQ ID NO 4. *See supra* Section VIII.C; EX1003(Tarte), ¶218.

E. Claims 4, 24

Giacino discloses claims 4 and 24.

For example, Giacino discloses that its meaty flavoring compositions can be a liquid. *See, e.g.*, EX1015(Giacino), 2:23-28 ("[The] composition … includes materials such as **water, edible oils** … to provide a medium for the reaction."), 6:36-39 ("[P]roducing beef flavor compositions involves refluxing an **aqueous pre-mix**."), claim 12 ("A composition … in an **aqueous** … vehicle."); EX1003(Tarte), ¶220.

Giacino also discloses that its meaty flavoring composition can be a powder. EX1015(Giacino), 9:70-10:2 ("The composition is ***spray dried*** to produce a beef flavor product."). A POSITA would understand that such a powder is a "bouillon powder" because it has a meaty flavor. *Id.*, 2:5-8. A POSITA would also understand that such a powder, when placed in a packet, is a "seasoning packet" and "flavoring packet." It would have been obvious to place the powdered meaty flavoring composition into a packet for ease of use and to preserve freshness when storing the flavoring composition. EX1003(Tarte), ¶¶221-23.

F. Claim 5

Giacino and Brown render claim 5 obvious because the modified meaty flavoring composition comprises soy leghemoglobin (*see supra* Section IX.B.2), which is a plant heme-containing protein. EX1003(Tarte), ¶¶224-25.

G. Claims 6, 22 ("further comprising…an extract of hydrolysate selected from…")

Giacino discloses claims 6 and 22 ("vegetable protein hydrolysate").

Giacino discloses that its meaty flavoring compositions include a "proteinaceous material," such as "edible protein hydrolysate." EX1015(Giacino), 3:3-5. The edible protein hydrolysates are preferably ***vegetable*** protein hydrolysates. *See id.*, 3:18-25; EX1003(Tarte), ¶226.

H. Claim 7

Giacino discloses claim 7 ("glutamic acid," "glycine," "thiamine").

Giacino discloses that its meaty flavoring compositions include thiamine. *See, e.g.*, EX1015(Giacino), 2:5-8, 5:1-10; *see supra* Section IX.B.4. Giacino also discloses that the compositions may include glutamic acid and/or glycine. *See id.*, 4:18-21, 5:1-10; EX1003(Tarte), ¶229.

I. Claims 8, 17

Giacino and Brown render obvious claims 8 and 17 ("sunflower oil").

Giacino's compositions include "edible oils" as a medium. EX1015(Giacino), 2:23-26, 5:22-25. However, Giacino does not expressly disclose the type of edible

oil that can be used. Brown expressly teaches using sunflower oil in its meat-flavored composition. EX1012(Brown), [00364]. A POSITA would have been motivated to use Brown's sunflower oil as Giacino's "edible oil" because Brown demonstrates to a POSITA that heating a composition that includes flavor precursors and specifically sunflower results in desirable cooked meat aromas. *Id.* Moreover, a POSITA would have understood based on Brown's teachings that sunflower oil would have been one choice out of a finite number of edible oils to use in Giacino's compositions, and hence it would have been obvious to try. EX1003(Tarte), ¶¶231-32. A POSITA would have had a reasonable expectation of success of adding sunflower oil since no more than routine skill (*e.g.*, measuring, mixing) would have been required. *Id.*, ¶233.

J. Claims 9, 22

Giacino discloses claims 9 and 22 ("albumin," "globulin").

Giacino teaches that its flavoring compositions include albumins and globulins. EX1015(Giacino), 3:3-10 ("Among the proteins which may be used are albumins, globulins…"). Giacino teaches that "[v]egetable derived" versions of these proteins are "preferred." *Id*. Hence, they are not animal products. EX1003(Tarte), ¶236.

Giacino and Brown in combination also disclose claims 9 and 22. Brown teaches using pea flour in its compositions. EX1012(Brown), [00364]. Pea flour

contains albumins and globulins. *See* EX1003(Tarte), ¶237; EX1067(Meng), 235; EX1083(Buffo), 293; EX1070(Karaca), 196. A POSITA would have been motivated to add pea flour to Giacino's compositions to serve as a vegetable source for "proteinaceous material," which Giacino teaches provides "variety" to the flavors produced. EX1015(Giacino), 2:52-3:2. EX1003(Tarte), ¶237. A POSITA would have had a reasonable expectation of success because no more than ordinary skill would be needed to mix in pea flour. *Id*.

K. Claim 10 ("food flavor additive composition prepared by a process of…")

1. Limitations 10[pre], 10[a], 10[b], 10[c], 10[e]

There is substantial overlap between independent claims 1 and 10. *See supra* Sections IX.B.1-5; EX1003 (Tarte), Section XII.D.

As discussed with respect to claim 1, the mixture of Brown's leghemoglobin and Giacino's cysteine, thiamine, ribose, among other compounds in Giacino's flavoring composition, is a "heme flavor reaction mixture." *Id.*, ¶242.

2. Limitation 10[d] ("heating…to at least 150°C for at least 1 minute")

Giacino explains that its compositions are preferably heated to a temperature between 200°F (93°C) and 420°F (216°C) for between 15 seconds and 6 hours to induce the required reactions that produce the meaty flavor. EX1015(Giacino), 6:26-31. Giacino further explains that when heat exchangers are used, "the reaction mixture can quickly be brought to the reaction temperature and then quickly cooled

in a second exchanger to a lower temperature at which no further reaction will take place." *Id.*, 6:48-52; *see also id.*, 6:68-71 (temperatures between 250°F (121°C) and 400°F (204°C) and heating times between 15 seconds and 3 minutes are preferred for heat exchangers). *Id.*, 6:68-71; EX1003(Tarte), ¶244.

Hence, Giacino discloses this limitation because its disclosed heating temperatures and times overlap with those recited in limitation 10[d]. EX1003(Tarte), ¶245.

3. Limitations 10[f] ("meaty flavor and/or meaty aroma" "during … and … after the heating")

Giacino and Brown render this limitation obvious.

As discussed above, heating Giacino's modified compositions, which include thiamine, cysteine, ribose, and soy leghemoglobin, would induce a Maillard reaction that produces volatiles having a meaty aroma/flavor. *See supra* Section IX.B.6; EX1003(Tarte), ¶249.

A POSITA would recognize that the volatiles that were produced during the heating step remain present after heating. EX1003(Tarte), ¶250.

L. Claim 11 ("further comprises a compound selected from the group…")

Giacino and Brown render claim 11 obvious.

A POSITA would have recognized that when the cysteine and ribose compounds are heated in Giacino's modified composition, a Maillard reaction would

occur causing the production of various volatile compounds including **2,5-dimethylpyrazine** and **2-methyl-thiazole**, which are both recited in claim 11. *See* EX1003(Tarte), ¶253; EX1024(MacLeod), 385.

M. Claim 12 ("compound is detectable in the headspace")

Giacino and Brown render claim 12 obvious.

A POSITA would have understood the volatile compounds produced during the heating process would be released into the volume of air above the composition (*e.g.*, headspace), and therefore would be detectable during and after heating. *See* EX1003(Tarte), ¶256.

N. Claim 14 ("heme-containing protein is present in an amount…")

Giacino and Brown render claim 14 obvious.

As discussed above, a POSITA would have been motivated to add leghemoglobin to Giacino's meaty flavoring composition with a reasonable expectation of success. *See supra* Section IX.B.2. As to the amount of such leghemoglobin to add, a POSITA would have added an amount expressly taught by Brown, namely, between 0.01% and 5% by weight of the meaty flavoring composition. EX1012(Brown), [00354]; *see also id.*, [00367] (disclosing various percentages between 0.01% and 5% by weight); EX1003(Tarte), ¶259.

A POSITA would have had a reasonable expectation of success since Giacino teaches that the ingredient amounts in its compositions can vary widely depending

on the desired characteristics. Thus, other existing ingredients in the composition would have been reduced to make room for the 0.01%-5% by weight leghemoglobin added. EX1003(Tarte), ¶¶259-60.

O. Claim 18 ("further comprising…an emulsifier [or] a gelling agent")

Giacino satisfies claim 18 because it discloses that its compositions include a plant-based ***emulsifier***, namely, gum arabic. EX1015(Giacino), 9:21-27; EX1074(dos Santos), 233 ("Arabic gum has wide industrial uses as … [an] ***emulsifier***, mainly in the food industry."); EX1122(Saha), 590; EX1003(Tarte), ¶262.

Additionally, Giacino, Brown, and MacLeod together disclose this claim. MacLeod discloses the use of starch and pectin in similar meat-flavored compositions. EX1024(MacLeod), 414. Pectin and starch are both plant-based ***gelling agents*** (and thickeners). EX1003(Tarte), ¶263; EX1071(Flutto), 4442, 4449; EX1074(dos Santos), 231; EX1122(Saha), 595.

A POSITA would have recognized that adding pectin or starch (as taught by MacLeod) to Giacino's meaty flavoring composition would thicken the mixture. A POSITA would have been motivated to thicken the compositions for use in gravies and sauces. EX1015(Giacino), 7:15-22; EX1003(Tarte), ¶264. A POSITA would have also recognized that adding pectin or starch would promote gelling of the composition, which would have been desirable to improve texture for Giacino's

"synthetic meat fibre" (*i.e.*, meat substitute) applications. EX1015(Giacino), 7:22-26; EX1003(Tarte), ¶265. Giacino invites such modification because it teaches incorporating "food additives" including "thickeners" and starches. EX1015(Giacino), 9:5-19 (thickener), 11:13 (cornstarch).

Separately, Brown teaches that adding transglutaminase stabilizes an emulsion of fat and protein into a ***gel*** to improve its texture. EX1012(Brown), [00319], [00322], [00400]-[00402], Fig. 11. Transglutaminase was a known gelling agent. EX1131(Nio), Abstract; EX1130(Kang), Abstract. A POSITA would have been motivated to add transglutaminase to Giacino's compositions (as taught by Brown) to improve the texture for Giacino's disclosed "synthetic meat fibres" application. EX1003(Tarte), ¶266.

P. Claim 19 ("further comprising adding an emulsifier and a gelling agent…prior to the heating")

Giacino, Brown, and MacLeod render obvious claim 19.

As discussed above, a POSITA would have added starch or pectin (gelling agents) and gum arabic (emulsifier) to Giacino's compositions. *See supra* Section IX.O. These compounds would have been added *before* the heating step. EX1003(Tarte), ¶269.

A POSITA would have understood that heating helps activate a gelling agent's desired gelling/thickening properties. EX1134(Lund), 249; EX1136(Whistler), 114, 124; EX1003(Tarte), ¶270. As for the emulsifier, its

presence in the mixture during the heating step is beneficial because the heat increases the fluidity of the mixture which would assist the emulsifier in creating an emulsion of the proteins and fats present in the composition. EX1003(Tarte), ¶271. Heating the composition containing these compounds (*e.g.*, starch or pectin and gum arabic) also helps disperse the compounds within the composition and promotes hydration of the gelling agents. *Id.*

Additionally, it would have been common sense to add the starch or pectin and gum arabic before the heating step at the same time all of the other compounds in Giacino's composition are combined. Otherwise adding these compounds after the heating step would necessitate an additional mixing step, which would unnecessarily complicate the process. *Id.*

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.

R. Claim 21 ("heme flavor reaction mixture is an oil-based mixture")

Giacino discloses that its compositions may be oil-based mixtures.

For example, Giacino teaches that its compositions preferably incorporate a

"vehicle," such as "edible oils … to provide a medium for the reaction." EX1015(Giacino), 2:23-28. Giacino further teaches that this edible oil medium may account for as much as ***95%*** of the composition by weight. *Id.*, 5:22-30. A POSITA would understand that such a composition is an "oil-based mixture." EX1003(Tarte), ¶275.

S. Claim 23

Giacino and Brown render claim 23 obvious.

As discussed above, Giacino and Brown render obvious the food-flavor additive composition of claim 1. *See supra* Section IX.B. Giacino discloses that its flavoring compositions are added to consumable food products, such as soups, gravies, and synthetic meats, to impart a meaty flavor/aroma. *See supra*, Section IX.B.1. A POSITA would understand that these food products are "subsequently heated or cooked." EX1015(Giacino), 6:71-7:2; EX1003(Tarte), ¶¶278-79.

X. GROUNDS 3A-3D: GIACINO, CONRAD, CRANE, PROULX, PERRET, MACLEOD

Giacino, Conrad, and Crane render obvious claims 1-2, 4-7, 9-12, 14-15, and 20-24 (Ground 3A). Adding Proulx renders obvious claims 3 and 16 (Ground 3B). Adding Perret renders obvious claims 8 and 17 (Ground 3C). Adding MacLeod renders obvious claims 18-19 (Ground 3D).

A. Overview of Giacino, Conrad, and Crane

As discussed above, Giacino discloses every limitation of the independent

claims except the "isolated heme-containing protein." *See supra* Section IX.A. To the extent it is determined that Brown is not prior art, the Challenged Claims are nevertheless unpatentable because a POSITA would have modified Giacino's flavoring compositions to include an isolated heme-containing protein based on Conrad's and Crane's teachings. Conrad discloses "process[es] for the preparation of meat replacement products." EX1013(Conrad), 1:11-14. Notably, Conrad discloses that adding isolated hemoglobin (*e.g.*, heme-containing protein) to a composition "gives a desired taste improvement as it ***improves the meat flavour*** of the final product." *Id.*, 4:3-16; EX1003(Tarte), Section XIII.A.

Crane discloses the production of heme-containing proteins (*e.g.*, hemoglobin, myoglobin, and leghemoglobin) using recombinant expression systems. EX1014(Crane), Abstract, [0021], [0060]-[0062]. Crane's teachings obviate the need to extract heme-containing proteins (*e.g.*, hemoglobin, myoglobin) from previously live animals. This avoids reliance on conventional animal husbandry and slaughter and/or generally costly and labor-intensive extraction methods traditionally needed to obtain these proteins and results in a composition "contain[ing] no animal products." EX1003(Tarte), Section XIII.A. Accordingly, adding heme-containing protein (as taught by Conrad and Crane) to Giacino's composition results in a modified composition that satisfies all limitations of the independent claims. EX1003(Tarte), ¶¶281-384.

B. Claim 1

1. Limitation 1[pre], 1[b], 1[c]

Giacino discloses these limitations. *See supra* Section IX.B.1, IX.B.3-4.

2. Limitation 1[a]

Giacino, Conrad, and Crane render obvious a food-flavor additive composition comprising an isolated heme-containing protein. As explained below, a POSITA would have been motivated to modify Giacino's meaty flavoring compositions by adding an isolated heme-containing protein (*e.g.*, recombinant bovine hemoglobin or plant leghemoglobin) to enhance the compositions' meaty flavor (as taught by Conrad and Crane) and fortify the compositions.

Generally, a POSITA would have been motivated to create a meat-flavored composition that closely mimics the attributes of conventionally sourced meat, including flavor, aroma, and beneficial nutritional aspects, to encourage consumption by consumers who ordinarily enjoy consuming conventionally sourced meat. Including heme-containing proteins, such as hemoglobin or leghemoglobin, in the composition would achieve these goals. EX1003(Tarte), ¶¶289, 305.

As to flavor and aroma, a POSITA would have been motivated to replicate the natural flavor and aroma of meat to persuade consumers that they are eating a familiar meat product. A POSITA would have recognized that one characteristic of conventionally obtained meat is that it produces a meaty aroma when cooked because of the volatile chemical compounds created when precursor compounds

within the meat undergo a chemical reaction (when heated). A POSITA would have been motivated to replicate that same effect in artificial meat-flavored compositions to mimic the flavors and aromas associated with cooked meat. *Id.*, ¶306.

Giacino attempts to achieve that goal with compositions that include flavor precursors, such as taurine, thiamine, cysteine, and ribose, that better replicate the "true flavor" of meat. *See* EX1015(Giacino), 1:51-59. Giacino expressly teaches that various additional ingredients can be incorporated into its compositions to "buil[d] upon the basic flavor." *See supra* Section IX.B.2; EX1003(Tarte), ¶¶307-08.

Conrad expressly teaches that "[t]he addition of blood/hemoglobin further gives a desired taste improvement as it improves the meat flavour of the final product." EX1013(Conrad), 4:14-16. Conrad teaches that hemoglobin can be isolated from blood before being added to the product. *Id.*, 4:7-9; EX1003(Tarte), ¶309.

Based on Giacino's and Conrad's teachings, a POSITA would have been motivated to add hemoglobin, or another functionally equivalent heme-containing protein (*e.g.*, leghemoglobin), to Giacino's meaty flavoring compositions to "improve the meat flavour of the final product." And, to avoid the consumption of conventionally sourced meat, a POSITA would have been motivated to substitute Conrad's "hemoglobin…of whole blood from slaughtered animals" with

recombinant hemoglobins, including either native animal hemoglobins (*e.g.*, bovine hemoglobin[11]) or non-animal hemoglobins (*e.g.*, plant leghemoglobin), created using known expression systems. EX1003(Tarte), ¶311

Crane discloses such expression systems used to manufacture diverse kinds of heme-containing proteins, such as hemoglobin, myoglobin, and leghemoglobin, which are "completely functional" and suitable for "commercial applications." EX1014(Crane), Abstract, [0021], [0024]. Using recombinant expression systems to source heme-containing protein would have also been a cost-effective option and would have produced the proteins with a high degree of purity. *Id.*, [0060]-[0062] ("The purified preparation of recombinant heme-binding protein …."), [0075] (95% purity). High purity is beneficial as it allows greater control over the amount of heme-containing protein added to the consumable, which promotes greater consistency in the end product. A POSITA would have also been motivated to use recombinantly sourced heme-containing protein to appeal to individuals who have concerns about environmental, health, and animal welfare impacts of consuming previously live animal products or who otherwise abstain from consuming such animal products. EX1003(Tarte), ¶310-11.

As to nutrition, a POSITA would have understood that meat is an important

[11] PO has argued in Litigation that recombinantly sourced proteins native to animals (*e.g.*, bovine myoglobin) are not "animal products." *See supra* Section V.A.

dietary source of heme iron, which has greater bioavailability than non-heme iron. *Id.*, ¶312. A POSITA would have recognized that the ingredients comprising Giacino's non-meat compositions (*e.g.*, thiamine, taurine, reducing sugars, cysteine, etc.) are not significant sources of iron, particularly heme iron. Accordingly, a POSITA would have also been motivated to add hemoglobin (*e.g.*, recombinant bovine hemoglobin or plant leghemoglobin) to increase heme iron in Giacino's meaty flavoring compositions. Doing so would have provided Giacino's compositions additional iron that had high bioavailability and better mimicked the beneficial nutritional features of meat. *Id.*, ¶313.[12]

A POSITA would have also had a reasonable expectation of success in modifying Giacino's compositions as described above. Only ordinary skill was required to add the recombinant hemoglobin to the structured protein product mixture in amounts taught by Conrad before transferring the mixture to a heat exchanger or batchwise open vessel for heating (as taught by Giacino). *See, e.g.*, EX1013(Conrad), 1:56-61, 4:32-40; EX1015(Giacino), 6:15-6:71, 8:33-36; EX1003(Tarte), ¶298-299. Moreover, the Maillard reaction was long known, including the identity of specific precursor compounds that, when reacted with heat, would produce a meaty flavor and aroma. EX1003(Tarte), ¶300. Additionally, it would have been straightforward to apply Crane's teachings to express recombinant

[12] *See supra* n.10.

heme-containing proteins from expression systems for use in the meat/food-flavor compositions of Giacino. *Id.*, ¶301; EX1007(Batt), ¶¶31-32, 49-53.

3. Limitation 1[d]

Giacino's meaty flavoring compositions contain no animal products. *See supra* Section IX.B.5. Adding recombinant hemoglobin (*e.g.*, bovine hemoglobin[13] or plant leghemoglobin) would continue to satisfy this limitation. EX1003(Tarte), ¶¶316-17.

4. Limitation 1[e]

Heating Giacino's compositions produce at least two volatile compounds having a meat-associated aroma. *See supra* Section IX.B.6. A POSITA would have recognized that adding recombinant hemoglobin/leghemoglobin would only further contribute to the composition's meaty aroma because Conrad expressly discloses that hemoglobin "improves [] meat flavour." EX1003(Tarte), ¶¶320-21.

C. Claims 2, 15

Giacino, Conrad, and Crane render claims 2 and 15 obvious ("hemoglobin" or "leghemoglobin").

Adding recombinant ***hemoglobin*** or ***leghemoglobin*** to Giacino's meaty flavoring compositions satisfies these claims. *See supra* Section X.B.2; EX1003(Tarte), ¶324.

[13] *See supra* n.11.

D. Claims 3, 16

Giacino, Conrad, Crane, and Proulx render claims 3 and 16 obvious (SEQ ID NO 4).

As discussed above, a POSITA would have added hemoglobin (recombinant bovine hemoglobin or plant leghemoglobin) to Giacino's compositions. *See supra* Section X.B.2. As to the specific type of plant leghemoglobin added, it would have been obvious to use soy leghemoglobin (*i.e.*, *Glycine max* leghemoglobin) based on Proulx's teachings. EX1003(Tarte), ¶327.

Proulx discloses the use of soy leghemoglobin as an iron fortificant for foods. EX1019(Proulx), Abstract. Proulx also teaches that soy leghemoglobin "showed similar bioavailability" to that of bovine hemoglobin in a food matrix. *Id*.; EX1003(Tarte), ¶328.

Hence, a POSITA would have been motivated to use soy leghemoglobin as the hemoglobin of choice because it would have predictably provided heme iron having a bioavailability on par with bovine hemoglobin. It would have also been obvious to try using soy leghemoglobin based on the finite number of hemoglobins to choose from. A POSITA would have also had a reasonable expectation of success at recombinantly expressing and using soy leghemoglobin, which would have required no more than conventional techniques (*e.g.*, use of known soy leghemoglobin sequence in a recombinant expression system and mixing the

expressed soy leghemoglobin into the meaty flavoring composition). EX1003(Tarte), ¶329.

E. Claims 4, 24

Giacino discloses these claims because its compositions may be spray dried powders (*e.g.*, bouillon powder) or liquid compositions. It would have been obvious to package the powders in seasoning or flavoring packets. *See supra* Section IX.E.

F. Claim 5

Adding recombinant ***leghemoglobin*** to Giacino's meaty flavoring compositions satisfies this claim because it is a plant heme-containing protein. *See supra*, Section X.B.2; EX1003(Tarte), ¶333.

G. Claims 6-7, 9, 22

Giacino satisfies these claims because its compositions may include vegetable protein hydrolysates, thiamine, glutamic acid, glycine, albumins, and globulins. *See supra* Section IX.G-H, IX.J.

H. Claims 8, 17

Giacino, Conrad, Crane, and Perret render claims 8 and 17 obvious ("safflower oil").

Perret discloses simulated meat flavoring compositions that provide a meaty aroma/flavor. EX1020(Perret), 1:10-11, 1:63-69, 2:1-38, 4:36-48; EX1003(Tarte), ¶337. Perret's compositions include "edible fat," such as "safflower oil." *Id.*, 4:6-29. Similarly, Giacino's compositions include "edible oils" as a medium.

EX1015(Giacino), 2:23-26, 5:22-25. A POSITA would have been motivated to use Perret's safflower oil for Giacino's "edible oils" because Perret teaches that such fat leads to a "very pleasing product" having a "roast meat flavor and odor." EX1020(Perret), 4:6-29. It would have also been obvious to try given the finite number of edible oils. EX1003(Tarte), ¶338. A POSITA would have had a reasonable expectation of success of adding safflower oil since no more than routine skill (*e.g.*, measuring, mixing) would have been required. *Id.*, ¶339.

I. Claim 10

1. Limitations 10[pre], 10[a], 10[b], 10[c], 10[e]

There is substantial overlap between claims 1 and 10. *See supra* Sections X.B.1-3.

The mixture of recombinant hemoglobin/leghemoglobin, taurine, cysteine, thiamine, ribose, and other ingredients in Giacino's composition constitute a "heme flavor reaction mixture." EX1003(Tarte), ¶344.

2. Limitation 10[d]

Giacino discloses this limitation because it teaches heating its compositions to 200°F (93°C) and 420°F (216°C) for between 15 seconds and 6 hours, which overlap with the claimed ranges of the limitation ("at least 150°C for at least 1 minute"). *See supra* Section IX.K.2.

3. Limitations 10[f]

Giacino, Conrad, and Crane render this limitation obvious because heating

Giacino's modified composition induces a Maillard reaction that produces volatiles having a meaty aroma/flavor. *See supra* Sections IX.K.3, X.B.4; EX1003 (Tarte), ¶¶348-49.

J. Claim 11

Giacino, Conrad, and Crane render this claim obvious because heating cysteine and ribose produces, *inter alia*, 2,5-dimethylpyrazine and 2-methyl-thiazole. *See supra* Sections IX.L (claim 11), X.B.4 (claim 1[e]); EX1003(Tarte), ¶352.

K. Claim 12

Giacino, Conrad, and Crane render this claim obvious because volatiles are released in the composition's headspace. *See supra* Sections IX.M, X.B.4; EX1003(Tarte), ¶355.

L. Claim 14

Giacino, Conrad, and Crane render claim 14 obvious.

A POSITA would have modified Giacino's meaty flavoring composition by adding recombinant hemoglobin/leghemoglobin. *See supra* Section X.B.2. As to the amount of such recombinant hemoglobin/leghemoglobin added, a POSITA would use the concentrations of heme-containing protein in Conrad.

Conrad discloses a food product ("wheat meat") having a total weight of 2100g that includes 30g heme-containing protein (hemoglobin), which represents ***1.43%*** by weight heme-containing protein. EX1013(Conrad), 4:33-40;

EX1003(Tarte), ¶¶359-68. Conrad also more generally teaches that its food products preferably contain about ***1.25%-1.89%*** by weight heme-containing protein (hemoglobin). EX1003(Tarte), ¶¶369-70 (citing EX1013(Conrad), 1:56-61, 4:5-10; EX1139(Weed), 584). A POSITA would have had a reasonable expectation of success of adding the recombinant hemoglobin/leghemoglobin into Giacino's flavoring compositions at the concentrations discussed above because no more than conventional methods (*e.g.*, measuring, mixing) would have been required. EX1003(Tarte), ¶371.

Separately, a POSITA would have also recognized that the concentration of heme-containing protein in the flavoring composition would be adjusted as part of routine experimentation to find the precise concentration needed to obtain an optimized balance between the desired flavor profile and nutritional content (*e.g.*, iron). This experimentation would result in compositions having heme-containing protein within the claimed 0.01%-5% range. EX1003(Tarte), ¶372.

M. Claim 18

As discussed above, Giacino satisfies claim 18 because it discloses using an emulsifier, gum arabic, in its compositions. *See supra* Section IX.O.

Additionally, Giacino, Conrad, Crane, and MacLeod render claim 18 obvious. As explained above, a POSITA would have added a gelling agent (as taught by MacLeod) to Giacino's compositions to thicken the compositions and/or promote

gelling, which would have been desirable for certain applications of the compositions including gravies, sauces, and synthetic meat fibres. *See id.*; EX1003(Tarte), ¶¶374-77.

N. Claim 19

Giacino, Conrad, Crane, and MacLeod render claim 19 obvious.

A POSITA would have added an emulsifier, such as gum arabic (as taught by Giacino), and a gelling agent, such as pectin or starch (as taught by MacLeod), to Giacino's compositions *before* the heating step because the heat would activate the gelling agent's desired gelling/thickening properties, assist in creating an emulsion by increasing the fluidity of the mixture, and helps disperse the emulsifier and gelling agent throughout the mixture. *See supra* Section IX.P. It would also obviate the need for additional mixing step after heating. *Id.*; EX1003(Tarte), ¶¶379-82.

O. Claims 20-21

Giacino discloses claims 20-21 because its compositions can be either aqueous solutions or oil-based mixtures containing up to 95% oil as a medium. *See supra* Sections IX.Q-R.

P. Claim 23

Giacino, Conrad, and Crane render claim 23 obvious.

As discussed above, Giacino, Conrad, and Crane render obvious the food-flavor additive composition of claim 1. *See supra* Section X.A. And, as also discussed above, Giacino discloses that its flavoring compositions are added to

consumable food products, and subsequently heated/cooked. *See supra* Section IX.S.

XI. GROUNDS 4A-4B: GIACINO, PROULX, CONRAD, PERRET, MACLEOD

Giacino, Proulx, and Conrad render obvious claims 1-7, 9-12, 14-16, and 20-24 (Ground 4A). Adding Perret renders obvious claims 8 and 17 (Ground 4B). Adding MacLeod renders obvious claims 18-19 (Ground 4C).

A. Overview of Giacino, Proulx, and Conrad

As discussed above, Giacino discloses every limitation of the independent claims except the "isolated heme-containing protein." *See supra* Section IX.A. To the extent it is determined that Brown is not prior art, the Challenged Claims are nevertheless unpatentable because a POSITA would have modified Giacino's flavoring compositions to include an isolated heme-containing protein based on Proulx's and Conrad's teachings.

Proulx teaches that soy leghemoglobin (*e.g.*, heme-containing protein) can be added to foods to fortify them with heme iron, which is known for having high bioavailability and high heat stability relative to non-heme iron. EX1019(Proulx), Abstract, 1520-22. Conrad discloses that adding isolated hemoglobin (*e.g.*, heme-containing protein) to a composition "gives a desired taste improvement as it improves the meat flavour of the final product." EX1013(Conrad), 4:3-16; EX1003(Tarte), Section XIV.A.

Accordingly, adding heme-containing protein (as taught by Proulx and Conrad) to Giacino's composition results in a modified composition that satisfies all limitations of the independent claims. EX1003(Tarte), ¶¶385-452.

B. Claim 1

1. Limitation 1[pre], 1[b], 1[c]

Giacino discloses these limitations. *See supra* Section IX.B.1, IX.B.3-4.

2. Limitation 1[a]

Giacino, Proulx, and Conrad render obvious a food-flavor additive composition comprising an isolated heme-containing protein. As explained below, a POSITA would have been motivated to modify Giacino's meaty flavoring compositions by adding an isolated heme-containing protein (*e.g.*, isolated soy leghemoglobin) to fortify the compositions' with heme iron (as taught by Proulx) and enhance meaty flavor (as taught by Conrad).

Generally, a POSITA would have been motivated to create a meat-flavored composition that closely mimics the attributes of conventionally sourced meat, including flavor, aroma, and beneficial nutritional aspects, to encourage consumption by consumers who ordinarily enjoy consuming conventionally sourced meat. Incorporating heme-containing proteins, such as soy leghemoglobin, in the composition would achieve these goals. EX1003(Tarte), ¶¶390, 407.

First, a POSITA would have been motivated to mimic beneficial aspects of meat's ***nutritional content***. As described above, a POSITA would have understood

that meat (*e.g.*, beef) is an important dietary source of heme iron, and that Giacino's compositions are not significant sources of iron, including heme iron. *See supra* Section X.B.2. Hence, a POSITA would have fortified Giacino's compositions to better approximate the iron content of meat. EX1003 (Tarte), ¶¶391, 407.

Proulx describes methods for supplementing foods with heme iron, which was well-known to have greater bioavailability than non-heme iron. EX1019(Proulx), 1518, 1520. Proulx discloses that leghemoglobin found in soy root nodules supplies heme iron, and that soy leghemoglobin "showed similar bioavailability" to that of bovine hemoglobin in a food matrix. EX1019(Proulx), Abstract. Proulx further teaches using isolated soy leghemoglobin preparations having varying degrees of purity (*i.e.*, isolated heme-containing protein). *Id.*, 1519-20 (disclosing preparations having 21%, 54%, and 73% purity); EX1003(Tarte), ¶¶392, 408.

Accordingly, a POSITA would have been motivated to add isolated soy leghemoglobin, as taught by Proulx, into Giacino's meaty flavoring compositions to fortify the compositions with heme iron, which has greater bioavailability than non-heme iron. This would allow the compositions to better replicate the iron content of conventionally sourced meat and encourage consumers to consume meat substitutes made with the fortified meat-flavored compositions. A POSITA would have been additionally motivated to fortify the compositions with soy leghemoglobin because of the "high heat stability of…[heme] iron" (EX1019(Proulx), 1520, 1522), and

because soy root nodules are currently an untapped resource in soy production (*Id.*, 1522). EX1003 (Tarte), ¶¶393, 410-11.

Moreover, PO previously relied on Proulx as authoritative to show that the bioavailability of soy leghemoglobin was equivalent to that of bovine myoglobin (the primary source of heme iron in beef) in food. EX1052(GRAS), 7. Hence, PO agrees that adding soy leghemoglobin to meat-flavored compositions would enhance the compositions' nutritional profile. EX1003 (Tarte), ¶¶394, 409.

Second, a POSITA would have been motivated to replicate the natural ***flavor and aroma*** of cooked meat in Giacino's meaty flavoring compositions to persuade consumers that they are eating a familiar meat product. As discussed above, a POSITA would have known that conventionally obtained meat produces a meaty aroma when cooked due to precursor compounds within the meat, and that a POSITA would have been motivated to replicate that same effect in meat-flavored compositions. *See supra* Section X.B.2; EX1003(Tarte), ¶¶395, 413.

Giacino strives to achieve that goal with meaty flavoring compositions that include flavor precursors that when heated better replicate the "true flavor" of meat. *See* EX1015(Giacino), 1:51-59. Similarly, Conrad discloses that "[t]he addition of blood/hemoglobin further gives a desired taste improvement as it improves the ***meat flavour*** of the final product." EX1013(Conrad), 4:14-16. A POSITA would have recognized that, like bovine hemoglobin, soy leghemoglobin is also a heme-

containing protein and would thus improve "meat flavour" as taught by Conrad. 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.

Furthermore, a POSITA would have recognized that soy leghemoglobin is a non-animal source of heme iron, which obviates the need to rely on heme-containing proteins obtained from previously live animals (*e.g.*, bovine myoglobin or hemoglobin) that are associated with conventional animal husbandry. This would have appealed to consumers that for health, environmental, or personal reasons abstain from consuming meat. *Id.*, ¶398.[14]

A POSITA would have had a reasonable expectation of success in combining Giacino, Proulx, and Conrad to achieve the claimed invention. Only ordinary skill would have been required to prepare and assemble the ingredients taught in these references into a meaty flavoring composition. *Id.*, ¶¶401-402. Similarly, only ordinary skill would have been required to carry out Proulx's process steps for harvesting and isolating soy leghemoglobin. *Id*., ¶402. Moreover, the Maillard reaction was long known, including the identity of specific precursor compounds

[14] *See supra* n.10.

that, when reacted with heat, would produce a meaty flavor and aroma. *Id.*, ¶403.

3. Limitation 1[d]

Giacino's meaty flavoring compositions contain no animal products. *See supra* Section IX.B.5. Adding soy leghemoglobin would not change that fact. EX1003(Tarte), ¶¶416-18.

4. Limitation 1[e]

Heating Giacino's compositions produce at least two volatile compounds having a meat-associated aroma. *See supra* Section IX.B.6. A POSITA would have recognized that adding soy leghemoglobin would only further contribute to the composition's meaty aroma because Conrad discloses that hemoglobin (functionally equivalent to soy leghemoglobin) "improves [] meat flavour." EX1003 (Tarte), ¶¶419-22.

C. Claims 2, 15

Giacino, Proulx, and Conrad render claims 2 and 15 obvious ("leghemoglobin").

Adding ***soy leghemoglobin*** to Giacino's meaty flavoring compositions satisfies these claims. *See supra* Section XI.B.2; EX1003(Tarte), ¶424.

D. Claims 3, 16

Giacino, Proulx, and Conrad render claims 3 and 16 obvious (SEQ ID NO 4).

Adding ***soy leghemoglobin*** to Giacino's meaty flavoring compositions satisfies these claims because SEQ ID NO 4 identifies the polypeptide for *Glycine*

max leghemoglobin (*i.e.*, soy leghemoglobin). *See supra* Section XI.B.2; EX1003(Tarte), ¶¶425-26.

E. Claims 4, 24

Giacino discloses these claims because its compositions may be spray dried powders (*e.g.*, bouillon powder) or liquid compositions. It would have been obvious to package the powders in seasoning or flavoring packets. *See supra* Section IX.E.

F. Claim 5

Adding ***soy leghemoglobin*** to Giacino's meaty flavoring compositions satisfies this claim because it is a plant heme-containing protein. *See supra* Section XI.B.2; EX1003(Tarte), ¶429 .

G. Claims 6-7, 9, 22

Giacino satisfies these claims because its compositions may include vegetable protein hydrolysates, thiamine, glutamic acid, glycine, albumins, and globulins. *See supra* Section IX.G-H, IX.J.

H. Claims 8, 17

Giacino, Proulx, Conrad, and Perret render claims 8 and 17 obvious because a POSITA would have used Perret's safflower oil as the "edible oil" medium for Giacino's compositions. *See supra* Section X.H; EX1003(Tarte), ¶432.

I. Claim 10

1. Limitations 10[pre], 10[a], 10[b], 10[c], 10[e]

There is substantial overlap between claims 1 and 10. *See supra* Sections

XI.B.1-3.

The mixture of soy leghemoglobin, cysteine, taurine, thiamine, ribose, and other ingredients in Giacino's composition constitute a "heme flavor reaction mixture." EX1003(Tarte), ¶437.

2. Limitation 10[d]

Giacino discloses this limitation because it teaches heating its compositions to 200°F (93°C) and 420°F (216°C) for between 15 seconds and 6 hours, which overlap with the claimed ranges of the limitation ("at least 150°C for at least 1 minute." *See supra* Section IX.K.2.

3. Limitations 10[f]

Giacino, Proulx, and Conrad render this limitation obvious because heating Giacino's modified composition induces a Maillard reaction that produces volatiles having a meaty aroma/flavor. *See supra* Sections IX.K.3, XI.B.4; EX1003 (Tarte), ¶¶440-42.

J. Claim 11

Giacino, Proulx, and Conrad render this claim obvious because heating cysteine and ribose produces, *inter alia*, 2,5-dimethylpyrazine and 2-methyl-thiazole. *See supra* Sections IX.L (claim 11), XI.B.4 (claim 1[e]); EX1003 (Tarte), ¶¶444-45.

K. Claim 12

Giacino, Proulx, and Conrad render this claim obvious because volatiles are

released in the composition's headspace. *See supra* Sections IX.M, XI.B.4; EX1003(Tarte), ¶¶447-48.

L. Claim 14

Giacino, Proulx, and Conrad render claim 14 obvious.

A POSITA would have modified Giacino's meaty flavoring composition by adding soy leghemoglobin. *See supra* Section XI.B.2. As to the amount of soy leghemoglobin added, a POSITA would use the concentrations of heme-containing protein in Conrad, which are within or overlap with the claimed 0.01%-5% by weight range. *See supra* Section X.L. The same arguments equally apply here. EX1003 (Tarte), ¶450.

M. Claims 18-19

Giacino, Proulx, Conrad, and MacLeod render claims 18-19 obvious for the same reasons discussed above for Giacino, Conrad, Crane, and MacLeod. *See supra* Sections X.M-N.

N. Claims 20-21

Giacino discloses claims 20-21 because its compositions can be either aqueous solutions or oil-based mixtures containing up to 95% oil as a medium. *See supra* Sections IX.Q-R.

O. Claim 23

Giacino, Proulx, and Conrad render claim 23 obvious.

As discussed above, Giacino, Proulx, and Conrad render obvious the food-

flavor additive composition of claim 1. *See supra* Section XI.B. Giacino discloses that its flavoring compositions are added to consumable food products, and subsequently heated/cooked. *See supra* Section IX.S.

XII. SECONDARY CONSIDERATIONS

No secondary considerations of non-obviousness support the patentability of the ’096 patent claims.

A. No “Surprising” or “Unexpected” Results Support Patentability

PO cited experiments and affidavits in support of purportedly “surprising”/“unexpected” results from the combination of a heme protein (leghemoglobin) with ribose and cysteine compared to the same reaction conditions lacking the heme protein. EX1002, 237-38, 241-373. PO’s characterization of the significance of such experiments is meritless.

Neither PO’s arguments nor experimental data show that the resulting aroma of the heme protein-containing reaction(s) more accurately mimics the aroma of meat. PO’s tests do not include a comparative sensory evaluation connecting any particular combination of volatile reaction products to the desired meaty aroma. EX1005(McGorrin), Section VIII.D.1. PO and its experts relied on literature teaching that certain compounds are associated with meaty aroma, but, without knowing the sensory impact of any particular profile of volatile components, the mere production of volatiles does not support finding that the resulting aroma is

more meaty. *Id*.

Moreover, contrary to PO's expert's assertions (EX1002, 244-45), a POSITA would understand that merely increasing the amounts of certain compounds would *not* necessarily increase the desired aroma and could affect it adversely. EX1005(McGorrin), Section VIII.D.3; EX1017(Mottram), 421. Relatedly, four of the purportedly "novel" compounds produced by PO's leghemoglobin-containing reactions are *not* exclusively related to a meaty or beefy aroma. EX1005(McGorrin), Section VIII.D.4. Without sensory evaluation data it is unknown whether PO's detected volatiles in fact produce a beefy aroma.

PO's alleged evidence of unexpected/surprising results also lacks nexus to the Challenged Claims. For example, the experimental evidence Patent Owner proffered is not coextensive with the scope of the claimed sulfur and sugar compounds. EX1005(McGorrin), Section VIII.D.5. PO's experiments are also merely in line with the teachings of the prior art, both with respect to sulfur and sugar compounds as flavor precursors and the use of heme-containing protein to produce meaty flavor. *Id*.

B. PO's Volatiles Are Not Novel

Compounds, such as 2-methyl-3-furanthiol (MFT), bis(2-methyl-3-furyl)disulfide (MFT-MFT), 2-acetylthiazole, and thiophene, that PO urged were produced *exclusively* under the heme-containing conditions (EX1002, 244-45) are

long known to be Maillard reaction products even in the absence of heme-containing proteins. EX1005(McGorrin), ¶¶178-180; EX1045(Hofmann), Abstract; EX1093(Vauthey), Abstract; EX1118(Wang), Abstract. PO may argue that heme-containing proteins act as a catalyst to increase production of these compounds. But merely increasing volatiles does not increase aroma. EX1017(Mottram), 421; EX1005(McGorrin), Section X.D.3, ¶181.

C. A POSITA Would Not Be Discouraged from Adding a Heme Protein to a Meat Replica

Conventionally sourced meat contains myoglobin and hemoglobin, which naturally contribute to meaty aroma when cooked. EX1005(McGorrin), ¶132. A POSITA would recognize that, *over time*, heme-catalyzed oxidation could produce undesirable flavor, but this would not discourage a POSITA from incorporating a protein naturally present in meat into a meat flavored composition. *Id.*, ¶¶133, 137.

Moreover, the art recognized that lipid oxidation could contribute positively to meaty flavor. EX1005(McGorrin), ¶¶130-31. For example, Mottram teaches that phospholipids in meat "provide *lipid oxidation products during the initial cooking of meat which contribute to desirable aromas*." EX1017(Mottram), 420; *see also* EX1022(Yamaguchi), [0026] (polyunsaturated patty acids subjected to oxidation improve "body taste" of foods). Thus, it is inaccurate and an oversimplification for PO to argue that lipid oxidation always exerts a negative impact on aroma. *Id.*, ¶¶134-136.

D. Other Objective Indicia

1. No Long Felt But Unmet Need, Skepticism, or Failure of Others

In 2021, an independent study looked at which of eight different plant-based burgers, including PO's burger product, most closely resembled the aroma of a typical hamburger. The study relied on both gas chromatography analysis-mass spectrometry (GC-MS) *and* sensory evaluations to judge the burgers. The study found that PO's burger was not one of the top performers as it "gave off notes of yeast and grain," which are not typical aromas associated with cooked beef. EX1005(McGorrin), ¶¶219-23. Indeed, the burgers that came in first and second did not contain heme-containing proteins. *Id.*, ¶224. The researchers instead concluded that the winner's (Beyond Burger) improved aroma was due to its fatty acids, canola and coconut oil, which are more similar to animal fatty acids than the sunflower oil PO's burger product uses. *Id.*, ¶225. Hence, there is no "failure of others" or "long felt, but unmet need" that PO's heme-containing burgers provide. *Id.*, ¶¶226-28.

2. No Nexus to Commercial Success

Based on PO's public representations, PO's plant-based burgers include the heme-containing protein leghemoglobin. EX1121, 2-3. Dr. McGorrin opines that in his experience, meaty, beef-like aroma is contributed by a variety of factors such as the volatile products of the Maillard reaction and lipid degradation, not simply the presence of heme-containing proteins. EX1005(McGorrin), ¶¶231-32. Dr.

McGorrin explains that he is unaware of any nexus between the leghemoglobin in PO's products and any commercial success of such products. *Id.*, ¶¶234-35. Rather, PO's commercial success is attributable to its aggressive marketing campaign instead of any particular advantage gleaned from including leghemoglobin in its products. *Id.*, ¶¶238-39.

XIII. INSTITUTION WOULD BE EQUITABLE (§325(d))

The Board should not exercise its discretion to deny institution under 35 U.S.C. §325(d). First, the art asserted here is materially different from that examined in prosecution. Indeed, none of the present art was the basis for a rejection during prosecution. In Grounds 2A-2B, 3A-3D, and 4A-4C, Petitioner relies on, in part, Giacino, Perret, MacLeod, Conrad, and/or Crane, none of which were cited or discussed during prosecution. The remaining references—Brown and Proulx—were cited during prosecution, but were not used in a rejection.[15]

The references the Examiner *did* assert during prosecution (*e.g.*, Tong, Koutsidis, Jamieson) all relied on animal products (*e.g.*, beef, beef blood). *See supra* Section III.B. Applicant overcame the rejections by amending the claims to require "no animal products." *See id.* Notably, all of the grounds here are based on

[15] The Examiner briefly discussed Proulx in the Notice of Allowance (*see supra* Section III.B), but did not use it as the basis of a rejection.

simulated meat flavoring compositions that do not include animal products.[16] Hence, the art asserted here is materially different.

The Examiner also did not have the benefit of expert testimony. Here, Drs. Tarte and Batt opine that a POSITA would have been motivated to manufacture heme-containing proteins using recombinant technologies and add them to meat flavoring compositions to achieve the claimed invention. *See supra* Section X. The Examiner may not have appreciated that this was even possible. Nor did the Examiner have the benefit of Dr. McGorrin's testimony that the '096 patent claims were not entitled to the '816 Provisional priority date. Had the Examiner known that, she may have asserted Brown, which anticipates or renders obvious the Challenged Claims.

Also weighing against exercise of discretion is that the Examiner erred in dismissing Proulx from consideration. *See supra* n.3.

XIV. REQUIREMENTS FOR INTER PARTES REVIEW (37 C.F.R §§ 42.101, 42.104, and 42.108)

Petitioner certifies that the '096 patent is available for *Inter Partes* Review and that Petitioner is not barred or estopped from requesting this proceeding.

XV. CONCLUSION

Petitioner has demonstrated a reasonable likelihood that all Challenged

[16] *See supra* Section V.A.

Claims are unpatentable.

XVI. MANDATORY NOTICES

A. Real Party-in-Interest (37 C.F.R. § 42.8(b)(1))

Motif FoodWorks, Inc. is the real party-in-interest.

B. Related Matters (37 C.F.R. § 42.8(b)(2))

- 22-cv-00311-WCB, District of Delaware
- IPR2023-00206 ('096 Patent)
- IPR2023-00207 ('241 Patent)
- IPR2023-00208 ('250 Patent)
- IPR2023-00209 ('306 Patent)

C. Lead and Back-Up Counsel (37 C.F.R. § 42.8(b)(3)) and Service Information (37 C.F.R. § 42.8(b)(3)-(4))

Petitioner provides the following counsel and service information. Pursuant to 37 C.F.R. § 42.10(b), a Power of Attorney accompanies this Petition.

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Petitioner consents to electronic service at the email addresses listed above.

D. Payment of Fees (37 C.F.R. § 42.15(a))

The undersigned authorizes the Office to charge the fee required for this Petition for *Inter Partes* Review to Deposit Account No. 50-5708. Any additional fees that might be due are also authorized.

DATED: December 7, 2022

Respectfully submitted,

By: */Joseph Paunovich/*

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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(a) and (d), the undersigned hereby certify that the PETITION FOR *INTER PARTES* REVIEW complies with the type-volume limitation of 37 C.F.R. § 42.24(a)(i) and (b)(i) permitting a petition of up to 14,000 words because, exclusive of the exempted portions, it contains 14,000 words as counted by the word processing program used to prepare the paper.

Date: December 7, 2022

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CERTIFICATE OF SERVICE

In accordance with 37 C.F.R. §§ 42.6(e) and 42.105, the undersigned certifies that the foregoing PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,943,096 and supporting materials were served on Patent Owner by USPS Overnight Express Mail at the following address of record for the subject patent:

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Date: December 7, 2022

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