

**IN THE UNITED STATES DISTRICT COURT
FOR DISTRICT OF DELAWARE**

IMPOSSIBLE FOODS INC.,	)	
	)	
	)	
Plaintiff,	)	C.A. No. 22-311 (WCB)
	)	
v.	)	REDACTED
	)	
MOTIF FOODWORKS, INC.,	)	
	)	
Defendant.	)	
	)	
	)	

**PLAINTIFF IMPOSSIBLE FOODS INC.'S
OPENING CLAIM CONSTRUCTION BRIEF**

OF COUNSEL:

Wendy L. Devine
Kristina Hanson
Jessica Ramsey
Susannah M. L. Gagnon
WILSON SONSINI GOODRICH & ROSATI, P.C.
One Market Plaza
Spear Tower, Suite 3300
San Francisco, CA 94105
(415) 947-2000

WILSON SONSINI GOODRICH & ROSATI, P.C.
Ian R. Liston (#5507)
Jennifer A. Ward (#6476)
222 Delaware Avenue, Suite 800
Wilmington, DE 19801
(302) 304-7600
iliston@wsgr.com
jward@wsgr.com

Counsel for Plaintiff Impossible Foods Inc.

Matthew R. Reed
WILSON SONSINI GOODRICH & ROSATI, P.C.
650 Page Mill Road
Palo Alto, CA 94304
(650) 493-9300

Lorelei P. Westin
WILSON SONSINI GOODRICH & ROSATI, P.C.
12235 El Camino Real
San Diego, CA 92130
(858) 350-2300

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TABLE OF ABBREVIATIONS

Abbreviation	Phrase
Impossible	Impossible Foods Inc.
Motif	Motif FoodWorks, Inc.
'096 patent	U.S. Patent No. 9,943,096
'241 patent	U.S. Patent No. 11,224,241
'761 patent	U.S. Patent No. 10,863,761
'306 patent	U.S. Patent No. 10,039,306
'250 patent	U.S. Patent No. 11,013,250
Food Product Patents	'241 patent, '761 patent, '306 patent, '250 patent, and '096 patent, collectively
'492 patent	U.S. Patent No. 10,273,492
'656 patent	U.S. Patent No. 10,689,656
Yeast Patents	'492 and '656 patents, collectively
Alper, ¶ __	Declaration of Hal Alper, PhD, filed concurrently herewith
Ex.	Exhibits attached to Impossible's Opening Brief
Term __	Numbered list of terms in Section II of the Joint Claim Construction Statement (D.I. 94-1).

*** All emphasis herein is added, and all internal citations and quotations are omitted unless otherwise noted.**

I. INTRODUCTION

This case is about Motif’s infringement of several of Impossible’s patents covering its innovative meat-substitute products. Impossible fundamentally changed the meat-substitute industry with its novel food products containing heme. Those products were made possible by Impossible’s innovative recombinant yeast strains for production of heme. Rather than pursue its own innovations, Motif chose to copy Impossible’s proprietary food products and heme-generating yeast. To avoid accountability for its infringement, Motif now seeks litigation-driven constructions with no support in the patents and asserts that terms that are common to those of ordinary skill and readily understood based on the intrinsic record, are indefinite.

The intrinsic record supports Impossible’s constructions or that no construction is necessary.

II. LEGAL STANDARDS

A. Claim Construction

The claims of a patent define the scope of an invention, and claim construction is a question of law “exclusively within the province of the court.” *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372, 391 (1996). Claims are to be interpreted in view of the intrinsic record: the claim language, specification, and prosecution history. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc); *see also Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996); *Markman v. Westview Instruments*, 52 F.3d 967, 979-80 (Fed. Cir. 1995).

Claim terms should receive their plain and ordinary meaning as understood by a person of ordinary skill (“POSA”) during the relevant timeframe. *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 884 (Fed. Cir. 2008) (*citing Phillips*, 415 F.3d at 1313-14); *see also Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014). A party proposing to depart

from this meaning must demonstrate “why such an alteration is required.” *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1363 (Fed. Cir. 1999). Courts also may consider extrinsic evidence, such as expert testimony, dictionaries, and technical treatises and articles. However, “[i]f the meaning of a claim is unambiguous from the intrinsic evidence, then a court may not rely on extrinsic evidence for purposes of claim construction.” *Hockerson-Halberstadt, Inc. v. Avia Grp. Int’l, Inc.*, 222 F.3d 951, 955 (Fed. Cir. 2000); *see also Vitronics*, 90 F.3d at 1584.

“In general, a preamble limits the [claimed] invention if it recites essential structure or steps, or if it is ‘necessary to give life, meaning, and vitality’ to the claim.” *Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002); *see also Eaton Corp. v. Rockwell Int’l Corp.*, 323 F.3d 1332, 1339 (Fed. Cir. 2003) (“When limitations in the body of the claim rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the claimed invention.”).

A patent claim is not indefinite if, in the context of the specification and prosecution history, those skilled in the art would understand the scope of the invention with reasonable certainty. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014).

B. Person of Ordinary Skill in the Art

The understanding of a POSA at the time of invention “provides an objective baseline from which to begin claim interpretation.” *Phillips*, 415 F.3d at 1313. For the Food Product Patents, a POSA would have a graduate degree in food science, biology, chemistry, or a related field plus 2 years of experience as a food scientist. For the Yeast Patents, a POSA would have a graduate degree in chemical engineering, biochemistry, microbiology, or a related field, plus 2 years of experience in the design and use of recombinant protein expression techniques.

III. DISPUTED TERMS

The parties' proposed constructions for the disputed terms are set forth in Exhibit 1, which contains corrections of typographical errors in the Joint Claim Construction Statement filed on May 31, 2023 ("JCCS"). D.I. 94-1. The numbering of the disputed terms below and in Exhibit 1 is the same as in the JCCS.

A. "non-animal / free of animal"—Terms 1-4

As the Court noted in its November 2022 order denying Motif's Motion to Dismiss, the parties' dispute regarding terms 1-4 centers around whether these claims "cover any proteins that are not derived from an animal source, regardless of whether such proteins are chemically identical to those that are naturally present in animals" (Impossible's construction) or "cover only proteins that are not naturally present in animals" (Motif's construction). D.I. 31 at 4. The intrinsic evidence supports only the former.

The shared specification of the '250 and '306 patents teaches that the invention relates to food products and discusses "non-animal" ingredients (including proteins) in those food products in terms of how they are "derived." *E.g.*, '306 patent, 9:50-53 (meat substitutes can be "principally or entirely composed of ingredients **derived** from non-animal sources"); 9:61-10:3 ("the invention provides meat products substantially derived from animal sources (e.g. beef, chicken, turkey, or a pork product"); 17:58-60 (ingredients can be "**derived** from non-animal sources, e.g., plant, fungal, or microbial based sources"); 18:4-6 (proteins included in the food products of the invention "can be derived from non-animal sources such as plants, algae, fungi (e.g., yeast or filamentous fungi), bacteria, or Archaea"). That same specification teaches that such protein ingredients can be derived from a "non-symbiotic" source (*id.* at 21:66-22:1, 55:56-56:2) where they are recombinantly produced (*id.* at 20:64-21:1). Thus, the intrinsic evidence applicable to term 1 ("a non-animal heme-containing protein") characterizes proteins according

to the source from which they are derived—*i.e.*, obtained—and not whether they are chemically identical to proteins naturally present in animals.

The specification of the '761 patent (term 3) likewise discusses ingredients useful in the invention in terms of how they are “isolated” or “derived.” '761 patent, 4:32-34 (describing embodiments where the “isolated and purified iron-containing proteins are ***not isolated*** from an animal”); 4:47-52 (comparing “isolated and purified iron carrying proteins” to “myoglobin protein ***derived*** from an animal source”); 5:66-67 (“In some embodiments, said protein content is ***derived*** from one of more non-animal sources”).

The shared specification of the '096 and the '241 patents (terms 2-4) similarly states: “Food products described herein can be free of animal products (e.g., animal heme-containing proteins or other animal ***products***).” '096 patent, 18:13-15; *see also id.* at 2:43-50 (describing “plant-***derived*** heme protein” ingredients); 9:58-63 (“Heme-containing proteins can be isolated from bacteria[.]”). The patents specifically note that the “heme-containing proteins described herein” can have “at least 70% . . . or ***100%***[] sequence identity” to a number of hemoglobin and myoglobin proteins, including those of mammalian organisms. *Id.* at 10:7-41.

Moreover, the claims of the '096 and the '241 patents require adoption of Impossible's construction. These patents contain both independent claims requiring “no animal products” or “free of animal heme-containing protein” and claims that depend therefrom that require proteins having an amino acid sequence naturally present in animals. '096 patent, cl. 3 (encompassing SEQ ID NO. 18, *Bos taurus* (cattle)); '241 patent, cl. 7 (same).

The patents discuss the problems that the inventions address, which also support Impossible's construction. The patents note the environmental harms associated with animal farming and the negative impact on human health resulting from eating meat, and juxtapose the

worldwide hunger problem with the plentiful supply of commodity crops. *E.g.*, '306 patent, 1:33-2:3; '761 patent, 1:18-60. In describing the advantages of the inventions, the patents note less energy, water, and land area use, lower “carbon footprint,” animal welfare benefits, and the ability to produce the consumables of the inventions “where animal farming is not practical or is not allowed.” '306 patent, 8:47-54, 11:19-32, 11:47-63, 12:12-27; '761 patent, 19:26-52, 20:1-16. The inventions address these problems, in part, by using proteins derived from non-animal sources.

In support of its motion to dismiss, Motif stated “to cover animal heme-containing proteins that are produced without animals,” the patentee should have crafted claims directed to “the methods used to produce the protein.” D.I. 28 at 3. Motif’s argument runs contrary to established claim construction principles, disregards the intrinsic evidence, and relies on the misconception that a protein is defined only by where its sequence naturally exists. Motif’s proposed construction is untenable as applied to the claimed inventions, which relate to a recombinant protein *derived* or *isolated* from a non-animal genetically engineered organism, as the specification explains. *See* discussion *supra*.

Impossible’s construction is consistent with the plain and ordinary meaning of the disputed terms, as Motif’s own non-litigation statements reflect. For example, in its GRAS petition submitted to FDA, Motif describes its myoglobin as “[y]east-derived heme protein (non-animal)” with “a protein sequence that is identical to bovine myoglobin.” D.I. 22-2, Ex. 8 at 3; *see also*, Ex. 2 at IF_0013551 (Motif’s CEO stating “[W]e’re very confident that inclusion of [bovine myoglobin] will preserve a vegan claim for a customer. There’s no direct animal provenance, it’s not based on an animal source.”). In a document entitled [REDACTED]

[REDACTED]

Ex. 3 at 8. Thus, consistent with the specifications—but contrary to its proposed claim construction—Motif understands that it is the source from which a protein is derived that renders it “non-animal,” not its amino acid sequence. Whether a protein is “animal” or “non-animal” depends on the organism producing that protein—*i.e.*, the source from which the protein is derived—not sequence similarity to a mammalian protein. Engineering a yeast cell to produce a protein with the same amino acid sequence as a mammalian protein does not yield an animal product, much as engineering a pig to produce a plant protein does not yield a plant product.

Motif’s construction ignores the claims, the intrinsic record, and the plain and ordinary meaning in the art. Such a construction must be rejected.

B. “heme-containing protein”—Terms 5-6

Motif’s invalidity contentions do not allege that terms 5-6 are indefinite. Ex. 4. Motif’s indefiniteness argument in claim construction seemingly results from Motif’s incorrect construction of terms 2-3. As discussed above, terms 5-6 encompass amino acid sequences that “are the same as those found in an animal.” ’096 patent, SEQ ID NO. 18 (amino acid sequence of mammalian *Bos taurus* myoglobin); ’241 patent (same); *see also* Ex. 5 at IF_0013563 (“Myoglobin is a cytoplasmic hemoprotein, expressed solely in cardiac myocytes and oxidative skeletal muscle fibers . . . [.]”). Because (1) Motif’s proposed constructions for terms 2-3 would exclude any protein with an amino acid sequence found in an animal, and (2) terms 5-6 appear in claims that depend from claims containing terms 2-3, Motif’s constructions render the dependent claims containing terms 5-6 outside the scope of their corresponding independent claims. Such a construction is contrary to 35 U.S.C. § 112(d) (pre-AIA ¶ 4) (“[A] claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by

reference all the limitations of the claim to which it refers.”); *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380 (Fed. Cir. 2006) (observing that 35 U.S.C. § 112 “stresses that a dependent claim must add a limitation to those recited in the independent claim” and rejecting a construction of an independent claim that “might render the dependent claim invalid”).

The proteins recited in terms 5 and 6 are well known and understood to a POSA. Motif’s construction distorts the plain and ordinary meaning of terms 1-4, which indicates not indefiniteness, but rather that Motif’s construction must be rejected. *Phillips*, 415 F. 3d at 1327 (noting that validity analysis “look[s] to whether it is reasonable to infer that the PTO would not have issued an invalid patent, and that the ambiguity in the claim language should therefore be resolved in a manner that would preserve the patent’s validity”).

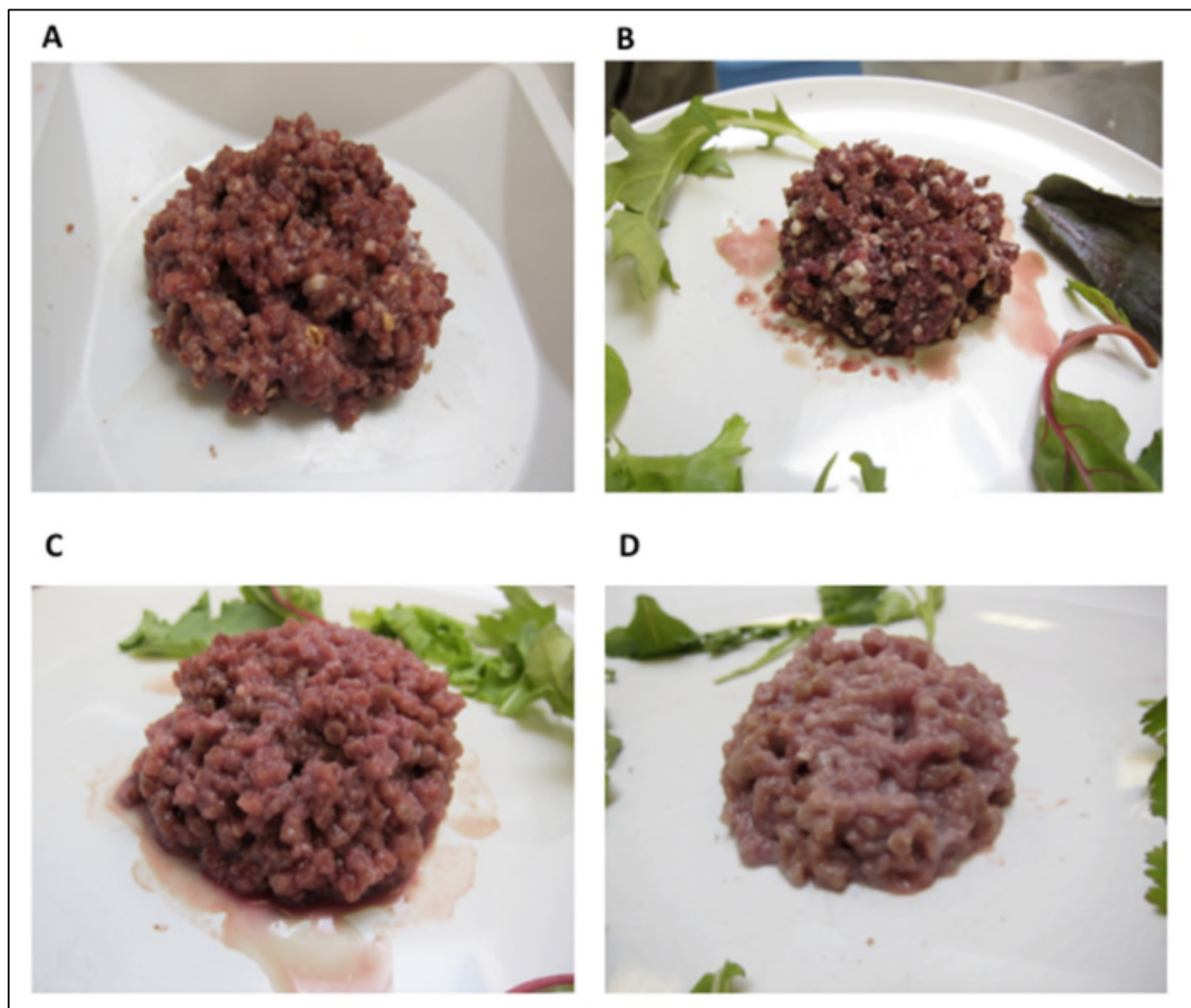
C. “replica”—Terms 15-17

Motif’s proposed constructions incorrectly (1) contradict the plain meaning of “replica,” and (2) add a requirement that replicas are “separate” or “visually distinguishable.” Motif’s constructions lack support from the intrinsic record.

First, according to the plain meaning of replica, muscle tissue is not a muscle replica and fat tissue is not a fat replica. Thus, to the extent that Motif’s constructions encompass actual muscle or fat tissue, they must be rejected. Evaluating Motif’s petition for IPR of the ’761 patent, the PTAB reached that same conclusion, construing “muscle replica” (term 15) to mean “a composition approximating the taste, texture or color of an equivalent muscle tissue derived from an animal source” that “may include components derived from an animal source, but *does not include muscle tissue itself*.” Ex. 6 at 9. The Board also construed “replica” to “exclude[] the actual material being replicated or approximated.” *Id.* In reaching its conclusion, the Board noted that the specification explains that a “muscle tissue replica approximates the taste, texture

or color of an equivalent muscle tissue derived from an animal source” (’761 patent, 5:34–36) and that components (*e.g.*, myoglobin) can be “derived from animal sources.” *Id.* at 25:42-47. The Board grounded its construction in the intrinsic evidence and correctly understood the meaning of the “replica” terms.

Second, there is no support in the specification for Motif’s proposed reading into the claims of “separate” and “visually distinguishable.” Indeed, the specification describes a ground beef replica as an example and includes the following illustration in Figure 15:



Motif’s construction would exclude this embodiment—where the muscle replica and fat tissue replica are *neither* separate nor visually distinguishable—from the claims, contrary to Federal

Circuit law. *MBO Lab'ys, Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1333 (Fed. Cir. 2007) (“[A] claim interpretation that excludes a preferred embodiment from the scope of the claim is rarely, if ever, correct.”).

For these reasons, the Court should reject Motif’s proposed constructions of terms 15 and 16.

Regarding term 17, Motif’s contention that a POSA would not know whether a replica “approximates” meat (Ex. 4 at 79) ignores the specification and the law of claim construction. The specification teaches, *inter alia*, that the “physical organization” of the inventive meat substitute is characterized by the “localization, organization, assembly, or orientation of the muscle, fat, and/or connective tissue replicas.” ’761 patent, 23:24-27. Further, the patent explains that the “physical organization” being mimicked can be that of ground meat or other known cuts of animal tissue, such as filet mignon. *Id.* at 23:32-41. That teaching is supported by the examples, including pictures of products approximating the physical organization of meat. *Id.*, Figs. 15-16. Motif’s argument, which assumes that a POSA would not know how such meat products are physically organized and could not recognize a non-meat product that mimicked that organization, falls far short of clear and convincing evidence of indefiniteness.

The teaching of the specification is sufficient for a POSA to understand with reasonable certainty whether a replica “approximates the physical organization of meat.” *Biosig Instruments, Inc. v. Nautilus, Inc.*, 783 F.3d 1374, 1378 (Fed. Cir. 2015) (“Claim language employing terms of degree has long been found definite where it provided enough certainty to one of skill in the art when read in the context of the invention.”); *Masimo Corp. v. Philips Elec. N. Am. Corp.*, No. 09-80-LPS, 2016 WL 6542726, at *19 (D. Del. Oct. 31, 2016) (“A patent is presumed to be valid. [A] party alleging indefiniteness must prove by clear and convincing

evidence that the claims fail to ‘inform those skilled in the art about the scope of the invention with reasonable certainty.’” (quoting *Nautilus*, 572 U.S. at 910)). Indeed, Motif and its expert witness were able to understand the scope of term 17 with reasonable certainty for purposes of Motif’s unsuccessful IPR petition. Ex. 7 at 17-18; Ex. 8, ¶¶ 180-184.

D. “a concentration of at least 1.5 mM”—Term 21

Motif’s addition of the language “in a liquid composition” to term 21 lacks support in the intrinsic record and obscures the plain and ordinary meaning. Term 21 recites concentration of the “compound selected from cysteine, cystine, thiamine, methionine, and mixtures of two or more thereof” in units of molarity, meaning a quantity of the “compound selected from cysteine, cystine, thiamine, methionine, and mixtures of two or more thereof” is measured as a volume of liquid, thus the addition of “in a liquid composition” is redundant. Ex. 9. Further, Motif’s construction incorrectly recharacterizes the claimed “compound” as an undefined “*liquid composition*.”

Motif’s contention that term 21 has no patentable weight is also wrong. Term 21 has patentable weight because it provides structural and functional differences to the claimed product as compared to a product without term 21. The ’241 patent provides numerous examples of flavor precursors of various concentrations producing different and improved meat-like flavor and aroma profiles distinguishing the invention from the prior art. *E.g.*, ’241 patent, 20:7-35 (Example 1), 21:15-32 (Example 2). Thus, “a concentration of at least 1.5 mM” imparts structural and functional novelty to the claim. *Amgen Inc. v. F. Hoffmann-La Roche Ltd.*, 580 F.3d 1340, 1365-67 (Fed. Cir. 2009) (process had patentable weight when a compound purified from a different source than a prior art compound had a higher molecular weight and different chemical charge).

E. “food flavor additive composition”—Term 22

Motif’s proposed construction distorts the plain meaning of term 22 by improperly adding a use requirement (“added to a food product”) into a composition claim. Term 22 describes the composition of claim 1 of the ’096 patent, which comprises three recited components: (1) “an isolated heme containing protein” (2) “a compound selected from glucose...”; and (3) “a compound selected from cysteine...[.]” The claim further requires that the composition is a food flavor additive (*i.e.*, an additive that varies/adjusts the flavor and/or aroma of a food), that does not contain animal products, and when the composition is cooked, at least two volatile compounds that have a meat-associated aroma are produced. There is no language requiring that the claimed composition be “added to a food product” as required by Motif’s construction and there is nothing in the specification or the prosecution history supporting the addition of that method step. Accordingly, Motif’s construction should be rejected. *Bayer Pharma AG v. Watson Lab ’ys, Inc.*, No. 12-1726-LPS, 2014 WL 4954617, at *10 (D. Del. Sept. 30, 2014) (rejecting construction that added method limitation to product claim); *Union Oil Co. of Cal. v. Atl. Richfield Co.*, 208 F.3d 989, 995 (Fed. Cir. 2000) (rejecting claim construction that “would mutate [composition claims] into method claims.”).

F. Limitations specifying compounds—Terms 7-14

As with term 22, each of Motif’s constructions for terms 7-14 insert a requirement into the claims that the recited structural component be “added.” With respect to the ’761, ’096, and ’250 patents, these terms are in composition claims. Likewise, these terms are not found in the method steps of the claims of the ’306 patent—they are recited in the portion of the claims defining a composition (“meat replica matrix”). There is nothing in the specifications or the prosecution histories supporting the addition of a method step of “adding” to those claimed compositions. For that reason alone, Motif’s constructions should be rejected.

Motif's proposed constructions also incorrectly import "as a flavor precursor" into claims across all five patents. Terms 7-14 are readily understood as written and the intrinsic evidence does not support adding such a limitation:

- Terms 7 and 11 describe sugar and sulfur content of the muscle replica claimed in claim 1 of the '761 patent. The specification of the '761 patent does not contain the phrase "flavor precursor." The specification does describe sulfur and sugar content of the inventive muscle replica. *E.g.*, '761 patent, 26:23-43, 34:19-27. While the specification states that in some embodiments, flavor can be produced during cooking by chemical reactions involving, *inter alia*, sulfur compounds and sugars (*id.* at 36:28-33), it does not indicate that any sugar or sulfur content in the inventive meat replica must be a "flavor precursor."
- Terms 8 and 12 recite sugar and sulfur contained in the meat replica matrix claimed in the '250 and '306 patents. The shared specification of the '250 and '306 patents states that the content of the meat replica achieves the "look and feel" and aroma of meat, not just the flavor. '250 patent, 45:6-10. Like the '761 specification, the shared specification of the '250 and '306 patents discusses sugar and sulfur content of the inventive consumable products, and that discussion does not indicate that such content must be "added as a flavor precursor." '306 patent, 28:22-35, 30:66-31:15.
- Terms 9, 10, 13, and 14 recite ingredients in the meat-like food product of the '241 patent and the food flavor additive of the '096 patent. The shared specification of the '241 and '096 patents discusses that sugars and sulfur can be flavor precursors, but notes that they can be added "in purified form" or as part of

“ingredients in the uncooked consumable food product that contain” them. ’096 patent, 2:50-59.

Thus, sugar and sulfur content is not required, as Motif’s construction mandates, to be “added as a flavor precursor.”

G. “aroma”—Terms 23-25

The preamble of term 23, “[a] method for making a meat replica matrix having a beef-like aroma,” provides antecedent basis to the same terms in the body of the claims and sets out the relationship between the “meat replica matrix” and the step of generating volatile compounds “associated with a beef-like aroma.” *Eaton*, 323 F.3d at 1340 (preamble limiting where it described structures that “give[] meaning and purpose to the manipulative steps” of the body of the claim).

Motif’s contention that a POSA would not be reasonably certain of what a “beef-like aroma” and “meat associated aroma” are ignores the knowledge of a POSA and the teaching of the specifications and prosecution history. The shared specification of the ’241 and ’096 patents indicates that different types of meat have specific “[f]lavor and aroma profiles” that arise via “chemical reactions [with] the heme co-factor” that can be analyzed by gas chromatography-mass spectrometry (“GC-MS”). ’096 patent, 14:9-14; *see also id.*, Table 9. The shared specification of the ’250 and ’306 patents also provides the “specific volatile odorants that are elevated in beef compared to chicken when analyzed by GC-MS.” ’250 patent, 52:7-16.

Moreover, as evidenced by the prosecution history of the ’096 patent, meat- and beef-like aromas were known in the art. Ex. 10 (IF_0000052-1341, 292-296) (Holz-Schietinger Declaration describing twenty-eight volatile compounds “associated in the art, directly or indirectly, with a beef (or meat) aroma”); *id.* at 289 (“The Cadwallader Declaration and the Peterson Declaration confirm that the GC-MS experiments performed in the Holz-Schietinger

Declaration are art-recognized methods that support a correlation between the volatile compound profile produced in an aqueous thermal reaction sample and that produced in a food matrix[.]”).

H. “transcriptional activator”—Terms 18-20

The intrinsic evidence of the Yeast Patents contradicts Motif’s proposed construction and supports a plain and ordinary meaning for terms 18-20.

First, Motif’s constructions conflate two *different* molecular components: (1) a nucleic acid sequence encoding Mxr1 (terms 19 and 20), and (2) a nucleic acid sequence to which Mxr1 binds (term 18).¹ The language of ’492 patent claim 14 refers to both components, making clear that “a nucleic acid molecule encoding a Mxr1 transcriptional activator” and “a Mxr1 transcriptional activator sequence” are distinct elements. Alper, ¶¶ 52–56. Because Motif proposes the same construction for these distinct limitations, Motif duplicates the former limitation while erasing the latter. *Id.*, ¶¶ 55–56.

Second, Motif’s insertion of “native” introduces a limitation that has no support in the intrinsic evidence. Notably, ’656 patent claim 1 recites “[a] methylotrophic yeast cell” that is not restricted to any particular genus or species for either the cell or the transcriptional activator. *Id.*, ¶ 58. Likewise, ’656 patent claim 26—which recites a “*Pichia* yeast cell” and “a nucleic acid encoding a Mxr1 transcriptional activator sequence from *P. pastoris*”—does not require that the transcriptional activator sequence be native. *Id.*, ¶ 59. While the claim requires that the activator sequence is from *P. pastoris*, it does **not** require that the yeast cell is *P. pastoris*; it could be a different *Pichia* species. Such a combination would mean that the transcriptional activator sequence is distinctly **not native**. The Yeast Patent specifications are clear on this point:

¹ With respect to ’656 patent claim 26, although Motif identified the term separately for construction, term 18 is an excerpted portion of term 20.

Similar to the exogenous nucleic acid encoding the transcriptional activator, a heterologous nucleic acid refers to any nucleic acid sequence that is ***not native*** to the genome or in the genome of an organism (e.g., a heterologous nucleic acid can be a nucleic acid from one microorganism (e.g., one genus or species of methylotrophic yeast) that is introduced into ***a different genus or species*** of methylotrophic yeast).

'656 patent, 5:31-37; *see also* Alper, ¶¶ 57–62.

I. “promoter element”—Term 26

Motif’s contention that a POSA would not know whether “‘promoter element’ contains an entire endogenous promoter or merely some portion thereof” (Ex. 4 at 87) is wrong for several reasons.

First, the promoter element of the claims is not limited to “endogenous” but may be either endogenous or exogenous. Alper, ¶ 64. Second, the specification provides multiple examples and explanations that make clear to a POSA that “promoter element” can be an entire promoter sequence or a functional part thereof. For example, the specification defines a promoter as a type of expression element: “One example of an ***expression element*** is a promoter sequence.” ’656 patent, 10:1-2. The specification states that “[e]xpression elements include ***nucleic acid sequences that direct and regulate expression*** of nucleic acid coding sequences.” *Id.* at 9:66-10:1. The specification explains that a promoter is a type of “expression element” with a particular position and function:

[A] promoter or other expression element(s) [is] ***positioned*** relative to a nucleic acid coding sequence in such a way as ***to direct or regulate expression***[.]

Id. at 4:47-50. Thus, the specification teaches, and a POSA would understand, that “promoter element” unambiguously refers to a nucleic acid sequence that directs or regulates transcription of downstream genes—and that sequence can be an entire promoter or some functional portion thereof. Alper, ¶¶ 63–68. The claim language reinforces this meaning where the words

“methanol-inducible” or “constitutive” precede “promoter element,” referencing a mechanism by which the promoter element may regulate expression. *E.g.*, ’656 patent, cl. 1; Alper, ¶¶ 35, 65–66.

Third, the specification repeatedly states that the invention encompasses both an entire promoter or a portion thereof that directs or regulates expression. *E.g.*, ’656 patent, 4:54-55 (a “promoter, or a promoter element therefrom, can be used”); 4:56-60 (“[A] commonly used... promoter from *P. pastoris* is the promoter, or a portion thereof, from the [AOX1] gene[.]”); 6:33-34 (“a constitutive promoter or constitutive promoter element”); 6:38-39 (“the promoter, or a portion thereof”); 6:41-42 (“promoters, or promoter elements therefrom”); 6:59 (same); 7:5-6 (same). For avoidance of *all* doubt, the specification provides the codes associated with representative promoter element sequences that are publicly available in the GenBank database. ’656 patent, 4:60-5:11; *id.* at 6:37-51.²

For these reasons, the intrinsic evidence is consistent with the plain and ordinary meaning of a “promoter element.” Alper, ¶¶ 63–67.

Moreover, Motif’s IPR petitions belie its present position that “promoter element” is indefinite. Motif (along with its experts) had a sufficient understanding of “promoter element” to argue that prior art references taught this limitation. Ex. 11 at 28; *id.* at 33 (“Tsutsumi discloses co-expressing Mxr1 in the same cells under the control of a *promoter element*.”).

² Motif’s contentions contain two “non-limiting examples” of alleged lack of clarity in the claim language (Ex. 4 at 87–88). However, those examples reflect Motif’s misunderstanding of terms 18-20, as explained above, not indefiniteness.

WILSON SONSINI GOODRICH & ROSATI, P.C.

/s/ Jennifer A. Ward

Ian R. Liston (#5507)

Jennifer A. Ward (#6476)

222 Delaware Avenue, Suite 800

Wilmington, DE 19801

(302) 304-7600

iliston@wsgr.com

jward@wsgr.com

Counsel for Plaintiff Impossible Foods Inc.

OF COUNSEL:

Wendy L. Devine

Kristina Hanson

Jessica Ramsey

Susannah M. L. Gagnon

WILSON SONSINI GOODRICH & ROSATI, P.C.

One Market Plaza

Spear Tower, Suite 3300

San Francisco, CA 94105

(415) 947-2000

Matthew R. Reed

WILSON SONSINI GOODRICH & ROSATI, P.C.

650 Page Mill Road

Palo Alto, CA 94304

(650) 493-9300

Lorelei P. Westin

WILSON SONSINI GOODRICH & ROSATI, P.C.

12235 El Camino Real

San Diego, CA 92130

(858) 350-2300

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CERTIFICATE OF COMPLIANCE

I certify that this document complies with Paragraph 13 of Court's Scheduling Order (D.I. 37) because it contains 4,601 words as determined by the word count feature of Microsoft Word (excluding the caption, tables, and signature blocks).

/s/ Jennifer A. Ward

Jennifer A. Ward (#6476)