

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. 10,863,761

“Methods and Compositions for Consumables”

Inter Partes Review No. 2022-00887

**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 10,863,761
UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. §§ 42.100 *et seq.***

TABLE OF CONTENTS

	<u>Page</u>
TABLE OF EXHIBITS	v
LIST OF CHALLENGED CLAIMS	1
I. INTRODUCTION	4
II. OVERVIEW OF THE ART	4
A. Scientific Background	4
1. Meat Characteristics.....	4
2. Meat Replicas.....	5
3. Muscle Replicas	6
4. Fat Tissue Replicas	7
5. Connective Tissue Replicas	8
B. '761 Patent Background	9
C. '761 Patent Prosecution History.....	12
D. Person of Ordinary Skill in the Art	14
III. PRIORITY DATE	14
IV. CLAIM CONSTRUCTION	15
A. “muscle replica”	15
B. “fat tissue replica”	17
C. “approximates the physical organization of meat”	17
D. “connective tissue replica”	18
V. STATEMENT OF RELIEF REQUESTED	19
A. Identification of Challenge (37 C.F.R. §§ 42.104(b)).....	19
B. Ground of Challenge (37 C.F.R. § 42.204(b)(2))	19
VI. SUMMARY OF PRIOR ART.....	20
A. “McMindes” (EX1003)	20
B. “Ljublinskij” (EX1004).....	20
C. “Sonac” (EX1005).....	21

D.	“Crane” (EX1012).....	21
E.	“Proulx” (EX1009).....	22
VII.	GROUND 1: MCMINDES ANTICIPATES CLAIMS 1-11, 13-14, 16-17.....	22
A.	Claim 1.	22
1.	1[pre].	22
2.	Element 1[a][1].	24
3.	Element 1[a][2].	25
4.	Element 1[a][3].	32
5.	Element 1[b].	34
6.	Element 1[c].	37
B.	Claim 2.	38
C.	Claim 3.	40
D.	Claim 4.	41
E.	Claim 5.	42
F.	Claim 6.	42
G.	Claim 7.	43
H.	Claim 8.	43
I.	Claim 9.	43
J.	Claim 10.	44
K.	Claim 11.	47
L.	Claim 13.	48
M.	Claim 14.	48
N.	Claim 16.	51
O.	Claim 17.	53
VIII.	GROUND 2: MCMINDES AND KNOWLEDGE OF A POSITA RENDERS OBVIOUS CLAIM 15	54
A.	Claims 1.....	54
B.	Claim 15.	54

IX.	GROUND 3: MCMINDES IN VIEW OF LJUBLINSKIJ RENDERS OBVIOUS CLAIMS 1-11 AND 13-17.....	56
A.	Claim 1.	56
1.	1[pre]-1[a][1].	56
2.	Element 1[a][2].	57
3.	Element 1[a][3]-1[c].	63
B.	Claim 2-11, 13-17.....	63
X.	GROUND 4: MCMINDES IN VIEW OF SONAC RENDERS OBVIOUS CLAIMS 1-11 AND 13-17.....	63
A.	Claim 1.	63
1.	1[pre]-1[a][1].	63
2.	Element 1[a][2].	63
3.	Element 1[a][3]-1[c].	65
B.	Claim 2-11, 13-17.....	65
XI.	GROUND 5: MCMINDES IN VIEW OF CRANE AND (LJUBLINSKIJ OR SONAC) RENDERS OBVIOUS CLAIM 12	65
A.	Claim 12.	66
XII.	GROUND 6: MCMINDES IN VIEW OF PROULX AND LJUBLINSKIJ RENDERS OBVIOUS CLAIM 12	70
A.	Claim 12.	70
XIII.	NO SECONDARY CONSIDERATIONS APPLY	73
XIV.	INSTITUTING <i>INTER PARTES</i> REVIEW WOULD BE EQUITABLE.....	76
A.	35 U.S.C. § 325(d) Factors Support Institution	76
1.	<i>Advanced Bionics</i> Part 1	76
2.	<i>Advanced Bionics</i> Part 2	77
B.	<i>NHK-Fintiv</i> Factors Also Support Institution	80
1.	<i>Fintiv</i> Factor 3	80
2.	<i>Fintiv</i> Factor 2	81
3.	<i>Fintiv</i> Factor 4.....	81

4.	<i>Fintiv</i> Factor 1	82
5.	<i>Fintiv</i> Factor 5	82
6.	<i>Fintiv</i> Factor 6	82
XV.	REQUIREMENTS FOR INTER PARTES REVIEW (37 C.F.R. §§ 42.101, 42.104, and 42.108)	83
XVI.	CONCLUSION.....	83
XVII.	MANDATORY NOTICES	83
A.	Real Party-in-Interest (37 C.F.R. § 42.8(b)(1)).....	83
B.	Related Matters (37 C.F.R. § 42.8(b)(2)).....	83
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))	83
D.	Payment of Fees (37 C.F.R. § 42.15(a))	84

TABLE OF EXHIBITS

Exhibit No.	Description
EX1001	U.S. Patent No. 10,863,761
EX1002	File History of U.S. Patent No. 10,863,761
EX1003	International Patent Application Publication No. WO 2006/041966 (“McMindes”)
EX1004	Russian Patent No. 2,274,003 (“Ljublinskij”) and certified translation
EX1005	Harimix Proteins: Color Enhancement of Meat (brochure) (“Sonac”)
EX1006	Declaration of Dr. Rodrigo Tarté dated April 19, 2022
EX1007	<i>Curriculum Vitae</i> of Dr. Rodrigo Tarté
EX1008	European Patent Application No. 1,759,593 A1 (“Van den Briel”)
EX1009	Proulx et al., <i>Iron Bioavailability in Hemoglobin from Soy Root Nodules Using a Caco-2 Cell Culture Model</i> , 54 J. Agric. Food Chem. 1518-22 (2006) (“Proulx”)
EX1010	Brewer, <i>The Chemistry of Beef Flavor – Executive Summary</i> , Cattlemen’s Beef Board (2007) (“Brewer”)
EX1011	Asgar et al., <i>Nonmeat Protein Alternatives as Meat Extenders and Meat Analogs</i> , 9 Comprehensive Rev. Food Sci. & Food Safety 513-29 (2010) (“Asgar”)
EX1012	U.S. Patent No. 9,085,766 (“Crane”)
EX1013	Excerpts of File History of U.S. Patent Application No. 13/941,211

Exhibit No.	Description
EX1014	U.S. Provisional Patent Application No. 61/572,205
EX1015	Lim et al., <i>Response to Consumer Demand for Reduced-Fat Foods; Multi-Functional Fat Replacers</i> , 11 Japan J. Food Eng'g 147-52 (2010)
EX1016	Goto et al., <i>Iron Fortification of Rice Seed by the Soybean Ferritin Gene</i> , 17 Nat. Biotech. 282-86 (1999)
EX1017	Pearson & Gillett, PROCESSED MEATS 53-78 (3d ed. 1996) (Chapter 3: Curing)
EX1018	Ueda et al., <i>Characteristic Flavor Constituents in Water Extract of Garlic</i> , 54 Agric. Biol. Chem. 163-69 (1990)
EX1019	Proulx, <i>Diversified Strategies for Improving Iron Bioavailability of Maize</i> (Ph.D. thesis), Iowa State University (2007)
EX1020	Calkins & Hodgen, <i>A Fresh Look at Meat Flavor</i> , 77 Meat Sci. 63-80 (2007)
EX1021	Dary et al., <i>Iron Compounds for Food Fortification: Guidelines for Latin America and the Caribbean 2002</i> , 60 Nutrition Revs. S50-S61 (2002)
EX1022	Jenschke et al., <i>Unsaturated Fatty Acids and Sodium Affect the Liver-Like Off-Flavor in Cooked Beef</i> , 85 J. Anim. Sci. 3072-78 (2007)
EX1023	Randle et al., <i>Quantifying Onion Flavor Compounds Responding to Sulfur Fertility-Sulfur Increases Levels of Alk(en)yl Cysteine Sulfoxides and Biosynthetic Intermediates</i> , 120 J. Am. Soc. Hort. Sci. 1075-81 (1995)
EX1024	Flückinger-Isler et al., <i>Dietary Components of Malt Extract Such as Maltodextrins, Proteins and Inorganic Salts Have Distinct Effects on Glucose Uptake and Glycogen Concentrations in Rats</i> , 124 J. Nutrition 1647-53 (1994)

Exhibit No.	Description
EX1025	Hou et al., <i>Genetic Variability of Seed Sugar Content in Worldwide Soybean Germplasm Collections</i> , 49 Crop Sci. 903-12 (2009)
EX1026	Bengoechea et al., <i>Rheology and Microstructure of Gluten and Soya-Based o/w Emulsions</i> , 46 Rheol. Acta 13-21 (2006)
EX1027	Tzen et al., <i>Oleosin Isoforms of High and Low Molecular Weights Are Present in the Oil Bodies of Diverse Seed Species</i> , 94 Plant Physiol. 1282-89 (1990)
EX1028	Li et al., <i>Purification and Structural Characterization of the Central Hydrophobic Domain of Oleosin</i> , 277 J. Biol. Chem. 37888-95 (2002)
EX1029	Comparison of U.S. Provisional No. 61/347,193 with U.S. 9,085,766 (claims)
EX1030	<i>Stays Pending IPR in Del. District Courts Are Here to Stay</i> , Law360 (Mar. 11, 2022), available at https://www.law360.com/technology/articles/1472447/stays-pending-ipr-in-del-district-courts-are-here-to-stay
EX1031	Time to Trial of Patent Cases in the District of Delaware (LexMachina, last accessed Apr. 5, 2022)
EX1032	<i>Impossible Foods Hires a Veteran of Apple Ads to Beef Up Its Creative Marketing</i> , AdWeek (Apr. 13, 2021), available at https://www.adweek.com/brand-marketing/impossible-foods-hires-a-veteran-of-apple-ads-to-beef-up-its-creative-marketing/
EX1033	<i>Heme, Health, and the Plant-Based Diet</i> , Impossible™ website, available at https://impossiblefoods.com/blog/heme-health-the-essentials
EX1034	<i>Beyond Meat vs. Impossible Foods: The very real battle between the biggest 'fake-meat' competitors</i> , Klue, available at https://klue.com/blog/beyond-meat-vs-impossible-foods-the-very-real-battle-between-the-biggest-fake-meat-competitors

Exhibit No.	Description
EX1035	GRAS Notice No. 737: GRAS Notification for Soy Leghemoglobin Protein Preparation Derived from <i>Pichia Pastoris</i> , submitted by Impossible Foods Inc. (Oct. 2, 2017), available at https://www.fda.gov/media/124351/download
EX1036	U.S. Provisional Patent Application No. 61/347,193
EX1037	Palazolo et al., <i>Emulsifying Properties and Surface Behavior of Native and Denatured Whey Soy Proteins in Comparison with Other Proteins. Creaming Stability of Oil-in-Water Emulsions</i> , 81 J. Am. Oil Chemist's Soc'y 625-32 (2004)
EX1038	Basman et al., <i>Effects of Transglutaminase on SDS-PAGE Patterns of Wheat, Soy, and Barley Proteins and their Blends</i> , 67 J. Food Sci. 2654-58 (2002)
EX1039	Motoki et al., <i>Transglutaminase and its Use for Food Processing</i> , 9 Trends Food Sci. & Tech. 204-10 (1998)
EX1040	Al-Karadaghi et al., <i>Crystal Structure of Ferrochelatase: the Terminal Enzyme in Heme Biosynthesis</i> , 5 Structure 1501-10 (1997)
EX1041	Warriss & Leach, <i>The Influence of Slaughter Method on the Residual Blood Content of Meat</i> , 29 J. Sci. Food Agric. 608-10 (1978)
EX1042	Foster et al., <i>A Randomized Trial of a Low-Carbohydrate Diet for Obesity</i> , 348 New Eng. J. Med. 2082-90 (2003)
EX1043	Halton et al., <i>Low-Carbohydrate-Diet Score and the Risk of Coronary Heart Disease in Women</i> , 355 New Eng. J. Med. 1991-2002 (2006)
EX1044	<i>Beef, round, top round roast, boneless, separable lean only, trimmed to 0" fat, select, raw</i> , FoodData Central (U.S. Dep't Agriculture), available at https://fdc.nal.usda.gov/fdc-app.html#/food-details/746761/nutrients

Exhibit No.	Description
EX1045	<i>Beef, loin, top loin steak, boneless, lip-on, separable lean only, trimmed to 1/8" fat, choice, raw</i> , FoodData Central (U.S. Dep't Agriculture), available at https://fdc.nal.usda.gov/fdc-app.html#/food-details/746759/nutrients
EX1046	Purslow, <i>Intramuscular Connective Tissue and its Role in Meat Quality</i> , 70 Meat Sci. 435-47 (2005)
EX1047	International Patent Application Publication No. WO 2005/019165 ("de Roos")
EX1048	Kang et al., <i>Comparative Study of the Quality Characteristics of Defatted Soy Flour Treated by Supercritical Carbon Dioxide and Organic Solvent</i> , 54 J. Food Sci. & Tech. 2485-93 (2017)
EX1049	Boye et al., <i>Comparison of the Functional Properties of Pea, Chickpea and Lentil Protein Concentrates Processed Using Ultrafiltration and Isoelectric Precipitation Techniques</i> , 43 Food Res. Int'l 537-46 (2010)
EX1050	Krebs et al., <i>Efficacy and Safety of a High Protein, Low Carbohydrate Diet for Weight Loss in Severely Obese Adolescents</i> , 157 J. Pediatrics 252-58 (2010)
EX1051	Declaration of Dr. Sylvia Ellis-Hall dated April 19, 2022
EX1052	Declaration of Dr. Carl Batt dated April 19, 2022
EX1053	<i>Curriculum Vitae</i> of Dr. Carl Batt
EX1054	Tarté, <i>Meat-Derived Protein Ingredients</i> , in <i>INGREDIENTS IN MEAT PRODUCTS: PROPERTIES, FUNCTIONALITY AND APPLICATIONS</i> 145-71 (R. Tarté ed., Springer Science+Business Media, LLC 2009)
EX1055	Bourtoom, <i>Edible Films and Coatings: Characteristics and Properties</i> , 15 Int'l Food Res. J. 237-48 (2008)

Exhibit No.	Description
EX1056	Day et al., <i>Wheat-Gluten Uses and Industry Needs</i> , 17 Trends in Food Sci. & Tech. 82-90 (2006)
EX1057	Hoare et al., <i>Precipitation of Food Proteins and Their Recovery by Centrifuging and Ultrafiltration</i> , 34B J. Chem. Tech. Biotech. 199-205 (1984)
EX1058	Olivares et al., <i>Hemoglobin-Fortified Biscuits: Bioavailability and its Effect on Iron Nutriture in School Children</i> , Archivos Latinoamericanos de Nutricion, Vol. XL, No. 2, 209-20 (1990)
EX1059	Ortiz-Monasterio et al., <i>Enhancing the Mineral and Vitamin Content of Wheat and Maize through Plant Breeding</i> , 46 J. Cereal Sci. 293-307 (2007)
EX1060	Paoli et al., <i>Structure-Function Relationships in Heme-Proteins</i> , 21 DNA & Cell Biology 271-80 (2002)
EX1061	Reizenstein, <i>Cattle Haemoglobin—A Possible Dietary Iron Supplement</i> , 31 British J. Haematology 265-68 (1975)
EX1062	Sadler, <i>Meat Alternatives – Market Developments and Health Benefits</i> , 15 Trends in Food Sci. & Tech. 250-60 (2004)
EX1063	Sault et al., <i>A Review of Developments in Simulated Meats</i> , 23 Q. Rev. of Agric. Econ. 209-21 (1970)
EX1064	Suman et al., <i>Myoglobin Chemistry and Meat Color</i> , 4 Ann. Rev. Food Sci. & Tech. 79-99 (2013)
EX1065	Yang et al., <i>Roles of Components of Rice-Based Fat Substitute in Gelation</i> , 40 Food Res. Int'l 1155-60 (2007)
EX1066	Berk, TECHNOLOGY OF PRODUCTION OF EDIBLE FLOURS AND PROTEIN PRODUCTS FROM SOYBEANS 97-105 (1992) (Chapter 7: Textured Soy Protein Products)
EX1067	Hendrowarsito, <i>Melt Transformation Extrusion of Soy Protein</i> (M.S. thesis), Ohio University (1984)

Exhibit No.	Description
EX1068	Keerati-u-rai et al., <i>Soy Protein Functionality: Emulsion and Gels</i> , in COMPREHENSIVE BIOTECHNOLOGY, § 4.45, 543-51 (Elsevier Sci. 2011)
EX1069	William Shurtleff & Akiko Aoyagi, HISTORY OF MEAT ALTERNATIVES (Soyinfo Center 2014), <i>available at</i> https://www.soyinfocenter.com/books/179
EX1070	Gennadios et al., <i>Edible Coatings and Films Based on Proteins</i> , in EDIBLE COATINGS AND FILMS TO IMPROVE FOOD QUALITY, 201-77 (John M. Krochta et al. eds., Technomic Publishing Co. 1994)
EX1071	<i>What's Your Beef – Prime, Choice or Select?</i> USDA Blog, posted by Larry Meadow (Sept. 12, 2019), <i>available at</i> https://www.usda.gov/media/blog/2013/01/28/whats-your-beef-prime-choice-or-select?page=1
EX1072	U.S. Patent No. 7,507,428 (“Numata”)
EX1073	Great Britain Patent No. 1,023,334 (June 1966)
EX1074	Renkema et al., <i>The Effect of pH on Heat Denaturation and Gel Forming Properties of Soy Proteins</i> , 79 J. Biotech. 223-30 (2000)
EX1075	Frustaci & O’Brien, <i>The Escherichia coli visA Gene Encodes Ferrochelatase, the Final Enzyme of the Heme Biosynthetic Pathway</i> , 175 J. Bacteriology 2154-56 (1993)
EX1076	Iwanaga et al., <i>Extraction and Characterization of Oil Bodies from Soy Beans: A Natural Source of Pre-Emulsified Soybean Oil</i> , 55 J. Agric. Food Chem. 8711-16 (2007)
EX1077	Scott et al., <i>Elevation of Oil Body Integrity and Emulsion Stability by Polyoleosins, Multiple Oleosins Units Joined in Tandem Head-to-Tail Fusions</i> , 8 Plant Biotech. J. 912-27 (2010)
EX1078	Tzen et al., <i>Surface Structure and Properties of Plant Seed Oil Bodies</i> , 117 J. Cell Biol. 327-35 (1992)

Exhibit No.	Description
EX1079	Fellows, <i>Food Biotechnology</i> , in FOOD PROCESSING TECHNOLOGY: PRINCIPLES AND PRACTICE 229-70 (3d ed. 2009)
EX1080	U.S. Patent No. 6,261,827 (“Elrod”)
EX1081	Color Figures of U.S. Patent No. 10,863,761 downloaded from the Supplemental Content tab of the file wrapper of the ’761 patent in USPTO PAIR
EX1082	<i>Curriculum Vitae</i> of Dr. Sylvia Ellis-Hall
EX1083	Attachments to the Declaration of Dr. Sylvia Ellis-Hall

LIST OF CHALLENGED CLAIMS

Claim 1	
Element No.	Claim Limitation
1[pre]	A beef replica product, comprising
1[a][1]	a) a muscle replica
1[a][2]	comprising 0.1%-5% of a heme-containing protein,
1[a][3]	at least one sugar compound and at least one sulfur compound; and
1[b]	b) a fat tissue replica comprising at least one plant oil and a denatured plant protein,
1[c]	wherein said muscle replica and fat tissue replica are assembled in a manner that approximates the physical organization of meat.
Claim 2	
The beef replica product of claim 1, further comprising a connective tissue replica.	
Claim 3	
The beef replica product of claim 1, wherein the denatured plant protein comprises one or more isolated non-heme-containing proteins.	
Claim 4	
The beef replica product of claim 3, wherein each of said one or more isolated non-heme-containing proteins is derived from a different plant species.	
Claim 5	
The beef replica product of claim 3, wherein said one or more isolated non- heme-containing proteins is selected from the group consisting of: ribosomal proteins, actin, hexokinase, lactate dehydrogenase, fructose bisphosphate aldolase, phosphofructokinases, triose phosphate isomerases, phosphoglycerate kinases, phosphoglycerate mutases, enolases, pyruvate kinases, glyceraldehyde-	

3-phosphate dehydrogenases, pyruvate decarboxylases, translation elongation factors, ribulose-1,5-bisphosphate carboxylase oxygenase (Rubisco), ribulose-1,5- bisphosphate carboxylase oxygenase activase (Rubisco activase), albumins, glycinins, conglycinins, globulins, vicilins, conalbumin, gliadin, glutelin, gluten, glutenin, hordein, prolamin, phaseolin protein, proteinoplast, secalin, extensins, triticeae gluten, zein, a seed storage protein, oleosins, caloleosins, steroleosins or other oil body proteins, vegetative storage protein A, vegetative storage protein B, and moong seed storage 8S globulin.
Claim 6
The beef replica product of claim 1, wherein said beef replica product does not contain one or more of methylcellulose, carrageenan, caramel color, konjac flour, gum arabic, and acacia gum.
Claim 7
The beef replica product of claim 1, wherein said beef replica product contains less than 1% wheat gluten.
Claim 8
The beef replica product of claim 1, wherein said beef replica product contains no wheat gluten.
Claim 9
The beef replica product of claim 1, wherein said beef product does not contain one or more of soy protein isolate, soy protein concentrate, or tofu.
Claim 10
The beef replica product of claim 1, wherein said beef product contains less than 5% carbohydrates.
Claim 11
The beef replica product of claim 1, wherein said beef replica product is characterized by one or more of the following: contains no tofu, contains no soy protein, contains less than 1% cellulose, contains less than 5% insoluble carbohydrates, or contains no wheat gluten.

Claim 12
The beef replica product of claim 1, wherein said beef replica product contains no animal products and less than 5% carbohydrates.
Claim 13
The beef replica product of claim 1, wherein said beef replica product contains no wheat gluten and less than 5% insoluble carbohydrates.
Claim 14
The beef replica product of claim 3, comprising: a) 60-90% water; b) 5-30% protein content; c) 1-20% of a fat; wherein said one or more isolated non-heme-containing protein comprises one or more isolated plant proteins.
Claim 15
The beef replica product of claim 1, wherein said plant protein is an oil body protein.
Claim 16
The beef replica product of claim 2, wherein (i) said muscle replica accounts for 40-90% of said product by weight, (ii) said fat tissue replica accounts for 1-60% of said product by weight.
Claim 17
The beef replica product of claim 2, wherein the connective tissue replica comprises a precipitated plant protein.

I. INTRODUCTION

Motif FoodWorks, Inc. (“Petitioner”) respectfully requests *inter partes* review of U.S. Patent No. 10,863,761 (“’761 patent”). Patent Owner (“PO”), Impossible Foods, Inc., sued Petitioner alleging infringement of the ’761 patent in the District of Delaware, Case No. 22-cv-00311, on March 9, 2022 (“the Litigation”). Petitioner seeks review of all ’761 patent claims.

II. OVERVIEW OF THE ART

A. Scientific Background

Non-meat ingredients that replicate meat date back centuries. EX1006§VII.B; EX1069, 29; EX1051¶¶339-342. Products routinely incorporated soy protein in plant-based meat analogs. EX1006¶116. Plant proteins are now widely appreciated as an inexpensive ingredient to mimic the texture and nutritional quality of meat. EX1006¶¶115-116; EX1069, 151.

1. Meat Characteristics

Meat characteristics such as color, appearance, nutritional content, texture, taste, and smell have been engineered into meat replicas for decades. EX1006§§VII.B, D; EX1072, 1:53-58. It is well-known that Maillard reactions give cooked meats their distinctive flavor. EX1006¶109; EX1047, 4:20-22 (cysteine compounds impart “a meat-like taste” to “both meat and non-meat” foodstuffs). It is also well-known that heme iron in meat positively contributes to flavor and aroma,

is largely responsible for meat color, and provides nutritional benefits.

EX1006§§VII.A.2, VII.A.5, VII.D.1; EX1017, 64-66.







Heme-proteins come from many sources: muscle, other animal tissues, plants, fungi, and recombinant expression systems, among others. EX1006§VII.A.2; EX1016, 282 (“increasing the ferritin content of cereals by genetic engineering may help to solve the problem of dietary iron deficiency”); EX1051¶¶59-65. Heme-proteins are used for many purposes. EX1006§§VII.A.2, VII.A.5, VII.D.1. For example, heme-proteins are added to foods to fortify diets of people who do not eat meat or suffer from iron malnutrition. EX1006§VII.D.1; EX1059; EX1051¶¶273-279. This is a focus in plant-based foods, which can contain low levels of iron. EX1006§VII.D.1; EX1059, Abstract. Another known use of heme-proteins is to provide pigment to mimic real meat color. EX1006§VII.A.2; EX1064, 80; EX1051¶¶308-314.

2. Meat Replicas

Meat substitutes generally are designed to replicate muscle, fat, and connective tissue of meat. EX1006¶80. Because there is no universal organization of meat components—muscle, fat, and connective tissue—meats vary in how the components are organized. EX1006§VII.A.1.

Beef, for example, exists in different natural and human-processed forms. EX1006§VII.A.1. Beef can be cut or processed into various physical forms.

EX1006§VII.A.1. Each has a different organization and appearance, as shown in the exemplary images below:

<p><u>Raw Ground</u></p> 	<p><u>Cooked Ground</u></p> 
<p><u>Sausage</u></p> 	<p><u>Hot Dogs</u></p> 
<p><u>Raw Slices</u></p> 	<p><u>Cured Slices</u></p> 

3. Muscle Replicas

There are different types of muscle: skeletal, cardiac, and smooth.

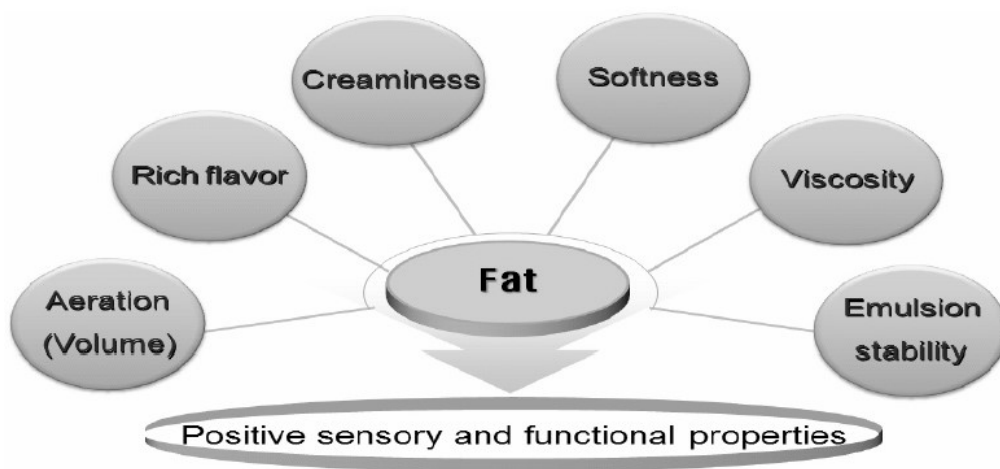
EX1006¶76. Different muscle tissues, even of the same type, have different

characteristics including color, appearance, and texture, for example. EX1006, EX1006§VII.A.1.

Muscle replicas that mimic properties of meat have existed for decades. EX1006§§VII.B, D; EX1061, 265; EX1051¶¶287-293. Muscle replicas, like real meat, vary depending on the animal species and type of muscle that they are attempting to replicate. EX1006§VII.D.

4. Fat Tissue Replicas

Fat tissue provides a range of properties to meat:



EX1006§VII.A.3; EX1015, 148; EX1051¶¶56-58. Fat tissue replicas have existed for decades. EX1006§VII.D; EX1015, 148 (“[F]at replacers which are fat substitutes and fat mimetics (also called analogs and mimics), have been widely used.”). These replicas “can take the place of all or some of the fat in foods and yet give similar organoleptic properties to the foods.” EX1006¶135; EX1015, 148.

One form of fat replica is an oil-in-water emulsion. EX1006¶138; EX1001, 29:38-40 (in embodiments, “the fat replica is an emulsion...”). Plant proteins, such as native and denatured soy isolates, have long been known to act as emulsifying agents. EX1006¶136; EX1037, 625 (“The use of denaturation to enhance the surface and emulsifying properties of whey soy proteins would allow their use in food emulsions.”); EX1051¶¶159-165. Cross-linking enzymes, such as transglutaminase, also can cause emulsions to gel, simulating fat tissue properties. EX1006¶139; EX1039, 204; EX1051¶¶173-179.

5. Connective Tissue Replicas

Connective tissues, like muscle and fat, vary in form and provide a variety of properties to meat, including texture. EX1006§VII.A.4. “Muscle cells are held together by connective tissue,” EX1011, 522; EX1051¶¶52-55, and the amount and thickness of connective tissue contributes to meat’s texture. EX1006§VII.A.4; EX1046, 439, 441; EX1051¶¶214-220.

Compositions that mimic properties of real connective tissue have existed for decades. EX1006§VII.D.3; EX1011, 516. For example, gluten’s “adhesive and film forming property binds” other ingredients together like connective tissue. EX1006¶141; EX1011, 516. Similar binders, such as starch, contribute to product “[t]exture/bite” like connective tissue. EX1006¶141; EX1011, 522. Additionally, transglutaminase has been used to cross-link (bind) proteins in soy and wheat,

EX1006¶142; EX1038, 2657; EX1051¶¶166-172, and “prevent[] deterioration in textures” like connective tissue. EX1039, 208. Many connective tissue replicas are available “[t]o make a similar-product texture”—namely, “fibrous texture, comparable to that of meat.” EX1006¶143; EX1011, 522.

B. ’761 Patent Background

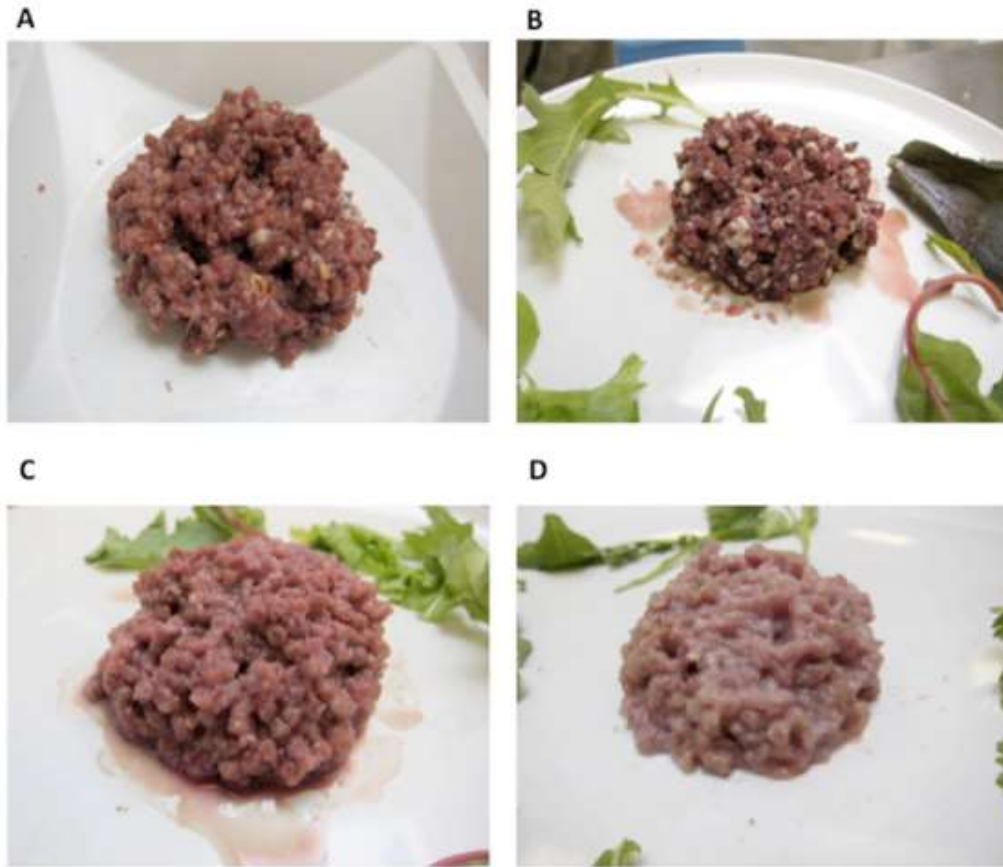
The ’761 patent claims are directed to beef replicas. According to the Abstract, “[d]isclosed [in the ’761 patent] are improved methods and compositions which more accurately replicate the characteristics that consumers value in the preparation and consumption of meat.” EX1001, Abstract. The patent purports to solve well-known problems such as: “[a]nimal farming...negative environmental impact. ...The consumption of meat...negative impact on human health. ...[and] [h]unger.” EX1001, 1:18-40. Such problems—and purported solutions—are not unique to the ’761 patent. *See infra* Sections IX.A.2, X.A.2, XI.A, XII.A (motivation to combine). Patent claim 1 is exemplary of the purported invention. EX1001, 49:13-20.

Patent Figures 8-16 depict embodiments of this purported invention. For example, Figures 10 and 11, reproduced below, depict “dark” and “white” muscle replicas, with a uniform, homogenous brown color throughout the material:

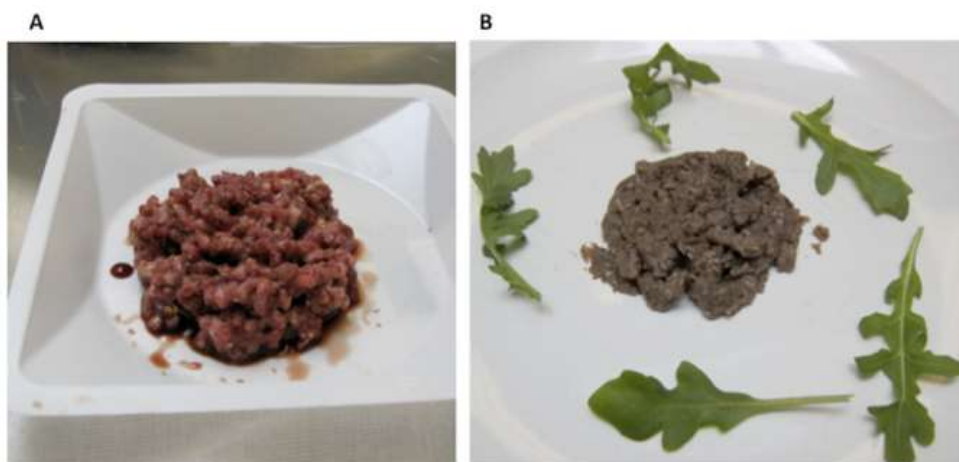


EX1001, Fig. 10, Fig. 11, 17:12-27 (reciting “thoroughly mixed” materials), 44:53-45:15; EX1081.

Figure 15 depicts ground beef “prototype patt[ies]”—an example physical organization of meat—that were made by combining different percentages or compositions of muscle, fat, and connective tissue replicas, resulting in coloration of varying uniformity:



EX1001, Fig. 15, 17:49-65, 46:22-38; EX1081. Finally, Figure 16 shows a ground beef replica patty before (left panel) and after (right panel) “cooking for about 2 minutes”:



EX1001, Fig. 16, 17:66-18:7, 46:39-49; EX1081.

Although these images show beef replica forms resembling ground beef patties, the claims are not limited to any particular form. EX1001, 23:24-41.

C. '761 Patent Prosecution History

The '761 patent issued from U.S. Application No. 15/985,697 ("697 application") after a single office action and claim amendments. EX1002. The patent is a continuation of abandoned U.S. Application No. 13/941,211 ("211 application"). EX1001, 1. During prosecution of the '211 application, after nearly five years of prosecution and unable to overcome prior art rejections, EX1013, 3-6, 24-30, 36-38, 52-61, 65-67, 93-101, PO abandoned the '211 application and filed the '697 application. *Id.*, 105-111; EX1002, 1.

The Examiner rejected the '697 application claims as obvious over the same art raised against its parent '211 application—Van den Briel (EX1008) in view of Proulx (EX1009; EX1051¶¶47-49) and Brewer (EX1010; EX1051¶¶50-51), and in view of Proulx, Brewer, and Asgar (EX1011). EX1002, 114-120, 2986-2997. The Examiner found that Van den Briel teaches a muscle replica, fat replica, connective tissue replica, and most other claim limitations, and in view of the other references rejected each of the then-pending claims as obvious. EX1002, 2989-2995.

In response, PO amended the claims to, *inter alia*, add a limitation that the claimed "fat tissue replica" includes "a denatured plant protein." EX1002, 3058.

PO argued that Van den Briel does not “disclose or even suggest a fat tissue replica including a denatured plant protein,” and that none of Proulx, Brewer, or Asgar “cure the deficiencies of *Van den Briel*” as to that added limitation. EX1002, 3063-3066. PO also argued there was no motivation to combine Van den Briel and Proulx to make a beef replica with leghemoglobin, a plant protein. EX1002, 3064-3065. PO did not otherwise contest the Examiner’s findings of other elements in the prior art. EX1002, 3066-3067.

In the Notice of Allowance, the Examiner did not comment on PO’s motivation argument (EX1002, 3096-3104), an argument previously rejected during prosecution of its parent ’221 application, EX1013, 53-54, 58-61, 94, 100-101, but allowed the ’697 application amended claims for the sole reason that the substantively considered prior art did not “disclose a fat replica comprising at least one plant oil and denatured plant protein.” EX1002, 3102-3103. This finding was erroneous at least because Van den Briel discloses that a plant protein—gluten—could be used in an oil-in-water emulsion (a fat replica) for its product, and because a POSITA would recognize that gluten would be denatured during the preparation of the product. *See* Section VII.A.5; EX1006¶¶66-67; EX1008, [0004]. The Examiner did not have the benefit of an expert’s explanation of fat replica technology or the correct interpretation of Van den Briel, as in the present Petition and accompanying expert declaration.

D. Person of Ordinary Skill in the Art

The '761 patent is directed to the art of food science and recombinant protein expression. A POSITA would have a Bachelor of Science degree in food sciences, biology, chemistry, microbiology, or a related discipline. A POSITA would also have a Master's degree or Ph.D. in food science or at least three years of experience working as a food scientist. EX1006¶36; EX1052¶37.

III. PRIORITY DATE

The '761 patent claims priority to, among others, U.S. Provisional Application No. 61/572,205 ("205 provisional") (EX1014), filed on July 12, 2011. EX1001, 1. However, the claims are not entitled to that provisional filing date because it lacks written description to support the claims. *See, e.g., Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

For example, claim 1 recites "a muscle replica comprising 0.1%-5% of a heme-containing protein." EX1001, 49:13-15. But this limitation is not described in the '205 provisional. *See* EX1014, 8-20; EX1006§V.E. While the '205 provisional describes a meat replica comprising 0.1-5% *carbohydrates* (EX1014, [0028]), the only disclosed percentage range for an added heme-containing protein is 0.4%-1% (EX1014, [0041]). *See, e.g., Indivior UK Ltd. v. Dr. Reddy's Labs. S.A.*, 18 F.4th 1323, 1329 (Fed. Cir. 2021) (affirming the Board's finding of no written description support for a claimed range). Because this unsupported claim limitation

(0.1%-5% of a heme-containing protein) is an element of all claims (EX1001, 49:12-50:48), none of the claims are entitled to the '205 provisional filing date.

IV. CLAIM CONSTRUCTION

In the Litigation, no contentions or claim constructions have been exchanged and no claim construction order has been issued.

A. “muscle replica”

The term “muscle replica” has a plain meaning and does not require construction. However, a POSITA would understand that it must encompass compositions that mimic at least one muscle property such as color, appearance, or texture before or after cooking. EX1006¶¶166-167; *Oatey Co. v. IPS Corp.*, 514 F.3d 1271, 1276 (Fed. Cir. 2008) (“We normally do not interpret claim terms in a way that excludes embodiments disclosed in the specification.”)

For example, the patent describes “the muscle tissue replica approximates the taste, texture or color of an equivalent muscle tissue derived from an animal source.” EX1001, 5:21-36; EX1006¶168. Similarly, the “invention provides a meat substitute product that...replicates or approximates key features of animal skeletal muscle...[s]uch a composition will be labeled herein as ‘muscle replica’,” *id.*, 25:35-42, and “proteins may be artificially designed to emulate physical properties of animal muscle tissue.” *Id.*, 26:5-7; EX1006¶168. For one such exemplary property, the patent discloses that “meat products comprise...muscle” and replicas may mimic

it by being formed into “fibers that replicate muscle” using extrusion and other methods that are “well known in the art.” *Id.*, 25:48-50, 26:44-57; EX1006¶169. The patent makes clear that, “[i]n some embodiments, the muscle replica and/or meat substitute product comprising the muscle replica are partially derived from animal sources.” *Id.*, 25:42-45; EX1006¶169. In fact, dependent Claim 12’s limitation requiring “no animal products” creates a presumption that independent Claim 1, and every other claim, may encompass replicas made with animal products. *Id.*, 50:26-28; *RF Delaware, Inc. v. Pacific Keystone Techs., Inc.*, 326 F.3d 1255, 1263 (Fed. Cir. 2003) (Under the doctrine of claim differentiation, “each claim in a patent is presumptively different in scope.” (citation omitted)). Figures 10 and 11, reproduced above, depict examples of muscle replicas embraced by the patent. *Id.*, 17:12-27, 44:53-45:15.

The array of potential properties of “muscle replicas” is akin to how the patent describes meat substitute properties generally. *Id.*, 1:67-2:5 (“meat substitute composition accurately mimics [listing various properties of meat]...in its raw state and in a cooked state”), 20:24-44 (describing various mechanical, geometric and other properties of meat that can be defined and compared to meat), 22:13-15 (“the consumable is tested for similarity to meat during or after cooking”); EX1006¶170.

B. “fat tissue replica”

The term “fat tissue replica” has a plain meaning and does not require construction. However, a POSITA would understand that it must encompass compositions that mimic at least one fat tissue property such as color, appearance, or texture before or after cooking. EX1006¶¶174-175; *Oatey*, 514 F.3d at 1276.

For example, the patent discloses “a composition...which recapitulates key features of animal fat. ...Such a composition will be labeled herein as a ‘fat replica’.” EX1001, 27:10-19; EX1006¶176. Like muscle replicas, “[i]n some embodiments, the fat replica and/or meat substitute product comprising the fat replica are partially derived from animal sources.” *Id.*, 27:17-19, 50:26-28; EX1006¶176.

Consistent with the claim language, the patent describes an “emulsion” embodiment: “the fat replica is an emulsion comprising a solution of one or more proteins and one or more fats suspended therein as droplets...derived from plant-based oils.” EX1001, 29:38-53; EX1006¶177. The patent further discloses in such embodiments that the “proteins can stabilize emulsified fats...[and] form gels upon denaturation..., which replicate the appearance and texture of animal fat.” *Id.*, 28:20-24; EX1006¶177.

C. “approximates the physical organization of meat”

The term “approximates the physical organization of meat” does not require construction in this proceeding. However, a POSITA would understand that it must

encompass compositions that mimic at least one meat property such as shape, cut and preparation before or after cooking. EX1006¶¶180-181; *Oatey*, 514 F.3d at 1276.

For example, the patent describes known physical organizations that approximate meat in terms of certain shapes, cuts and preparations of meat. EX1001, Fig. 15-16, 23:24-41 (“organization...can be manipulated by controlling the localization, organization, assembly, or orientation of the muscle, fat, and/or connective tissue replicas...[to] recapitulate the physical organization of different cuts or preparations of meat...[such as] natural ground meat [patties]..., ribeye, filet mignon, London broil, among others.”); EX1006¶182. The approximate physical organization of meat is further illustrated in Figures 15 and 16, which depict beef replica ground in the shape of round patties and with varying levels of homogenous coloration before and after cooking. EX1006¶182.

D. “connective tissue replica”

The term “connective tissue replica” has a plain meaning and does not require construction. However, a POSITA would understand that it must encompass compositions that mimic at least one connective tissue property such as texture or appearance before or after cooking. EX1006¶¶185-186; *Oatey*, 514 F.3d at 1276.

For example, the patent discloses “a composition...which recapitulates...textural and visual features of animal connective tissue. Such a

composition will be labeled herein as ‘connective tissue replica’.” EX1001, 30:51-63; EX1006¶187. The patent further describes “a protein content...assembled into structures approximating the texture and visual appearance of connective tissue or skin,” which can “comprise one or more isolated, purified proteins.” *Id.*, 10:60-65, 23:43-45; EX1006¶188. Like muscle and fat replicas, “[i]n some embodiments, the connective tissue replica and/or meat substitute product comprising the connective tissue replica are partially derived from animal sources.” *Id.*, 30:60-63, 50:26-28; EX1006¶187.

V. STATEMENT OF RELIEF REQUESTED

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

Petitioner requests *inter partes* review and cancellation of all claims.

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

No.	Claims	Ground for Challenge
1	1-11, 13-14, 16-17	§ 102: McMindes
2	15	§ 103: McMindes and knowledge of a POSITA
3	1-11, 13-17	§ 103: McMindes in view of Ljublinskij
4	1-11, 13-17	§ 103: McMindes in view of Sonac

5	12	§ 103: McMindes in view of Crane and (Ljublinskij or Sonac)
6	12	§ 103: McMindes in view of Proulx and Ljublinskij

VI. SUMMARY OF PRIOR ART

A. “McMindes” (EX1003)

McMindes is prior art under (pre-AIA) 35 U.S.C. § 102(b). McMindes was filed as PCT Application No. PCT/US2005/035904 and published on April 20, 2006.

McMindes generally relates to soy protein-containing food products and processes for preparing them. EX1003, Title. These products “may be 100% meat free or may contain up to 50% of a meat.” *Id.*, [0002]. McMindes teaches the desirability of making soy-based meat substitutes “which more closely resemble[] meat,” including “in texture and moisture content” and with “appropriate nutritional values,” *id.*, [0008], and it discloses ingredients and methods for this purpose.

B. “Ljublinskij” (EX1004)

Ljublinskij is prior art under (pre-AIA) 35 U.S.C. § 102(b). Ljublinskij was filed as Russian Application No. 2004106009/13 and published on April 20, 2006.

Ljublinski relates to technology for producing hemoglobin from blood. EX1004, Abstract. It teaches that hemoglobin is a natural dye and can be used as a “source of biologically available iron in manufacturing functional foodstuffs,” including non-animal food products, “for the prophylaxis and treatment of iron

deficiency conditions.” *Id.*

C. “Sonac” (EX1005)

Sonac Loenen B.V. markets and sells a line of food colorants called “Harimix proteins.” EX1005, 2; EX1006¶¶153. The company has publicly distributed informational materials about Harimix proteins, including the brochure relied upon herein (“Sonac”). EX1006¶¶153-154. Sonac is prior art under (pre-AIA) 35 U.S.C. § 102(b). Sonac was publicly available at least as early as January 3, 2008. EX1006¶¶154-156; EX1054, 170; EX1051¶¶242-247.

Sonac discloses that the “functional” component of “Harimix” colorants, which enhance and improve meat-like coloring in food products, is hemoglobin. EX1005, 1-3.

D. “Crane” (EX1012)

Crane was filed as U.S. Patent Application No. 13/113,769 on May 23, 2011, published on November 23, 2011, and claims priority from U.S. Provisional Application No. 61/347,193 filed on May 21, 2010.¹ Crane issued as U.S. Patent No. 9,085,766 on July 21, 2015. As a result, Crane is prior art under (pre-AIA) 35 U.S.C. § 102(e) if any ’761 patent claims are entitled to the July 12, 2011 effective

¹ Crane’s claims are supported by its provisional disclosure. EX1029; EX1036; EX1052¶¶54-128. Accordingly, Crane is entitled to a priority date of May 21, 2010.

filing date of the '761 patent's '205 provisional. *See* Section III (Priority Date).

Crane is otherwise prior art under (pre-AIA) 35 U.S.C. § 102(a)(2).

Crane is directed to methods of producing purified recombinant heme-binding proteins, including leghemoglobin, for commercial applications. EX1012, Abstract.

E. “Proulx” (EX1009)

Proulx is prior art under (pre-AIA) 35 U.S.C. § 102(b). Proulx was published on January 31, 2006. EX1051¶¶47-49.

Proulx is directed to the use of plant-derived leghemoglobin to fortify non-animal food products. EX1009, Abstract. It teaches that heme-containing proteins from plant sources, like leghemoglobin, are “value-added product[s] that can provide highly bioavailable iron as a food fortificant.” *Id.*

VII. GROUND 1: MCMINDES ANTICIPATES CLAIMS 1-11, 13-14, 16-17

McMindes expressly discloses each limitation of the '761 patent claims 1-11, 13-14, 16-17 and therefore anticipates the claims as set forth below. EX1006§§X.

A. Claim 1.

1. 1[pre].

A beef replica product, comprising:

To the extent the preamble is limiting, McMindes's stated goal is to provide “a structured meat product” that “closely simulate[s] natural steaks and roasts in appearance, taste, texture and nutritional value,” which a POSITA would understand refers to beef. EX1003, [0004]; EX1006¶196. McMindes's examples describe the

preparation of “soy protein containing food product having the color appearance of a cooked medium rare steak,” in the form of “slabs, strips, cutlets, patties or steaks.”

EX1003, [000119-123].

As depicted in Figure A and explained further below, McMIndes describes preparation of its products in terms of the proportions of soy protein material (A), humectant (B), water (C), and meat (optionally). The examples set forth below are all based on specific embodiments expressly disclosed in McMIndes.

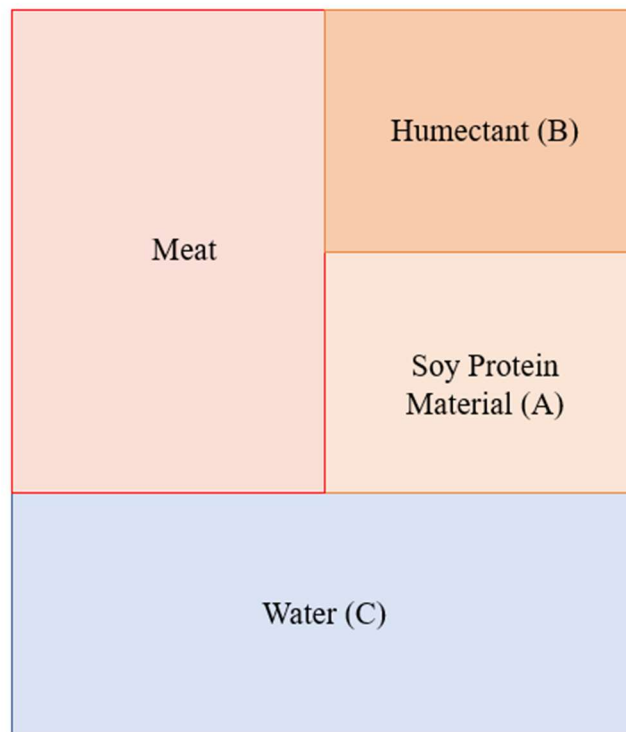


Figure A

2. Element 1[a][1].

A muscle replica

McMindes provides multiple elements that mimic one or more muscle properties. It discloses a muscle replica prepared from “a soy protein material selected from the group consisting of a soy protein flour, a soy protein concentrate, a soy protein isolate and mixtures thereof.” *E.g.*, EX1003, [00013]. The chosen soy protein is “heated along with water” and “extruded” using “well known” methods, creating an “extrudate [that] generally expands to form a fibrous cellular structure.” EX1003, [00039]. “[F]lavor ingredients” that “provide a meat-like flavor” “are also mixed and extruded with the soy protein material.” EX1003, [00053]. McMindes teaches that “the extrudate resembles from a cubic chunk of meat to a steak filet” and the extrusion process can be adjusted to “decrease[] the cubic chunk-like nature of the extrudate and increase[] the filet-like nature of the extrudate.” EX1003, [00080].

McMindes further discloses combining the soy protein material with colorants “to provide eye appeal” and “replicate the various colors of meat in both the uncooked state and the various cooked states.” EX1003, [00086]. It teaches that, “[i]n the cooked states, the interior color of the product, is a red, reddish-brown or brown color and the exterior color is brown.” EX1003, [00016]. This coloration is achieved using “caramel” and “carmine” to produce a product that “when cooked

and compared to a steak appears rare, medium rare, medium well done and well done depending upon the colorants used and the amounts of colorants used.” EX1003, [00088].

3. Element 1[a][2].

comprising 0.1%-5% of a heme-containing protein

“For those who choose to consume meat,” McMindes’s beef replica can contain animal meat, including “skeletal meats, such as” beef shoulder and beef flank. EX1003, [000114]. As explained, like McMindes, the ‘761 patent expressly contemplates the use of real meat in the claimed beef replica and its replica components. *See* Sections IV.A,C,E. Beef contains the heme-containing proteins myoglobin and hemoglobin. EX1006§VII.A.2; ¶¶207-208; EX1001 34:47-48. Bovine skeletal muscle contains between **4 mg/g and 20 mg/g myoglobin**. EX1006¶207; EX1017, 65 (identifying “values for myoglobin for fresh bovine skeletal muscle...beef, 4 to 10 mg/g; and old beef animals, 16 to 20 mg/g”); EX1051¶¶66-72. Accordingly, a POSITA would understand it contains between **0.4% and 2% myoglobin**. EX1006¶208; EX1001, 37:26-30 (“[O]ne of the main iron-carrying proteins is myoglobin. It is estimated that . . . young beef has 0.4-1.0%; and old beef has 1.5-2.0%.”). A POSITA would understand that muscle also contains trace hemoglobin (*e.g.*, from residual blood following exsanguination). EX1006¶209; EX1041, 609 (0.89 mg/g in lambs); EX1051¶¶187-193; EX1017, 64.

The percentage of heme-proteins in McMIndes's products can be calculated relative to the total product or the muscle replica as follows. EX1006¶248, §X.A.3.

Total Product. As depicted in Figure B below, one exemplary product expressly disclosed by McMIndes includes 50% beef and 50% non-meat material before water is added. EX1003, [0002], [000108], [000109], [000115]; EX1006¶¶220-221. Using exemplary ratios expressly taught in McMIndes², *e.g.*, a POSITA would understand that McMIndes discloses an exemplary hybrid product with 1 part soy protein material (A) : 1 part humectant (B) : 4 parts water (C) : 2 parts beef (125 grams per part for a 1000-gram product). EX1006¶221.

² EX1003, [000108] (teaching “ratio of...(A)...to...(B)...is...generally from 1-10 to 1...and most preferably from 1-3 to 1,” which encompasses 1:1 ratio), [000109] (teaching “ratio of...(A)...to...(C) is...from 1 to 2-10...and most preferably from 1 to 2-5,” which encompasses 1:4 ratio); EX1006¶221. To the extent PO argues the examples herein are not expressly disclosed, they would have been obvious to a POSITA based on McMIndes's expressly disclosed ratios. EX1006¶221.

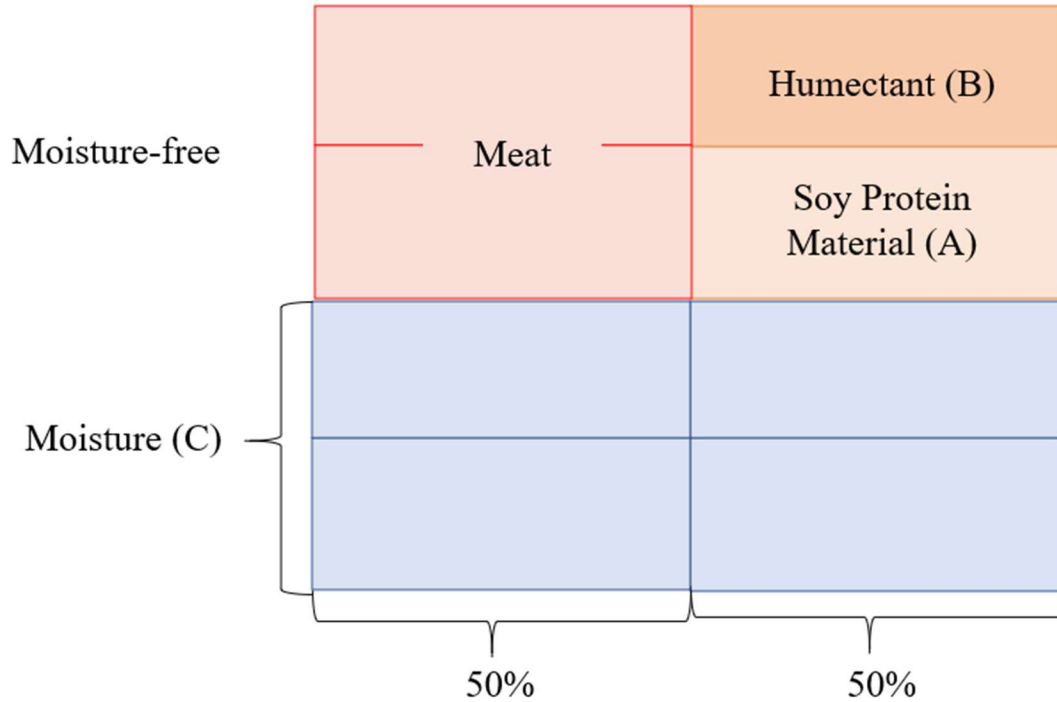


Figure B

Using these proportions, and knowing the myoglobin concentration range of **4-20 mg/g** in beef, a POSITA would calculate the myoglobin weight percentage range in this exemplary product as follows (EX1006¶232):

Fig. B Product	Total Myoglobin	Weight%
250 grams beef : 250 grams non-meat material (A+B) : 500 grams water (C)	1.0-5.0 grams	0.1%-0.5%

Based on this calculation, a POSITA would know that the myoglobin percentage range in the McMindes product (0.1%-0.5%) *falls entirely within* the claimed heme-protein range (0.1%-5%). EX1006¶233. A POSITA would

understand that the McMindes hybrid product could also contain trace levels of hemoglobin, which could increase the overall concentration of heme-containing protein, but not outside of the claimed range. EX1006¶233.

Moreover, a POSITA would understand that exemplary hybrid products could be constructed across the entire scope of ratios and embodiments taught in McMindes to adjust the percentage of myoglobin in the products within the claim range. EX1006¶238. For example, a POSITA would understand from its ratios that McMindes also expressly discloses an exemplary hybrid product, as depicted in Figure C, with 1 part (A) : 1 part (B) : 2 parts (C) : 2 parts meat (approximately 166.7 grams per part for a 1000-gram product). EX1006¶222; EX1003, [000108], [000109].

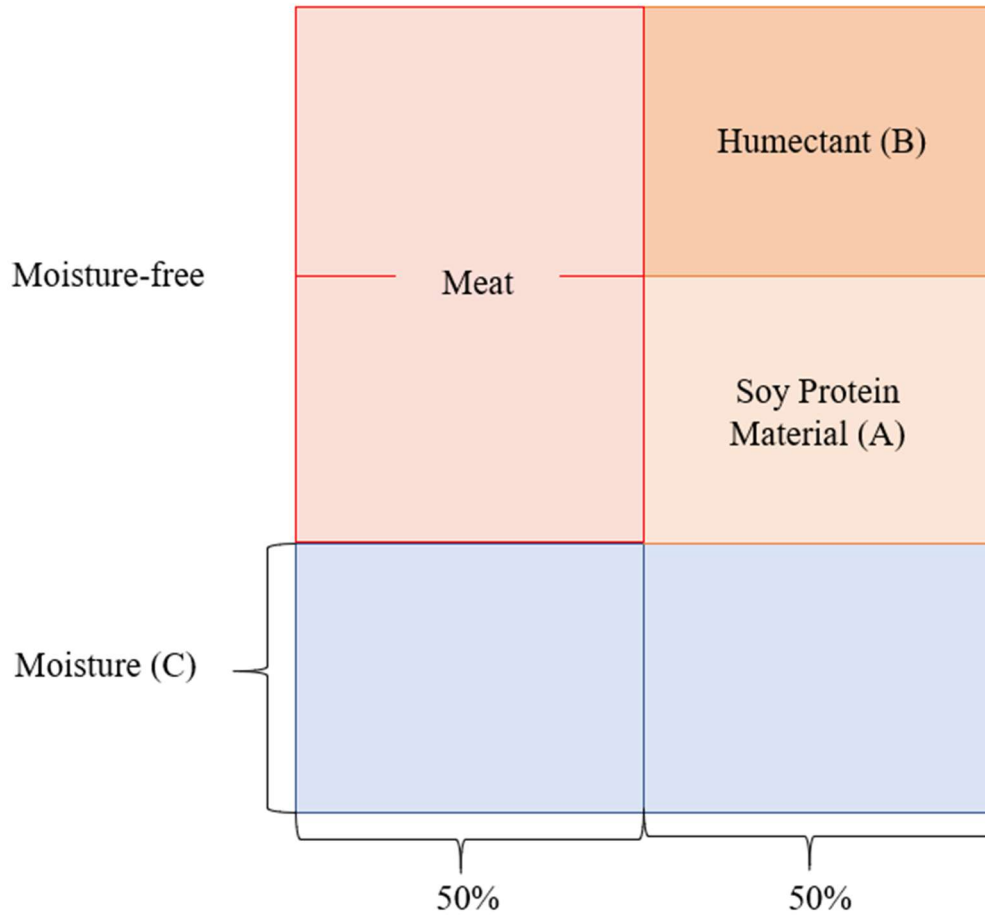


Figure C

Similarly, using these proportions, and knowing the myoglobin concentration range in beef, a POSITA would calculate the myoglobin weight percentage range in this exemplary product as follows (EX1006¶234):

Fig. C Product	Total Myoglobin	Weight%
333.3 grams beef : 166.7 grams (A) : 166.7 grams (B) : 333.3 grams (C)	1.3-6.6 grams	0.13%-0.66%

Likewise, a POSITA would know that the range of myoglobin weight percentages in this product (0.13%-0.66%) *falls entirely within* the claimed 0.1%-5% range. EX1006¶235. Trace hemoglobin also would not increase the heme-protein percentage outside of the claimed range. EX1006¶235.

Muscle Replica: A POSITA would also understand that the percentage of heme-containing proteins alternatively could be determined relative to the claimed “muscle replica.” EX1006¶236. A POSITA would understand that this portion of the McMindes product can be defined in different ways: *e.g.*, hydrated soy material alone, or in combination with colorant³ and meat, but not including the “fat replica” (*e.g.*, emulsion). EX1006¶¶236-237.

³ McMindes’s humectant can include a colorant “in the range of between 0.1% to 5%....” EX1003, [00091] (*e.g.*, 1%, or 10 grams in the exemplary 1000-gram product). *See* Figure D.

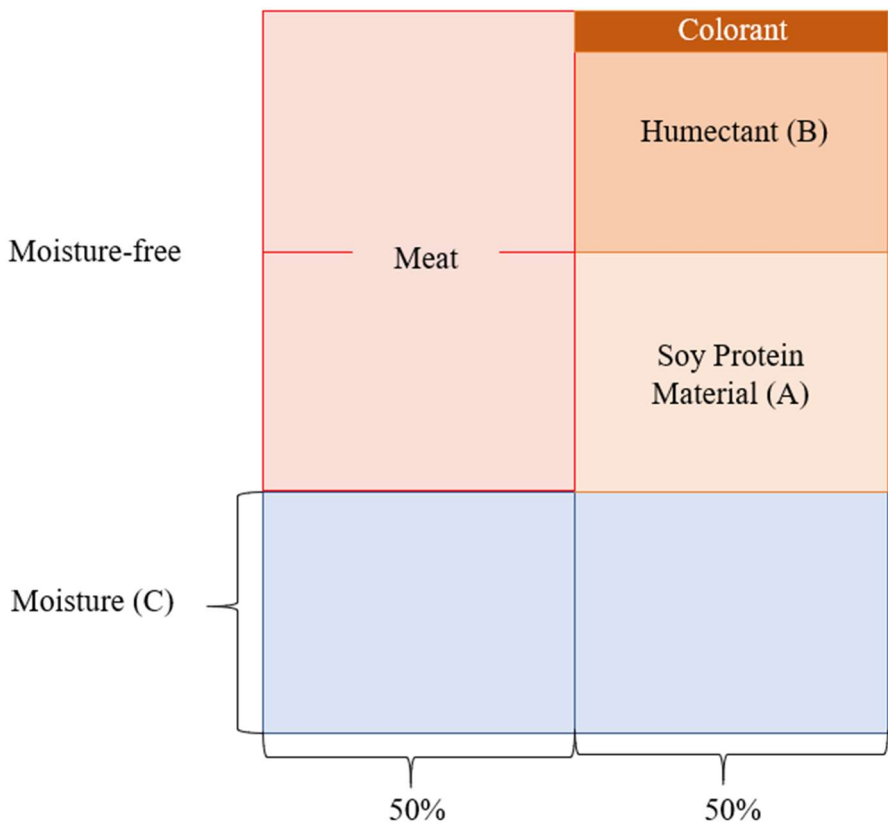


Figure D

Per the Figure C calculations and values above, the total myoglobin range is 1.3-6.6 grams, and a POSITA would calculate the myoglobin weight percentages relative to the muscle replica as follows (EX1006¶¶222, 238-243):

“Muscle Replica”	“Muscle” Weight (g)	Heme Weight%
(A)+(C)	500	0.26%-1.32%
(A)+(C)+Colorant	510	0.25%-1.29%
(A)+(C)+Colorant+Meat	843.3	0.15%-0.78%

A POSITA would know that the heme-protein weight percentages in the McMindes product relative to the muscle replica (e.g., 0.15%-1.32%) thus *remains entirely within* the claimed 0.1%-5% range. EX1006¶245. Here again, trace hemoglobin would not increase the heme-protein percentage outside of the claimed range. *Id.*

* * *

McMindes also explains that its “soy protein containing food product may be a 100% meat-free product or may contain up to 50% by weight meat **on a moisture free basis.**” EX1003, [00016]. While a POSITA would understand this qualifier to refer to the ratio of meat before adding water to the soy protein material, EX1006¶217-219, a POSITA could alternatively construct McMindes’s disclosed hybrid products by accounting for the inherent moisture of the components before adding 50% by weight “moisture free” meat to the hybrid product. EX1006¶251-254. The effect of this approach is that the amount of meat and heme-protein in the hybrid products increase but remain within the claimed range. EX1006¶253-254, Appendix A.

4. Element 1[a][3].

at least one sugar compound and at least one sulfur compound

To achieve a meat-like flavor, McMindes adds “commercially available” flavor ingredients to the soy protein material used to prepare the muscle replica in

its beef replica products. EX1003, [00053]. These flavor ingredients can include, *e.g.*, “seasonings, herbs, spices, pepper, onion powder, garlic powder, savory powders, extracts of mushrooms and natural flavoring extracts (NFE).” EX1003, [00092]; EX1006¶256.

A POSITA would understand that these added flavor ingredients contain the claimed compounds. EX1006¶257. For example, a POSITA would know that McMIndes’s onion and garlic powders contain S-alk(en)yl-L-cysteine sulfoxides, and that cysteine is a sulfur-containing amino acid that produces volatile sulfur compounds during cooking. EX1006¶¶257-258; EX1018, 163; EX1051¶¶73-79; EX1023, 1075; EX1051¶¶106-112. In fact, it was long known that “characteristic flavor and fragrance components are mostly produced during the cooking process by chemical reactions involving one or more amino acids, fats, peptides, nucleotides, organic acids, sulfur compounds, sugars and other carbohydrates.” EX1001, 36:29-34; EX1006¶264; EX1002, 2991 (Examiner finding “beef flavor and aroma attributes upon cooking the meat are imparted by maillard reaction products, where the role of reducing sugars is well known, and by sulfur containing amino acids (*i.e.*, methionine and cysteine)...therefore it would have been obvious to a skilled artisan...to have added to the meat analog beef flavor contributors”).

McMIndes also teaches adding “malt extract” to the muscle replica, which a POSITA would know contains sugar compounds. EX1003, [00053]; EX1006¶261;

EX1024, 1647 (“[M]alt extract is composed of glucose, maltose and glucose oligomers...”); EX1051¶¶113-119. McMIndes also teaches adding caramel, which a POSITA would know “is prepared by...heat treatment of carbohydrate or saccharide materials such as dextrose, invert sugar, lactose, malt syrup, molasses, [and] sucrose,” i.e., sugar compounds. EX1003, [00089]; EX1006¶262.

To the extent the claimed sugar and sulfur compounds need not be separate added components in the beef replica, a POSITA would also know that McMIndes’s soy protein flour contains sugars and sulfur-containing compounds. EX1006¶263-264. Specifically, a POSITA would understand that soy protein flour, which is defatted and comprises 49%-65% protein content, contains a carbohydrate remainder with these compounds. EX1006¶263; EX1025, 903 (“Soybean seed contains approximately...33% carbohydrates; up to 16.6% of the carbohydrates are soluble sugars....includ[ing] glucose, fructose, sucrose, raffinose, and stachyose.”); EX1051¶¶120-126; EX1048, Table 2 (identifying amino acid composition of soy flour, including sulfur-containing cysteine and methionine); EX1051¶¶221-227.

5. Element 1[b].

a fat tissue replica comprising at least one plant oil and a denatured plant protein,

McMIndes discloses a composition that mimics at least one fat tissue property. The ’761 patent teaches that the “fat replica” can be an “emulsion comprising a

solution of one or more proteins and one or more fats suspended therein as droplets.”

EX1001, 29:38-40. McMIndes’s beef replica likewise contains a “humectant,” which contains an “oil-in-water emulsion” and one or more plant proteins as claimed. EX1003, [00013], [00032], [00085], [000107]; EX1006¶266.

McMIndes’s humectant includes plant oils such as “peanut oil, canola oil, rapeseed oil, soybean oil, olive oil, sunflower oil, and corn oil.” *E.g.*, EX1003, [00098]. The humectant “functions to absorb and/or promote the retention of moisture,” which McMIndes teaches “results in juiciness on cooking and improves the taste of the meat,” which is a fat tissue property. EX1003, [0005], [0085]. A POSITA would therefore understand that McMIndes’s humectant (including the oil-in-water emulsion) mimics the moisture-promoting properties of fat tissue in McMIndes’s beef replica. EX1006¶¶266-267.

McMIndes’s emulsion also contains denatured plant proteins. Its “emulsifying agent is a soy protein material,” a plant protein. EX1003, [000107]. McMIndes product can also contain the plant protein gluten, which a POSITA would understand acts as an emulsifier. EX1006¶292; EX1026, 13 (“[O]il-in-water...emulsion stabilised by means of gluten and soya protein isolate...have been characterized...”); EX1051¶¶127-133.

A POSITA would understand that these plant proteins (*e.g.*, soy protein or gluten) would be denatured—during processing or cooking. EX1006¶¶268-270.

McMindes discloses, *e.g.*, that its “dough mixture is...fed into a cooking extruder to heat” and “shear” the mixture and subject it to “pressure...to plasticize the dough,” which a POSITA would understand denatures the emulsion protein. EX1003, [00074], [00075], [00010] (“gluten is denatured in the extrusion process”). In fact, a POSITA would understand that such manipulations—extruding, heating, shearing, pressuring—are performed to denature and change protein structure to make the products more fibrous and meat-like. EX1003, [00010] (“[P]ermanent alterations in the texture of the soy gluten base indeed result. Protein quality is also improved”), [00039] (“Upon extrusion, the extrudate generally expands to form a fibrous cellular structure”), [00076] (“The dough mixture is heated by the cooking extruder...[and] denatures the protein...enabling...[it] to plasticize”); EX1006¶268. Moreover, because the claims do not prohibit cooking and “heating denatures...protein,” the emulsion protein would denature when cooked. EX1003, [00076]; EX1006¶269. For example, McMindes teaches that its products are “roasted at 300°C to an internal temperature of 70°C,” (EX1003, [000120]-[000123]), which would denature its proteins, including the plant soy protein and gluten. EX1006¶269, 271; EX1074, 224.

6. Element 1[c].

wherein said muscle replica and fat tissue replica are assembled in a manner that approximates the physical organization of meat.

McMindes's products approximate the physical organization of meat. As explained, the '761 patent describes "the physical organization" in terms of "cuts or preparations of meat" including ground meat patties and steaks. *See* Section IV.D.; EX1006§IX.C. McMindes teaches "a structured meat product" that "closely simulate[s] natural steaks and roasts in appearance, taste, texture and nutritional value," including "distinctive characteristics" of "natural steak or roast." EX1003, [0004]; EX1006¶274. It discloses that its hydrated soy protein material, including but not limited to its meat-plant protein (*e.g.*, muscle replica) and humectant (*e.g.*, fat replica), described *supra* (Sections VII.A.2-5), "are combined in a mixing device...." EX1003, [000108]; EX1006¶274. The resulting "soy protein containing food product may be formed into strips, **steaks**, cutlets or **patties**, either by hand or by machine," which a POSITA would understand approximates meat's physical organization as described in the '761 patent.⁴ EX1003, [000112]; *see also id.*, [000120]-[000123] (Examples 1-4); EX1006¶274.

⁴ For McMindes's patties, a POSITA would know to adjust the extent of mixing McMindes's muscle and fat replicas to achieve a desired organization of the

B. Claim 2.

The beef replica product of claim 1, further comprising a connective tissue replica.

McMindes's products provide multiple elements that provide connective tissue's textural and/or visual properties. EX1001, 30:51-53; EX1006, §X.B. First, meat naturally contains connective tissue. EX1003, [0005] ("The texture and toughness of [meat] is determined by the arrangement of connective tissue in the muscle..."); EX1006¶279. Incorporating beef in McMindes's meat-plant hybrid (e.g., Examples 3-4) necessarily introduces connective tissue (and its textural and/or visual attributes) into the beef replica. EX1006¶279; EX1003, [000122], [000123].

Additionally, McMindes discloses using gluten in its products to create connective tissue-like texture. EX1006¶¶281-282. For example, "[v]arious mixtures of raw materials are being used to modify extruded soy product texture... When gluten is added...permanent alterations in the texture of the soy gluten base indeed result." EX1003, [00010]; EX1006¶282. In food products, gluten acts as a

components within such products similar to the depicted physical organizations in the '761 patent's Figures 15 and 16. EX1006¶276; EX1002, 2992-2993 (Examiner finding "obvious to a skilled artisan to have...adjusted the extent of mixing...to attain a meat analog with the appearance of real meat").

“stabilizer, thickener, surface finishing agent, and texturizing agent” by binding components of the product together and promoting a meat-like texture. EX1011, 516 (when heated, the “hydrated gluten mass coagulates irreversibly” “without loss of its unique structural order yielding a firm, nonsticky, moist, and resilient gel”); EX1006¶281. These properties derive from, among other things, the prolamin protein gliadin in gluten. EX1006¶282; EX1011, 515 (gluten contains gliadin); EX1001, 31:15-22 (describing prolamins including gliadin as “particularly favorable” proteins for fascia-type connective tissue “because of their...ability to readily form fibers...when spun or extruded”).

Similarly, McMIndes’s “starch material may also be used as an ingredient to be mixed and extruded with the soy protein material” of the muscle replica “to provide texture to the fibrous material produced.” EX1003, [00052]; EX1006, ¶¶283-284; *see also* EX1001, 31:45-50 (“Methods for forming fascia-type connective tissue...may include extrusion”). As McMIndes teaches, manipulating the manufacturing process temperature can cause the starch to gel, forming a connective tissue-like component in the product. EX1003, [00056]; EX1006¶284; EX1001, 29:34-37 (“starch” “can be used alone or in combination to thicken the gel, forming an architecture or structure for the consumable”). McMIndes also teaches that, in combination with other components such as gluten, its soy protein material contributes to the meat-like product texture of connective tissue. EX1006¶285-288;

EX1011 at 517 (“Important functional properties of soy protein in food systems are gelling/textural capabilities... .”); EX1003 at [00010].

C. Claim 3.

The beef replica product of claim 1, wherein the denatured plant protein comprises one or more isolated non-heme-containing proteins.

As explained (Section VII.A.5), the “denatured plant protein” in McMIndes’s “fat replica” can be, *e.g.*, gluten, a plant protein. Gluten is an example given by the ’761 patent for the claimed “one or more isolated non-heme-containing proteins.” EX1001, 2:33-54 (“[S]aid one or more isolated and purified proteins are selected from...gluten....”); *Id.*, 25:1-18 (disclosing “the one or more isolated proteins includes an abundant protein” and providing gluten as an exemplary abundant protein). Gluten is non-heme-containing. EX1001, 49:29-45 (listing “non-heme-containing proteins”).

McMIndes’s “‘gluten’ relates to a protein fraction in wheat flour.” EX1003, [00030]. A POSITA would understand that, as taught in McMIndes, gluten is isolated (*e.g.*, from wheat flour) for use in McMIndes’s products.⁵ EX1006¶294;

⁵ A POSITA would understand that the ingredients in the ’761 patent’s beef replica, when combined, are not “isolated.” EX1006, ¶294&n.9; EX1011, 519 (“Preparation

EX1003, [00030] (“In its freshly extracted wet state it is known as gum gluten, and when thereafter dried it becomes a free-flowing powder of high protein content and bland taste. It is generally used in food processing in that form.”). As explained, the gluten would be denatured during processing or cooking. Section VII.A.5.

The isolated, non-heme containing protein can also be soy protein isolate, as, McMindes teaches that soy protein material is the “emulsifying agent” of McMindes’s oil-in-water emulsion, which a POSITA would understand would also be denatured during processing or cooking (Section VII.A.5).

D. Claim 4.

The beef replica product of claim 3, wherein each of said one or more isolated non-heme-containing proteins is derived from a different plant species.

McMindes teaches that gluten can be obtained from one or more of different plant species including wheat, oats, rye, or barley. EX1003, [00028], [00030]; EX1006¶296. As explained, the gluten would be denatured during processing or cooking. Section VII.A.5. Moreover, gluten and soy protein material are derived from different plant species. EX1006¶296.

of protein isolates or isolates involving extraction and precipitation...has been used to obtain products with reduced levels of antinutritional factors...”).

E. Claim 5.

The beef replica product of claim 3, wherein said one or more isolated non-heme-containing proteins is selected from the group consisting of:...gluten...

As explained (Section VII.C), the one or more isolated non-heme-containing proteins in McMIndes's fat replica could be gluten.

F. Claim 6.

The beef replica product of claim 1, wherein said beef replica product does not contain one or more of methylcellulose, carrageenan, caramel color, konjac flour, gum arabic, and acacia gum.

The term "one or more" means "at least one of." *Zynga, Inc. v. Personalized Media Comm'ns, LLC*, IPR2013-00162, Paper 12 at 12 (PTAB July 25, 2013) (construing "one or more" and "at least one of" to "require[] only a single item identified in the claim limitation").

McMIndes does not teach or require methylcellulose, carrageenan, konjac flour, gum arabic, or acacia gum in its products. *See generally* EX1003; *e.g., id.* [000120]-[000123]; EX1006¶300-301.

G. Claim 7.

The beef replica product of claim 1, wherein said beef replica product contains less than 1% wheat gluten.

McMindes discloses the use of “gluten free” or “substantially gluten free” starches, which is “a factor of particular importance for people diagnosed with celiac disease or wheat allergies.” EX1003, [00028]; *see also id.* [00035] (disclosing embodiment of soy protein material mixed with rice flour (which is gluten-free), a gluten-free starch, or a mixture of the two); Claim 5; Examples 1-4. A POSITA would understand that a “gluten free” or “substantially gluten free” beef replica contains less than 1% gluten. EX1006¶303.

H. Claim 8.

The beef replica product of claim 1, wherein said beef replica product contains no wheat gluten.

As explained (Section VII.G), McMindes teaches “gluten free” beef replicas. EX1006¶305.

I. Claim 9.

The beef replica product of claim 1, wherein said beef product does not contain one or more of soy protein isolate, soy protein concentrate, or tofu.

As explained (Section VII.F), the term “one or more” means “at least one of.” McMindes does not teach or require tofu, or the use of soy protein isolate and soy

protein concentrate together, in its products. *E.g.*, EX1003, [000120]-[000123]; EX1006¶307.

J. Claim 10.

The beef replica product of claim 1, wherein said beef product contains less than 5% carbohydrates.

McMindes teaches reducing the carbohydrate percentage in its products by adjusting the proportions of water, soy protein material, and humectant (which contains carbohydrates). EX1001, [000108], [000109], [000112]. [000117]; EX1006¶¶309-310.

Using disclosed proportions (Section VII.A.3 and Figure E below), McMindes teaches an exemplary hybrid product divided into 42 parts as follows (approximately 23.8 grams per part for a 1000-gram product): 10 parts soy protein material (A) : 1 part humectant (B) : 20 parts water (C) : 11 parts beef⁶ (50% relative to the non-meat components A+B). EX1006¶¶311-313; EX1003, [000108], [000109].

⁶ Beef (after slaughter) has no detectable carbohydrates. EX1006¶315; EX1044; EX1045; EX1051¶¶208-213.

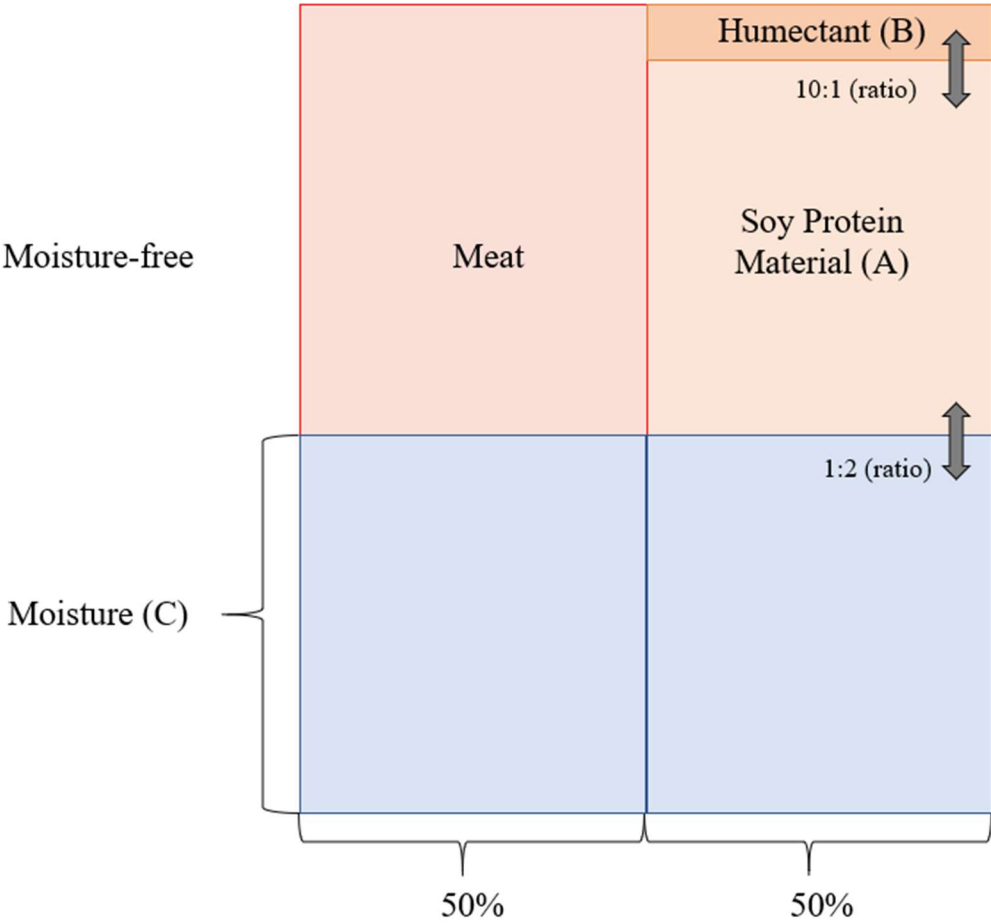


Figure E

A POSITA would calculate the weight of known non-carbohydrate components as follows (EX1006¶¶315-316):

Component	Parts	Weight (grams)
(A) (Protein) ⁷	9	214.2
(C)	20	476
Beef	11	261.8 ⁸
Total	40	952

A POSITA would thus know that the known non-carbohydrate components represent at least 95.2% of this exemplary 1000-gram hybrid product. EX1006¶317. A POSITA would also know that the remaining components of McMIndes’s product are not entirely comprised of carbohydrates. EX1006¶317. Accordingly, McMIndes teaches products with less than 5% carbohydrates.⁹ EX1006¶317; *see also id.* ¶¶318-

⁷ The soy protein material can be, *e.g.*, 90% (9 parts) soy protein. EX1003, claim 7; EX1006¶314.

⁸ Because beef contains, *e.g.*, 4 mg/g myoglobin, 261.8 grams beef contains at least 1.0472 grams myoglobin (0.11% myoglobin in 1000-gram product). EX1006¶317.

⁹ A POSITA would also understand that the percentage of carbohydrates in McMIndes’s products could be further reduced for those that desire a higher protein and/or lower carbohydrate diet by simply increasing the amount of protein or fat in the beef replica, effectively reducing the percentage carbohydrate content, or

323; *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1346 (Fed. Cir. 1999) (“[W]hen a patent claims a chemical composition in terms of ranges of elements, any single prior art reference that falls within each of the ranges anticipates the claim.”).

K. Claim 11.

The beef replica product of claim 1,...characterized by one or more of the following: contains no tofu,...contains less than 5% insoluble carbohydrates, or contains no wheat gluten.

As explained (Section VII.F), the term “one or more” means “at least one of.” McMIndes teaches gluten-free products (Section VII.H) with less than 5% carbohydrates (of any type) (Section VII.J) and does not teach or require tofu (Section VII.I).

reducing the carbohydrates directly. EX1006¶¶309-310; EX1042; EX1051¶¶194-200; EX1043; EX1051¶¶201-207; EX1050, Abstract (describing high protein, low carbohydrate diets as “safe and effective option for medically supervised weight loss”); EX1051¶¶235-241.

L. Claim 13.

The beef replica product of claim 1, wherein said beef replica product contains no wheat gluten and less than 5% insoluble carbohydrates.

As explained, McMindes teaches gluten-free products (Section VII.H) with less than 5% carbohydrates (of any type) (Section VII.J).

M. Claim 14.

The beef replica product of claim 3, comprising: a) 60-90% water; b) 5-30% protein content; c) 1-20% of a fat; wherein said one or more isolated non-heme-containing protein comprises one or more isolated plant proteins.

Using disclosed proportions (Section VII.A.3), McMindes teaches an exemplary hybrid product divided into 10 parts as follows (100 grams per part for a 1000-gram product): 1 part soy protein material (A) : 1 part humectant (B) : 6 parts water (C) : 2 parts beef (50% relative to the non-meat components A+B).¹⁰ EX1006¶329; EX1003, [000108-109], [000115].

¹⁰ 200 g beef contains between 0.8-4 g (0.08%-0.4%) myoglobin, which overlaps almost entirely with the claimed range. EX1006¶334; *Atlas*, 190 F.3d at 1346.

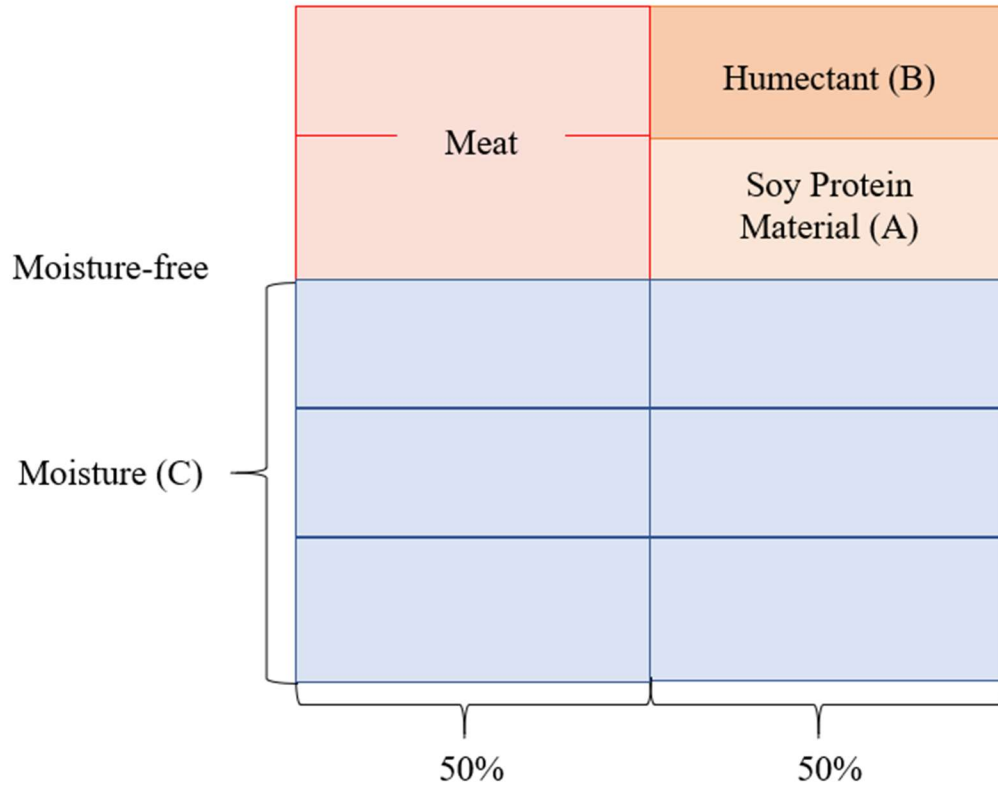


Figure F

McMindes further discloses that the real meat component may be up to 5-30% fat. EX1006¶330; EX1003, [000114]. A POSITA would thus calculate the component weight percentages within the claimed proportions as follows (EX1006¶331):

Component	Weight (g)	Weight%
Soy Protein (A) + Meat (Protein)	240-290 grams (A): 1 part x 100 grams Meat: (2 parts x 100 grams)–10 grams Meat: (2 parts x 100 grams)–60 grams	24%-29%
Meat Fat	10-60 grams (2 parts x 100 grams beef) x 0.05 (2 parts x 100 grams beef) x 0.3	1-6%
Humectant (B)	100 grams 1 part x 100 grams	10%¹¹
Water (C)	600 grams 6 parts x 100 grams	60%

Moreover, the isolated non-heme-containing plant protein can be gluten(s) or soy protein isolate. Sections VII.A and VII.C (claims 1, 3).

¹¹ A POSITA would know that the fat percentage within McMindes's product may be higher with the triglyceride and emulsion components of McMindes's humectant. EX1006¶333; EX1003, [00085]. However, even if the humectant was entirely fat, the overall fat percentage would still fall within the claimed range. EX1006¶333.

N. Claim 16.

The beef replica product of claim 2, wherein (i) said muscle replica accounts for 40-90% of said product by weight, (ii) said fat tissue replica accounts for 1-60% of said product by weight.

Using disclosed proportions (Section VII.A.3), McMindes teaches an exemplary hybrid product divided into 6¹² parts as follows (approximately 166.7 grams per part for a 1000-gram product): 1 parts soy protein material (A) : 1 part humectant¹³ (B) : 2 parts water (C) : 2 parts beef (50% relative to the non-meat components A+B).¹⁴ EX1006¶¶336-337; EX1003, [000108], [000109].

¹² A POSITA would understand that the connective tissue replica is part of the muscle replica. EX1006¶¶338-339; EX1011, 522 (“Muscle cells are held together by connective tissue”).

¹³ Colorant in the humectant can be, *e.g.*, 10 grams (1%). Section VII.A.3.

¹⁴ 50% beef contains between 0.1%-5% heme-containing protein. Section VII.A.3.

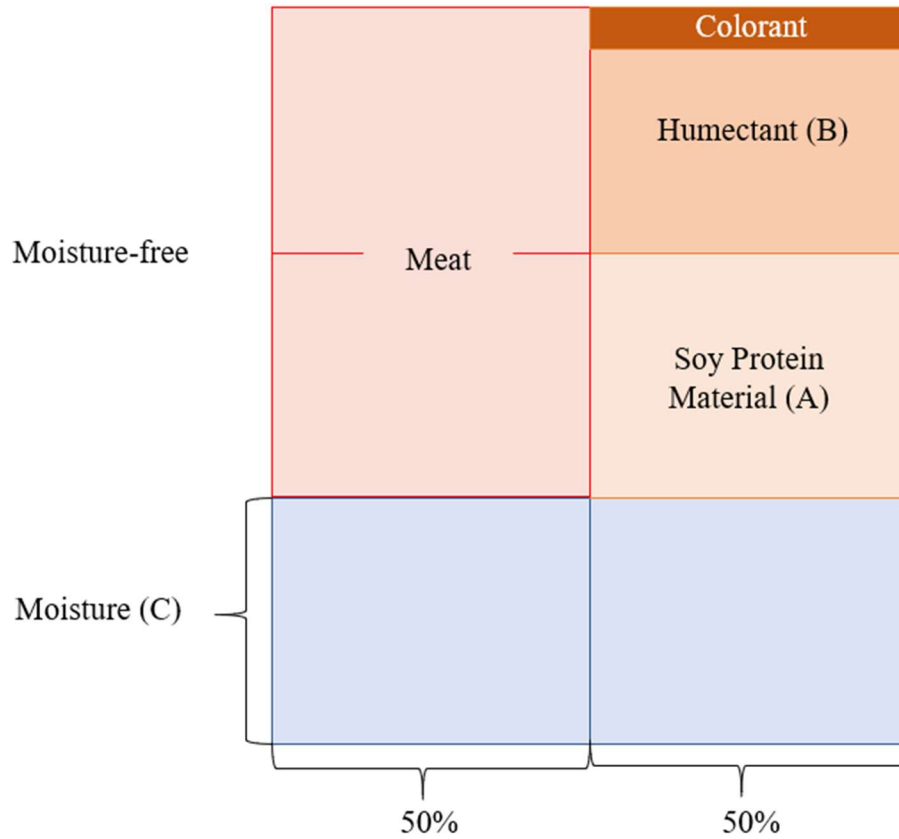


Figure D (reproduced)

A POSITA would calculate weight percentages within the claimed proportions as follows (EX1006¶341; Section VII.A.3):

“Muscle Replica”	“Muscle” Weight (g)	Weight%
(A)+(C)	500	50%
(A)+(C)+Colorant	510	51%
(A)+(C)+Colorant+Meat	843.3	84.3%
“Fat Replica”	“Fat” Weight (g)	Weight%
(B)	166.7	16.7%
(B)-Colorant	156.7	15.7%

O. Claim 17.

The beef replica product of claim 2, wherein the connective tissue replica comprises a precipitated plant protein.

McMindes teaches a soy protein isolate—a plant protein—precipitated from an acidified extract of defatted soy materials, and “[t]he precipitated protein curd is then separated from the remaining extract (whey).” EX1003, [00044-45]; EX1006¶345-346; EX1001, 43:1-52 (describing similar precipitation techniques for plant “Protein Purification for Components of the Replica”). As explained, McMindes discloses the use of various ingredients in conjunction with soy protein

material, such as the precipitated isolate, to mimic one or more connective tissue properties.¹⁵ EX1006¶344; Section VII.B.

VIII. GROUND 2: MCMINDES AND KNOWLEDGE OF A POSITA RENDERS OBVIOUS CLAIM 15

Petitioner raises Ground 2 to address the obviousness of Claim 15 based on McMindes and the knowledge of a POSITA. EX1006§XI.

A. Claims 1.

See Ground 1 analysis for McMindes’s disclosure of all Claim 1 elements.

B. Claim 15.

The beef replica product of claim 1, wherein said plant protein is an oil body protein.

A POSITA would be motivated to modify the teachings of McMindes, using the general knowledge and state of the art at least as of July 2011, to utilize an oil body protein as the denatured plant protein claimed in the ’761 patent.

¹⁵ The ingredients in the ’761 patent’s beef replica, when combined, are not “precipitated.” EX1011, 519; EX1049, 545 (describing precipitation techniques for plant proteins resulting in “concentration of...protein content by nearly 4-fold...[while retaining] good functional properties...(e.g., solubility, fat binding capacity, emulsifying stability and foaming properties)"); EX1051¶¶228-234.

As noted (Section VII.A.5), the fat replica can be “an emulsion comprising a solution of one or more proteins and one or more fats suspended therein as droplets.” EX1001, 29:38-40. Similarly, oil body proteins, including oleosins, encapsulate spherical droplets of plant oils called “oil bodies” present in oilseeds such as soybeans. Oleosins’ amphipathic structure—hydrophobic at the oil interface and hydrophilic at the surface of the oil body—makes them “natural...emulsifiers which enable a stable oil-in-water emulsion.” EX1006¶¶349-350; EX1077, 913; EX1051¶¶371-377.

A POSITA would be motivated to use oil body protein, such as oleosins, in the “fat replica” emulsion because oil body proteins’ structure naturally promotes emulsification. Others in the field recognized the value of oil (and oil bodies) and would have been motivated to use them in foodstuffs. EX1006¶351; EX1077, 913 (“[I]ntact [oil bodies] or [oil bodies] in which the majority of [oil] has been removed have a broad range of emulsification applications in food...”); EX1028, 37888 (“Oleosins appear to act as a natural emulsifying...agent at an oil/water interface. This suggests...application for oleosins in the stabilization of emulsion systems, in industries such as food processing...”); EX1051¶¶141-147; EX1076, 8712 (“[F]ood manufacturers could benefit from the preexisting natural protection of the soybean oil bodies to obtain a product that has improved stability...[and] neither emulsifiers nor homogenization procedures are required.”); EX1051¶¶364-370.

A POSITA would have a reasonable expectation of success of achieving the subject matter of claim 15 because techniques for extracting oil bodies and oleosins from oilseeds were long known in the art. EX1006¶352; EX1027, 1283; EX1051¶¶134-140; EX1076, 8712 (isolation of soybean oil bodies using aqueous-based flotation-centrifugation). Oil body proteins could also be used to prepare an emulsion using conventional techniques, *e.g.*, combining oil, water and the emulsifying agent, oleosins, to create a colloidal dispersion, or could be mixed into the dough of McMindes's product precursor material. EX1006¶353; EX1003, [00022-00023], [000107]. Moreover, as explained (Section VII.A.5), such proteins would also be denatured during processing or cooking.

IX. GROUND 3: MCMINDES IN VIEW OF LJUBLINSKIJ RENDERS OBVIOUS CLAIMS 1-11 AND 13-17.

Petitioner raises Ground 3 to address potential argument by PO that McMindes does not expressly disclose 0.1%-5% of a heme-containing protein based on McMindes's disclosed ratios analyzed in Ground 1. This Ground thus relies on McMindes in view of Ljublinskij's disclosure for incorporating hemoglobin in food products within the claimed range. EX1006§XII.

A. Claim 1.

1. 1[pre]-1[a][1].

See Ground 1 analysis.

2. Element 1[a][2].

Ljublinskij. Ljublinskij teaches that “hemoglobin...can be used as a natural dye, as it provides a stable coloring effect,” with the added benefit that hemoglobin use, as a “part of functional foods,” is “the most optimal means for the prevention and treatment of iron deficiency in the body.” EX1004, 5:27-29; 14:28-29.

Ljublinski teaches hemoglobin concentrations within the '761 patent claimed range that can fortify a meat-free product. EX1004, 14:33-15:5. Ljublinskij discloses consuming hemoglobin-enriched food products to treat anemia, including “clinical testing results of a confectionery bar enriched with hemoglobin with a purity of at least 60%,” using “[b]ars containing 4% hemoglobin (at least 6 mg of heme iron per 100 g of product).” EX1004, 14:33-15:5; EX1006¶¶367-368. Accordingly, Ljublinskij’s enriched bars contain at least 2.4%,¹⁶ and up to 4%, hemoglobin. Ljublinskij further teaches that “[t]he intake of hemoglobin-enriched bars made it possible to maintain a stable level of blood serum iron,” “maintain tissue iron reserves,” “and restore the initial hemoglobin level and the number of red blood cells in the blood.” EX1004, 15:7-9.

¹⁶ A bar containing 4% of 60%-pure Ljublinskij’s hemoglobin would contain 2.4% pure hemoglobin. EX1006¶368.

Combination of McMindes and Ljublinskij. McMindes and Ljublinskij are analogous art directed to the same field of endeavor as the '761 patent—improved food products. Sections II.B, VI.

Heme-proteins in McMindes's hybrid product—myoglobin and hemoglobin—contribute to its nutritional profile; *e.g.*, by providing heme iron. EX1006¶362; EX1001, 37:24-30 (“The main...nutritional definition of the color of meat is the concentration of iron carrying proteins in the meat. ...It is estimated that...young beef has 0.4-1.0%; and old beef has 1.5-2.0%.”). McMindes teaches a POSITA to prepare an improved meat replica by, *e.g.*, making its nutritional profile more meat-like. EX1006¶370-371; EX1003, [0004], [0008], [00012]. Because McMindes's hybrid product contains only some of the heme-containing proteins present in the same amount of natural meat, a POSITA would be motivated to incorporate additional heme-containing protein to enhance the hybrid's nutritive content, while not increasing the overall content of natural meat in the product. Ljublinskij provides a means to achieve this goal. Ljublinskij discloses using within 0.1-5.0% hemoglobin to iron-fortify food products and to provide desirable meat color. EX1004, 14:21-15:5, 6:36-40. Because Ljublinskij teaches that 2.4%-4.0% of hemoglobin is an effective fortificant, a POSITA would be motivated to incorporate Ljublinskij's hemoglobin at a concentration within the claimed range to improve the nutritional profile of McMindes's product. EX1006¶368.

Heme-proteins in McMindes's hybrid product also contribute to its desirable meat-like color. EX1001, 37:24-26. McMindes discloses that coloration is one way to improve a meat replica: "[i]n order to make such analog products more acceptable to the consumer, it is necessary to provide them with a color that is as close as possible to that of the natural meat protein based products." EX1003, [00003]. McMindes's "preferred" concentration of colorant is "between 0.1% to 5%." EX1003, [00091]. This range encompasses the amount of heme-protein in natural muscle. Section VII.A.3; EX1006¶371.

A POSITA would understand Ljublinskij's hemoglobin could be used in meat replicas that are either hybrid meat-plant products or purely plant-based products in order to achieve a concentration of heme-protein equivalent to natural muscle and hence the corresponding color of such meat. EX1006¶369; EX1001, 25:42-45 ("In some embodiments, the muscle replica and/or meat substitute comprising the muscle replica are partially derived from animal sources."), 50:26-28. To attain desirable coloration of the McMindes product, therefore, a POSITA would be motivated to incorporate Ljublinskij's hemoglobin at a concentration between 0.1-5.0%, precisely as claimed in the '761 patent.¹⁷ EX1006¶372; EX1001, 34:50-55 ("the [meat]

¹⁷ Similarly, the '761 patent Examiner observed that because the "effect of a compound is known to be a function of dosing, and since the iron bioavailability

replica contains between .01% to 5% by weight of a heme protein...it is understood that these percentages can vary in meat and the meat replicas can be produced to approximate the natural variation in meat”). For example, a POSITA would be motivated to substitute Ljublinskij’s hemoglobin for the colorants (*e.g.*, caramel and carmine) used in McMIndes’s products, or enhance them with it, because a POSITA would understand that hemoglobin could provide a more natural meat-like coloring than these ingredients. EX1006¶372.

A POSITA would reasonably expect success in combining McMIndes’s meat replica with Ljublinskij’s hemoglobin at a concentration sufficient to achieve the desired color and/or nutritional profile because McMIndes discloses conventional methods (*e.g.*, mixing) for incorporating colorants into its soy protein material. *E.g.*, EX1003, [000120], [000122]. Like McMIndes, Ljublinskij teaches that hemoglobin can be combined with non-meat products by mixing, which would require only ordinary skill in the art. EX1006¶373; EX1004, 14:24-25 (“Hemoglobin should be added in a pre-dissolved form with thorough mixing until homogeneous at a suitable stage in the preparation of dough, fillings, sausage meat, etc.”).

* * * * *

from leghemoglobin in food matrix is also known...it would have been obvious to a skilled artisan...to adjust the content of leghemoglobin in the meat.” EX1002, 2990.

The '761 patent acknowledges the desirability of preparing meat replicas “that appeal to the larger consumer segment accustomed to eating meat” and not merely to “a limited consumer base that is already committed to vegetarianism/veganism.” EX1001, 1:51-55. Similarly, McMindes’s meat replicas can—but need not—be free of animal products. *See* Section XII.A.3; EX1003, [00016], [000110], [000113-000114]. A POSITA thus would not be discouraged from using Ljublinskij’s animal-derived hemoglobin in McMindes’s beef replica product. EX1006¶374.

Petitioner anticipates that PO will argue that a POSITA would not be motivated to add Ljublinskij’s heme-containing proteins to McMindes because it could affect the organoleptic properties of the beef replica. EX1002, 3065 (PO argued “heme iron causes off flavors, oxidation, and rancidity”). This argument has no merit. First, the claims do not require any organoleptic properties, as these limitations were removed during prosecution. EX1002, 3058 (deleting, among other things, “wherein, upon cooking of the meat replica, two or more volatile compounds that are associated with a cooked meat aroma are produced in an increased amount relative to cooking a meat replica product lacking the heme containing protein”). Second, PO’s alleged basis for this argument (EX1002, 3064-3065) during prosecution is unsupported. Specifically, PO’s citation to the Proulx thesis during prosecution allegedly disparaging a combination with heme iron refers to different non-heme iron compounds (*e.g.*, FeSO₄). EX1019, 20, 29 (discussing non-heme

iron compounds and citing PAHO (EX1021, 6-9; EX1051¶¶92-98) (discussing fortification with non-heme iron compounds)); EX1051¶¶80-84. Indeed, the Proulx thesis concludes that “heme iron from plants may be a novel *value-added* food fortificant.” EX1019, xii. Similarly, PO’s citation to Calkins during prosecution, when read in full, criticizes suggestions that heme iron creates off-flavor by oxidizing lipids. EX1019, 70 (“It has been suggested myoglobin has a close relationship with lipid oxidation [] which could influence flavor. However, little evidence is present to support these theories”); *see also* EX1022, Abstract (“iron, heme iron, and pH had no effect in this study” on development of the liver-like off-flavor); EX1051¶¶99-105.

Moreover, to the extent that PO points to Ljublinskij’s disclosure that use of whole blood and its nonpurified components in food is limited by the “specific, metallic taste of blood, which persists in the end products,” EX1004, 14:18-20, Ljublinskij teaches that its “method allows obtaining, on a commercial scale, dissociated and stabilized hemoglobin that has no such taste,” EX1004, 14:21-32. A POSITA also would understand that tastes associated with hemoglobin generally (as taught in Ljublinskij or other sources) would not be objectionable in *meat* replicas since desirable meat taste is due, in part, to such proteins. EX1006¶377. As explained, the level of heme-containing protein in McMindes’s and Ljublinskij’s products overlaps with the level in natural meat. Sections IX.A.2, XII.A.3.

3. Element 1[a][3]-1[c].

See Ground 1 analysis.

B. Claim 2-11, 13-17.

See Grounds 1 and 2 analysis.

**X. GROUND 4: MCMINDES IN VIEW OF SONAC RENDERS
OBVIOUS CLAIMS 1-11 AND 13-17**

Petitioner raises Ground 4 to address potential argument by PO that McMindes does not expressly disclose 0.1%-5% of a heme-containing protein based on McMindes's disclosed ratios analyzed in Ground 1 or that a POSITA would not be motivated to combine Ljublinskij with McMindes. This Ground thus relies on McMindes in view of Sonac's disclosure for incorporating hemoglobin in food products within the claimed range. EX1006§XIII.

A. Claim 1.

1. 1[pre]-1[a][1].

See Ground 1 analysis.

2. Element 1[a][2].

Sonac. Sonac describes the use of protein colorants called "Harimix" to achieve a meat-like appearance in food products. EX1005, 1-3. It teaches that Harimix contains hemoglobin as "the functional protein," which "intensif[ies] the coloring" and gives meat products "a natural color," including beef products. EX1005, 1; EX1006¶¶384-385. It also teaches that Harimix provides better meat-

like coloring than other colorants, *e.g.*, carmine (taught in McMIndes). EX1006¶388.

Sonac discloses the concentrations of Harimix’s “protein content,” which a POSITA would understand to refer to hemoglobin. EX1006¶385; EX1005, 4. According to Sonac, “[t]he concentration of Harimix proteins which delivers optimal results depends on different factors, such as type of meat product, the extent of the color problem, and the use of other coloring ingredients.” EX1005, 3. A POSITA would understand that adding Harimix proteins to a product at the concentrations taught by Sonac would add between 0.1% and 5% of a heme-containing protein (hemoglobin) to the product. EX1006¶386, 390-392.

Combination of McMIndes and Sonac. For the same reasons provided regarding Ljublinskij for coloration (Section XI.A.2), a POSITA would be motivated to use Sonac’s Harimix colorants to achieve 0.1%-5% of a heme-containing protein in McMIndes’s beef replica to achieve real meat coloration. EX1006¶388-389. A POSITA would understand that higher concentrations of Harimix colorants than those taught in Sonac could be used to achieve the desired coloration in products that are meat-free or are only part meat. EX1006¶393. Moreover, to the extent that PO claims that a POSITA would be discouraged from adding hemoglobin to food products for coloring because of potential organoleptic effects, a POSITA would know that hemoglobin-based food additives like Harimix have been sold and used

in foods for multiple decades before the '761 patent. EX1006¶395. If a POSITA were discouraged from using such products, Harimix would not have been commercially viable for such a long period. EX1006¶395.

A POSITA would reasonably expect success in substituting Harimix colorants for McMindes's colorants (*e.g.*, caramel and carmine). EX1006¶394; EX1005, 2 (disclosing "Research Findings" showing Harimix's beneficial properties over other colorants, including carmine). McMindes teaches mixing colorants into its products during preparation, and Sonac similarly provides "very simple" instructions to "add [the colorant] to the dough during its preparation and mix[]." EX1005, 1. Determining the optimum concentration of hemoglobin to color the product would require only ordinary skill. EX1006¶394; EX1002, 2990.

3. Element 1[a][3]-1[c].

See Ground 1 analysis.

B. Claim 2-11, 13-17.

See Grounds 1 and 2 analysis.

XI. GROUND 5: MCMINDES IN VIEW OF CRANE AND (LJUBLINSKIJ OR SONAC) RENDERS OBVIOUS CLAIM 12

Petitioner raises Ground 5 to address Claim 12's "no animal products" limitation. This Ground thus relies on McMindes in view of Crane's method for producing heme-proteins with no animal products and (either Ljublinskij's or

Sonac's) disclosure for incorporating hemoglobin within the claimed range.

EX1006§XIV.

A. Claim 12.

The beef replica product of claim 1, wherein said beef replica product contains no animal products and less than 5% carbohydrates.

As explained, McMindes discloses (i) all Claim 1 elements in its hybrid meat-plant product expressly and alternatively in view of either Ljublinskij or Sonac in its hybrid and meat-free products, *see* Ground 1, 3-4, Sections VII, IX, and X, and (ii) products with less than 5% carbohydrates, *see* Ground 1, Section XII.J. A POSITA would be motivated to create meat-free low-carbohydrate food products because low-carbohydrate diets were known to be safe and effective, and to have a reduced heart disease risk when vegetable plants and fats are used. EX1006¶¶404-408; EX1050, Abstract; EX1042, 2087; EX1043, 2000.

The only animal products in McMindes (hybrid product), Ljublinskij and Sonac are heme-containing proteins but a POSITA would understand that such proteins were readily available from non-animal sources at the time of the invention. EX1006¶410; EX1052¶142-145.

Crane. Crane teaches methods for producing “homogeneous commercial heme-binding proteins with high activity” via “a straightforward and inexpensive method for high fidelity incorporation of heme into recombinantly overexpressed

heme proteins.” EX1012, 4:27-29, 4:33-41; EX1052¶142. Crane’s methods yield “proteins [that] are completely functional and are more suitable for...commercial applications” than prior art methods of producing heme-binding proteins, which include clinical and food products. EX1052¶141; EX1012, 6:43-50. These recombinant proteins can be, *e.g.*, globins of various kinds, including hemoglobin, myoglobin, and leghemoglobin. EX1012, 5:44-49; EX1052¶144. A POSITA would understand that these recombinant proteins—like naturally occurring globins—would be advantageous for enhancing meat-like color and nutrition profile. EX1052¶145; Sections IX.A.2. In addition, because Crane’s recombinant proteins are not extracted from animals, a POSITA would understand in the context of this patent that they are not animal products. EX1052¶145. Moreover, Crane discloses using recombinant leghemoglobin, a plant heme-protein. EX1052¶144.

Following Crane, a POSITA would reasonably expectation of success producing various recombinant heme-proteins. EX1052¶144; EX1012, 4:27-29. Crane teaches the production of heme-proteins via expression systems using “strong promoters to obtain a high level of...expression.” EX1012, 75:39-52; *see also id.* 87:65-67 (“[T]he simple and inexpensive method of co-expressing ferrochelatase is effective at producing fully incorporated heme proteins...”); EX1052¶144. Recombinant protein expression was a known solution for fortifying foods with iron in similar contexts. EX1052¶135; EX1016, 285 (“the seeds from the transgenic rice

accumulated up to threefold more iron...than normal seeds...[t]his achievement suggests that it may be feasible to produce ‘ferritin rice’ as an iron supplement in the human diet”).

Combining McMindes with Crane and (Ljublinskij or Sonac). As explained in Grounds 1, 3 and 4, Sections VII, IX, and X, McMindes would motivate a POSITA to create an improved beef replica by enriching and/or coloring the product with 0.1%-5% of Ljublinskij’s or Sonac’s hemoglobin.

Consistent with the ’761 patent, McMindes discloses that its products can be free of animal products for people “who for religious or health reasons choose to avoid meat products.” EX1003, [000113]; EX1001, 19:53-55 (“The consumable may provide alternatives to animal products...whose consumption is forbidden by religious beliefs”); EX1002, 2995 (“It would have been obvious to a skilled artisan at the time the invention was made...to have used only proteins from non-animal sources in order to appeal to consumers who desire foods comprising non-animal ingredients”). A POSITA would thus be motivated to modify the beef replica product resulting from the combination of McMindes with Crane and (Ljublinskij or Sonac) to create a meat-free product for the segment of customers who do not consume animal products. EX1006¶¶401-403; EX1052¶¶129, 143-146.

A POSITA would also be motivated to achieve Ljublinskij’s or Sonac’s fortification and/or coloration in McMindes’s meat-free product using globins such

as hemoglobin derived from non-animal sources. EX1006¶403; EX1052¶¶135, 143-145. One prior art solution to these problems that a POSITA would know of and be motivated to use is recombinant hemoglobin or leghemoglobin as taught by Crane. EX1052¶129-146. Indeed, a POSITA would know that more than a decade before the '761 patent's priority date, others had developed plants fortified with high levels of iron-containing proteins using recombinant techniques. EX1006¶¶415-416; EX1052¶133; EX1016, 282 (introducing soybean ferritin gene in rice plants to address iron deficiencies that affects up to 30% of the world's population, as ferritin is used as the storage form of iron). A similar approach is disclosed in the '761 patent. EX1001, 40:17-20 (“[L]eghemoglobin can be sourced from non-plant sources, such as from organisms such as bacteria or yeast which have been genetically modified to express high levels of leghemoglobin.”). Moreover, Ljublinskij and Sonac teach adding hemoglobin for nutritive and/or coloration within the claimed range and a POSITA thus would be motivated to incorporate Crane's heme-proteins at similar concentrations. EX1006¶409; Sections IX.A.2, X.A.2.

A POSITA would reasonably expect success in modifying McMindes's meat-free replica to add Crane's heme-proteins to achieve the claimed heme-protein range with no animal products as, *e.g.*, McMindes, Ljublinskij, and Sonac all teach that heme-proteins can be combined with beef replica products using ordinary skill and

conventional techniques (mixing). EX1006¶413; Sections Sections IX.A.2, X.A.2. Moreover, Crane’s method of producing such heme-proteins is “straightforward” for a POSITA. EX1006¶412; EX1052¶142; EX1012, 4:27-29 (“The present invention is a straightforward and inexpensive method for high fidelity incorporation of heme into recombinantly overexpressed heme proteins.”).

XII. GROUND 6: MCMINDES IN VIEW OF PROULX AND LJUBLINSKIJ RENDERS OBVIOUS CLAIM 12

Petitioner raises Ground 6 to address potential argument by PO that a POSITA would not be motivated to combine Crane with McMindes or in the event that PO attempts to swear behind Crane as 102(e) prior art. This Ground thus relies on McMindes in view of Proulx’s and Ljublinskij’s disclosure for incorporating heme-proteins to fortify foods within the claimed range. EX1006§XV.

A. Claim 12.

See Grounds 1, 3, 5, Sections XII, IX, XI, regarding McMindes’s disclosure of Claim 1 elements, less than 5% carbohydrates, and the only animal products in McMindes and Ljublinskij.

Proulx. Proulx teaches that “[h]eme iron in the human diet is generally present in animal sources as a part of hemoglobin and myoglobin” but “incorporation of animal-sourced heme iron is often unfeasible because of economic costs or because cultural and religious barriers forbid the consumption of meat.” EX1009, 1518, 1521. Like Ljublinskij, Proulx also discloses that “[i]ron deficiency is a major

nutritional problem” in these populations and “one major recommendation for improving iron status in populations is to incorporate sources of heme iron in the diet because of its high iron bioavailability.” *Id.* To that end, Proulx teaches that heme iron “is also found in many invertebrates, bacteria, fungi, and widely distributed in the plant kingdom.” EX1009, 1518. Proulx identifies one such plant heme-protein as “[l]eghemoglobin...[which] has been studied extensively.” *Id.*

Proulx further discloses that “fortification of food with iron has been a successful strategy for improving iron content of foods” but notes that “bioavailability of iron fortificants is often decreased due to the presence of inhibitors within the food matrix.” *Id.*, 1518. For this reason, Proulx assessed bioavailability of plant leghemoglobin compared to bovine hemoglobin in food matrix. *Id.*, Abstract. In matrix, Proulx found that leghemoglobin and bovine hemoglobin “showed similar bioavailability” and concluded that “heme iron from plant sources...can provide highly bioavailable iron as a food fortificant.” *Id.*

Combining McMindes and Ljublinskij with Proulx. As explained in Grounds 3 and 5, Sections IX and XI, McMindes would motivate a POSITA to create an improved beef replica by enriching the product with Ljublinskij’s hemoglobin within the claimed range. In light of McMindes’s, Ljublinskij’s, and Proulx’s teachings regarding meat-free products, Sections XII.A.3, IX.A.2, and XII.A, a POSITA would also be motivated to achieve Ljublinskij’s fortification levels in

McMindes’s meat-free product using hemoglobin or functionally similar heme-containing proteins derived from non-animal sources. EX1006¶422; EX1003, [000113]; EX1001, 19:53-55; EX1002, 2995. A POSITA would know that one such solution is the use of plant-derived leghemoglobin, as taught by Proulx. EX1006¶423; EX1009, 1521.

Proulx discloses “using plant [leg]hemoglobin as a heme iron source in diets that are consumed by humans.” EX1009, 1518; EX1006¶424. Proulx also teaches “results showing the bioavailability of [leg]hemoglobin...similar to that of heme iron from animal sources,” which presents “a unique alternative fortificant,...to improve the iron status of the population.” EX1009, 1521; EX1006¶425. A POSITA would be further motivated to use leghemoglobin as a fortificant because there is “minimal inhibition of heme iron, unlike nonheme iron, by dietary factors and...high heat stability of...[heme] iron.” EX1009, 1522; EX1006¶426. A POSITA would be still further motivated to use leghemoglobin because “[s]oy root nodules have no current use in agriculture production and as such may provide a novel value-added product for soy producers.” *Id.* Proulx thus concludes and a POSITA would know that “plant [leg]hemoglobins may have great potential to be used as a fortificant for improving nutrition.” *Id.* Moreover, Ljublinskij teaches adding hemoglobin—which is functionally equivalent to leghemoglobin—for nutritive and/or coloration within the claimed range and a POSITA thus would be

motivated to incorporate Proulx's leghemoglobin at similar concentrations. EX1006¶427; Section IX.A.2.

A POSITA would reasonably expect success in modifying McMindes's meat-free replica with Proulx's leghemoglobin to achieve the claimed range because Proulx "showed similar bioavailability" with bovine hemoglobin in food matrix. EX1006¶428; EX1009, Abstract. McMindes, Ljublinskij, and Proulx also teach that heme-containing proteins can be combined with beef replica products using ordinary skill and conventional techniques (mixing). EX1006¶428; Sections IX.A.2, X.A.2; EX1009, 1519. Moreover, Proulx teaches simple methods to obtain leghemoglobin. EX1006¶429; EX1009, 1519 (describing mechanical harvest, fraction, and purification steps).

XIII. NO SECONDARY CONSIDERATIONS APPLY

The instant Petition should also be granted because, to the extent PO proffers any "secondary considerations," Petitioner is not aware of any nexus that exists between such evidence and any patentable aspect of the claims.

Any asserted commercial success of PO's products, if covered by the claims, derives from unclaimed factors such as PO's commercial strategy:

[T]he majority of Impossible Food's initial partnerships...were more resilient during the [COVID-19] pandemic, allowing Impossible to scale quickly and reduce costs.

Impossible Food’s rapid growth over the pandemic—hitting production records and achieving greater economies of scale—allowed them to drastically slash their prices by 20% in restaurants and grocery stores earlier this year in an attempt to better compete with meat. They made their product more buyable to the broader consumer base...

EX1034, 4; EX1051¶¶154-156. PO has also hired seasoned advertising consultants to “supercharge its marketing efforts,” following its “intentionally aggressive ad campaign.” EX1032, 1-2; EX1051¶¶148-149.

Moreover, the purported discovery that led to PO’s products was known:

[W]e discovered that *one molecule—heme—is primarily responsible for generating the...flavor and aroma of cooked meat.*

When we mixed *leghemoglobin* with plant proteins, fats and other simple nutrients, it *transformed*...veggie burger *into...meat!*

EX1033, 2-3 (emphasis added); EX1051¶¶150-153.

PO admitted to the U.S. Food & Drug Administration, leghemoglobin is equivalent to other heme-containing proteins, including myoglobin in meat. EX1035, 7 (“animal myoglobins, plant hemoglobins and plant leghemoglobins [] are structurally very similar”); 24 (“there is no evidence to suggest that soy

leghemoglobin in food will behave any differently from the myriad other functionally equivalent and widely consumed globin proteins in the human diet”); EX1051¶¶157-158.

Moreover, inclusion of leghemoglobin (or any heme-protein) in a meat analog, absent more, is not patentable. EX1002, 2990 (“[I]t would have been obvious to a skilled artisan to have...fortified the meat analog with leghemoglobin in order to provide the consumer with a meat analog with improved nutritional value as it is fortified with iron, and also with a meat analog that is nutritionally similar to real meat”).

Rather, the ’761 patent was allowed because the Examiner (incorrectly) found that no substantively considered prior art reference disclosed a denatured plant protein in a fat replica. EX1002, 3103; Section II.C, *supra*. Indeed, the Examiner found that all other claimed limitations were present in the prior art. EX1002, 3102-3103.

Moreover, “aroma” and “flavor” are not limitations of any ’761 patent claim (and PO deleted a similar limitation during prosecution; EX1002, 3058). Regardless, as the Examiner recognized, the purportedly desirable aroma of PO’s products is the natural—and unpatentable—result of the prior art combination. EX1002, 2991-2992.

While it is not currently aware of any, Petitioner reserves the right to address other secondary considerations or evidence raised by PO.

XIV. INSTITUTING *INTER PARTES* REVIEW WOULD BE EQUITABLE

A. 35 U.S.C. § 325(d) Factors Support Institution

The Board should not exercise its discretion to deny institution under § 325(d) under the Board's *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (Feb. 13, 2020) decision.

1. *Advanced Bionics* Part 1

Grounds 1-6 are each based on McMindes, Ljublinskij, Sonac, Crane or Proulx. Although the U.S. counterpart of McMindes (US20060035003) and the publication of Crane were cited in IDSes (but not relied upon in any office action), Ljublinskij and Sonac were not cited in any IDS or otherwise presented during prosecution. Proulx is the only reference that was substantively considered during prosecution and the Examiner reached the same conclusion regarding lack of novelty and obviousness for the heme-containing protein element as set forth herein.

The Petition's combinations of references are also materially different from and not cumulative of art evaluated during prosecution. For example, Sonac materially differs from cited prior art because it teaches that hemoglobin confers a desirable meat-like color. Ljublinskij materially differs because it teaches that hemoglobin is a colorant and because it demonstrates that a non-meat product

enriched with hemoglobin at the claimed percentage range (0.1%-5.0%) can have a desirable nutrition profile (*e.g.*, treating iron deficiency).

Accordingly, **Factors (a) and (b)** each weigh against discretionary denial. *PEAG LLC v. Varta Microbattery GmbH*, IPR2020-01212, Paper 8 at 11-12 (Jan. 6, 2021) (finding “specific combinations” of references not same or substantially same as art previously presented, where one reference in each combination was cited in an IDS); *FireKing Security Prods., LLC v. Ellenby Techs., Inc.*, IPR2021-00531, Paper 15 at 10-14 (Aug. 23, 2021) (same); *see also Thorne Research, Inc. v. Trs. of Dartmouth College*, IPR2021-00268, Paper 21 at 9 (June 10, 2021).

Factor (d) also weighs against discretionary denial. McMindes’s counterpart and Crane were only cited in IDSes and not relied upon by the Examiner; Ljublinski and Sonac were never presented during prosecution. Neither the Applicant nor the Examiner discussed any of these references during prosecution, much less the specific combinations raised herein. There is no substantial overlap between prosecution arguments and the Petitioner’s arguments (*see* Sections VII-XII).

Thus, the first part of the *Advanced Bionics* framework counsels against discretionary denial. The Board need not address the second part of the framework.

2. *Advanced Bionics* Part 2

Even assuming that the Board were to find the first part of *Advanced Bionics* framework satisfied, the second part weighs heavily against discretionary denial.

The Examiner erred by overlooking the numerous teachings of McMIndes, including a fat replica with a denatured plant protein that the Examiner found lacking in Van den Briel. Petitioner’s additional evidence, including an expert declaration and materially different prior art, such as Ljublinskij and Sonac, not previously available during prosecution, warrants institution of *inter partes* review.

Factor (c) weighs strongly against discretionary denial because the asserted prior art—including McMIndes and Crane, as well as the other non-cited references—“was not the basis for a rejection and was not evaluated substantively at all during examination.” *Liquidia Techs., Inc. v. United Therapeutics Corp.*, IPR2021-00406, Paper 18 at 19 (Aug. 11, 2021); *accord Cellco P’ship v. Huawei Device Co.*, IPR2020-01117, Paper 10 at 13 (Feb. 3, 2021). Counterparts of McMIndes and Crane were cited by Applicant amongst **>700 references** during prosecution. EX1001, 1-12. “Other than initials on a lengthy IDS, nothing in the record indicates that the Examiner substantively considered” these particular references, much less the specific combinations raised herein. *Philip Morris Prods., S.A. v. RAI Strategic Holdings, Inc.*, IPR2020-00921, Paper 13 at 46-47 (Aug. 5, 2021). Here, as in other cases where the Board had granted institution, “the record is not sufficiently clear that the Examiner meaningfully considered the relevant disclosures of the asserted prior art references in the Petition or substantially similar references. Whether the prior art was the basis for a rejection is significant to this

analysis.” *Commscope Techs. LLC v. Dali Wireless Inc.*, IPR2020-01473, Paper 18 at 13 (Mar. 12, 2021); *accord Fellowes, Inc. v. Treefrog Devs., Inc.*, IPR2020-01435, Paper 12 at 14-15 (Feb. 22, 2021).

Factor (e) likewise weighs heavily in favor of institution because Petitioner has demonstrated material error during prosecution. As explained in Sections VII-XII, the Examiner erred by overlooking key teachings of McMIndes, failing to apply McMIndes in any rejections or to acknowledge that McMIndes teaches most claim limitations, including a fat replica with a denatured plant protein, and overlooking the significance of Crane and the obviousness of combining Crane with McMIndes and Ljublinskij or Sonac to achieve the claimed product that “contains no animal products.” See *Sketchers U.S.A., Inc. v. Nike, Inc.*, IPR2021-00160, Paper 10 at 19-21 (May 19, 2021); *Weatherford U.S., L.P. v. Enventure Glob. Tech., Inc.*, IPR2020-01700, Paper 14 at 12-13 (Apr. 14, 2021); *Analog Devices Inc. v. Xilinx, Inc.*, IPR2020-01596, Paper 12 at 11-13 (Apr. 14, 2021); *Liquidia*, at 19-20; *Commscope*, at 16; *Fellowes*, at 16-19; *Cellco*, at 13-14 (“Petitioner has sufficiently shown that the Examiner erred in a manner material to the patentability of the claims by pointing out the specific teachings of the prior art that the Examiner misapprehended or overlooked.”).

Factor (f) also strongly favors institution. As shown in Sections VII-XII, there is a reasonable likelihood that Petitioner will prevail on invalidity theories not

previously addressed. Petitioner has presented evidence not previously available during prosecution, including an expert declaration and materially different prior art, which in combination with McMIndes renders the claims obvious. *See Fellowes*, at 19-21; *Commscope*, at 16-17.

Each of Factors (c), (e), and (f) favors institution. Weighing them together, Petitioner has established material error by the Examiner in overlooking McMIndes alone and in combination with the additional references. Institution based on Grounds 1-6 is warranted under § 325(d).

B. *NHK-Fintiv* Factors Also Support Institution

The Board balances six factors in considering discretionary denial under 35 U.S.C. § 314(a). Here, the weight of these factors strongly favors institution. *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 at 6 (Mar. 20, 2020) (precedential).

1. *Fintiv* Factor 3

Investment in the Litigation has been minimal. PO filed and served its complaint on March 9, 2022, only six weeks ago. The court has not scheduled any hearings or issued any substantive orders. No motion for preliminary injunction has been filed, and no invalidity contentions have been exchanged. At this point, the court has invested literally no time in assessing the case. If instituted, this Proceeding will resolve issues concerning invalidity before the court does, promoting efficiency.

This factor favors institution. *Fintiv*, IPR2020-00019, Paper 11 at 11; *Peloton Interactive, Inc. v. Icon Health & Fitness, Inc.*, IPR2021-00342, Paper 14 at 13 (July 7, 2021).

2. *Fintiv* Factor 2

No trial date has been set in the Litigation. The median time to trial in the District of Delaware is 788 days—roughly twenty-six months from time of filing. EX1031. This factor favors institution. *Peloton*, IPR2021-00342, Paper 14 at 10.

3. *Fintiv* Factor 4

Final written decision will be reached long before trial in the Litigation and Petitioner would be subject to the estoppel applicable under 35 U.S.C. § 315(e)(2). Moreover, Petitioner stipulates that it will not pursue in the Litigation any grounds raised in this Petition.

This factor weighs at least marginally in favor of not exercising discretion to deny institution. *Cf. Sand Revolution II, LLC v. Cont'l Intermodal Grp.-Trucking LLC*, IPR2019-01393, Paper 24 at 12 n.5 (June 16, 2020) (informative).

4. *Fintiv* Factor 1

Petitioner is filing concurrently herewith a motion to stay the Litigation pending the result of this Petition. Delaware district courts routinely grant stays in connection with IPRs.¹⁸

A stay of litigation pending resolution of this Petition allays concerns about inefficiency and duplication of efforts. This factor thus favors institution. *Sand Revolution II*, Paper 24 at 7.

5. *Fintiv* Factor 5

The parties are the same in this proceeding and the Litigation. This factor should be given little weight in light of the early stage of the Litigation, Petitioner's concurrent motion to stay and stipulation discussed above.

6. *Fintiv* Factor 6

No other parties have sought review of the '761 patent. The merits of the Petition are particularly strong. The asserted art provides compelling evidence that anticipates and/or render obvious all claims. Had the Examiner either been aware of these references during prosecution, or not materially erred in ignoring their teachings, the Examiner would not have issued the '761 patent.

¹⁸ EX1030 (“[T]he District of Delaware routinely grants motions to stay pending IPR after institution...88%, 91% and 90% for 2019, 2020 and 2021, respectively.”).

This favors institution. *Fintiv*, IPR2020-00019, Paper 11 at 14-15 (merits “seem particularly strong”).

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

Petitioner certifies that the ’761 patent is available for *Inter Partes* Review and that Petitioner is not barred or estopped from requesting this proceeding.

XVI. CONCLUSION

Petitioner has demonstrated a reasonable likelihood that all ’761 patent claims are anticipated and/or obvious. Accordingly, review is requested.

XVII. MANDATORY NOTICES

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

Motif Food Works, Inc. is the real party-in-interest.

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

District of Delaware, Case No. 22-cv-00311.

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.

LEAD COUNSEL	BACK-UP COUNSEL
Joseph M. Paunovich (Reg. No. 59,044) qeimpossibleipr@quinnemanuel.com	James Glass (Reg. No. 46,729) Sandra Haberny (Reg. No. 64,150) Jihong Lou (Reg. No. 64,074) Landon Smith (Reg. No. 79,248) qeimpossibleipr@quinnemanuel.com

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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: April 20, 2022

Respectfully submitted,

By: /Joseph M. Paunovich/
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*Lead Attorney for Petitioner Motif
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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 13,699 words as counted by the word processing program used to prepare the paper.

Date: April 20, 2022

Respectfully submitted,

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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. 10,863,761** and supporting materials were served on Patent Owner by USPS Overnight Express Mail at the following address of record for the subject patent:

Dr. M. Angela Parsons
Fish & Richardson P.C.
P.O. Box 1022
Minneapolis, MN 55440-1022
Attorney Docket No. 38767-0019002

Courtesy copies of the same documents were served on Patent Owner by USPS Overnight Express Mail at the following address of record for litigation counsel:

Ian Robert Liston
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Date: April 20, 2022

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Case No.: IPR2022-00887

U.S. Patent No. 10,863,761

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