

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

IMPOSSIBLE FOODS INC.,

Plaintiff,

v.

MOTIF FOODWORKS, INC.,

Defendant.

C.A. No. 22-311 (WCB)

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

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Dated: July 7, 2023

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TABLE OF ABBREVIATIONS

Abbreviation	Phrase
Impossible	Impossible Foods Inc.
Motif	Motif FoodWorks, Inc.
'096 patent	Patent No. 9,943,096
'241 patent	Patent No. 11,224,241
'761 patent	Patent No. 10,863,761
'306 patent	Patent No. 10,039,306
'250 patent	Patent No. 11,013,250
Food Product Patents	'241 patent, '761 patent, '306 patent, '250 patent, and '096 patent, collectively
'492 patent	Patent No. 10,273,492
'656 patent	Patent No. 10,689,656
Yeast Patents	'492 and '656 patents, collectively
FFAC	food flavor additive composition
Alper	Declaration of Hal Alper, PhD (D.I. 107)
Alper Reply	Reply Declaration of Hal Alper, PhD, filed concurrently herewith
Batt	Declaration of Dr. Batt (D.I. 123)
Legako	Declaration of Dr. Legako (D.I. 122)
McGorrin	Declaration of Dr. McGorrin (D.I. 121)
Sarnoski	Declaration of Paul Sarnoski, PhD, filed concurrently herewith
Ex.	Exhibits attached to Impossible's Reply Brief.
Term	Numbered list of terms in Section II of the Joint Claim Construction Statement (D.I. 94-1).

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

I. INTRODUCTION

Motif's claim construction arguments disregard the intrinsic record, including the language of the claims, and are at odds with black letter law and Motif's own public statements.

Impossible respectfully requests that the Court adopt the plain and ordinary meaning of the disputed terms.

II. ARGUMENT

The parties' proposed constructions are set forth in Exhibit 1 to Impossible's Opening Brief. D.I. 106.

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

Impossible's construction reflects the plain and ordinary meaning of these terms. The specifications of the Food Product Patents and Motif's own statements make that clear—in the context of plant-based meat substitute food products, "animal" and "non-animal" indicate where synthesis occurred and from which the product, *e.g.*, protein, was derived. Sarnoski, ¶¶79-90.

Even the concern regarding allergic reactions that Motif focuses on supports Impossible's construction. Motif's GRAS notice discusses allergenicity due to "the presence of galactose- α -1,3-galactose," a carbohydrate, linked to "meat proteins" from "mammalian meat or innards." Ex. 12, MOTIF00008035. Motif told FDA that its "myoglobin is not glycosylated," because the protein is derived from "a taxonomically distant species[,] *P. pastoris*" that "would not produce endogenous [α -galactose]." *Id.*; Ex. 13 (α -Gal allergy is an allergy to red meat).¹ Thus, while a protein produced in transgenic yeast may have the amino acid sequence of a protein naturally found in cattle (like Motif's), that protein's characteristics change (*i.e.*, no longer implicating red

¹ That Motif made these statements after the priority date is of no moment as the ordinary meaning did not change between the priority date and Motif's statements.

meat allergy) *because* it is produced in that non-animal yeast, and is correctly described as “non-animal,” “vegan,” and “plant-based.” Sarnoski, ¶86. Motif’s citation to a generic dictionary definition of “animal” does not alter this plain and ordinary meaning. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1321 (Fed. Cir. 2005) (“The main problem with elevating the dictionary to such prominence is that it focuses the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent.”).

Thus, the characteristics of the protein/product are impacted by the place where it is generated. Motif’s insistence that this can only be captured with method-of-production claims is not supported by the law or intrinsic evidence. The Food Product Patents discuss compositions, characterizing them according to the source from which they are derived; that invention may be, and is, reflected in composition claims. Motif’s insistence that such characteristics be claimed as manufacturing methods and described as “essential” and “preferred” versions of such methods has no support in fact or law.

Motif’s misunderstanding of the plain and ordinary meaning of these terms is compounded by its incorrect understanding of myoglobin. Myoglobin is not, as Motif claims, “intrinsically” an animal protein. The Food Product Patents and the literature discuss non-animal myoglobin. *E.g.*, ’761 patent, 3:10-15 (“ciliate myoglobins”); Ex. 14, IF_0014526 (“Myoglobin (Mb) is a heme-containing globular protein that is found in abundance in myocyte cells of heart and skeletal muscle. Mb and Mb-like proteins are also found in many taxa, including bacteria, plants, fungi, and animals.”). Additionally, the ’306 patent specifically identifies protein from “a genetically modified yeast” as a “non-animal source.” ’306 patent, 28:38-41.

Motif’s tortured interpretation of the prosecution history ignores the evidence cited by its own expert. Dr. Batt cites to the prosecution of the ’211 Application, a predecessor to the Food

Products Patents. Dr. Batt states that Impossible has “expressly defined certain claims in terms of proteins’ source.” D.I. 123, ¶61. Each of the claims refer to the “isolated and purified protein,” which is defined in the specification as reducing “protein components other than the specified protein . . . relative to the source material.” Ex. 15, IF_0014564-565. These claims refer to where the protein was “derived from,” not where the amino acid sequence of the protein is naturally found. Following this line of claims cited by Dr. Batt, claim 17 (depending from claims 16 and 13) states that a protein isolated from a genetically modified yeast organism (such as *P. pastoris*) is “not isolated from an animal.” D.I. 123, ¶61. Claims 167 and 168 are likewise supportive of Impossible’s reading: “the *protein content is derived from* a non-animal source,” which includes “a genetically modified yeast.” *Id.* Therefore, Impossible’s construction is consistent with the language in the specification and the prosecution history. D.I. 106, 3-4; Sarnoski, ¶¶83, 88-90.

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

Motif’s misunderstanding of myoglobin (and other heme proteins) infects its analysis of the prosecution history. The notice of allowance for the ’306 patent reflects a conclusion by the examiner that the prior art did not disclose the claimed method of imparting organoleptic properties of meat to a meat replica by, *inter alia*, including heme derived from a non-animal source. D.I. 120-1, Ex. 6, 6-7. Consistent with that, the independent claims were amended to reflect that the heme is “non-animal.” *Id.* Motif’s conclusion that deletion of some of the heme-containing proteins in the dependent claims somehow indicates those are “animal” proteins is unsupported. Indeed, some of the proteins that were deleted are naturally found in both plants and animals (*e.g.*, myoglobin, peroxidase), and some of the proteins that were *not* deleted are found in both animals and plants (*e.g.*, hemoglobin). *Id.*, 3-6. Thus, there is no reason for the amendments to the dependent claims (that are not even at issue here) to be reasonably tied to

Motif's incorrect claim construction. *Phillips*, 415 F.3d at 1317 (“[B]ecause the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes.”); *HTC Corp. v. IPCom GmbH & Co., KG*, 667 F.3d 1270, 1276 (Fed. Cir. 2012) (reversing summary judgment of invalidity where “district court placed too much weight” on prosecution history, stating “[c]laim language and the specification generally carry greater weight than the prosecution history”).

Likewise, the deletion of original claim 10 in Application No. 14/797,006 does not support Motif's construction or arguments. D.I. 120-1, Ex. 10, 4. Claim 10 depended from claim 1. As originally written, claim 1 broadly recited “heme-containing protein” and claim 10 recited specific examples of such proteins. In the amendments cited by Motif, the scope of the heme-containing protein in claim 1 was narrowed specifically to SEQ ID NO:4, which is “a leghemoglobin such as that from *Glycine max.*” *Id.*, 3. Therefore, claim 10 was no longer necessary.

Motif's reliance on claim amendments during the prosecution of the '096 patent also does not support Motif's construction. There, prior to amendment, claim 36 claimed “a mammalian” “heme-containing protein” and depended from claim 31 required that the FFAC contain “no animal tissue derived components.” D.I. 120-1, Ex. 11, 7-8. This claim language shows that a “mammalian heme-containing protein” can be a protein that is not “derived from animal tissue,” (*i.e.* from a genetically modified yeast cell) which is consistent with Impossible's construction. *Id.*, 8. Notably, claim 33 was **not** amended and includes “myoglobin,” again showing that, consistent with Impossible's construction, myoglobin not produced by an animal “contains no animal products.” *Id.*, 7.

C. “replica”—Terms 15-17

There is no contradiction between Impossible’s construction and its response to Motif’s unsuccessful IPR petition. Impossible did not argue in the IPR that the physical organization of meat must be non-homogenous. Rather, Impossible correctly argued that the claims of the ’761 patent have separate *limitations* requiring a muscle replica and a fat replica, and Motif’s IPR petition failed to identify those limitations in the prior art, which disclosed (A) soy protein material, and (B) humectant. Impossible argued that Motif “provide[d] numerous possible ‘muscle replicas’ and ‘fat tissue replicas’ throughout the petition, both of which include components from the soy protein material (A) and the humectant (B) of [prior art].” D.I. 120-1, Ex. 12, 32. Motif’s failed IPR petition improperly disassembled the disclosure of the prior art and re-assembled it into the claims using hindsight—that is not a disclaimer of the homogenous meat substitutes disclosed in the ’761 patent nor does it inject a “separate” limitation into the ordinary meaning of the physical organization of meat.

Moreover, the PTAB’s construction of replica to mean a *replica*—not the thing that is being replicated—is correct. First, there is written description support for the plain reality that a muscle *replica* is not muscle and a fat tissue *replica* is not fat tissue. That support, as the PTAB recognized, is in the word *replica*. Sarnoski, ¶¶93-95. Second, the statement in the specification that such replicas can contain material derived from animal sources does not change the claimed muscle/fat replicas into the things they are replicating. D.I. 106, 7; Sarnoski, ¶¶97-98. Motif’s discussion of inclusion of actual meat in “meat substitutes” is irrelevant because the claims specify muscle and fat tissue *replicas* not “a meat substitute.” Third, that claims in a different patent (the ’306 patent) were not drafted identically to those of the ’761 patent also does not change the plain meaning of “replica.” Notably, during prosecution of the ’306 patent, neither the examiner nor the applicant stated that a “replica” is the same as what it replicates.

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

Motif’s argument that term 21 lacks patentable weight because it represents the concentration of a solute *added* to the product, and not the molar concentration in the assembled product, ignores the teachings of the specification. For example, the specification’s examples discuss the mM of compounds “contained” in food products, not added. *E.g.*, ’241 patent, 20:7-10 (“Replica burgers *containing*... cysteine (10mM), glutamic acid (10 mM)...”). This is consistent with the other amounts in the example being expressed in terms of percent precooked weight ingredient per weight total. *Id.*, 20:36-53. The applicant expressed the amount of the compounds and the ingredients in the assembled product as a *concentration*. Sarnoski, ¶116.

A POSA would understand the concentration of the sulfur containing compounds *in the assembled product* is relevant to achieve the aroma profile required by the claims. Sarnoski, ¶118. Moreover, the prosecution history is not silent regarding the concentration of compounds in the prior art. D.I. 120, 15. The applicant submitted a declaration from Dr. Davis examining the concentration of the sulfur compounds in a prior art corn flour tortilla cited by the Examiner. Ex. 16, ¶27; Sarnoski, ¶117. The Davis declaration reflects an understanding that “at least 1.5mM” of the sulfur compounds is measured in the assembled product.

E. “food flavor additive composition”—Term 22

Motif’s effort to change this composition claim into a method or product-by-process claim is not a mere issue of grammar. The claims of the ’096 patent are composition claims that do not require any step of “addition.” D.I. 106, 11. Both Motif’s original construction “composition *added* to a food product” and Motif’s new construction “composition that... when *added* to the food product” alter the plain meaning of the term.

Motif’s incorrect reading of the ’096 composition claims as method claims is evidenced by its arguments. For example, Motif contends there is some temporal requirement for when the

FFAC becomes a FFAC—the time when only the three recited components are present and the (non-existent) method step of “adding” the FFAC to some other food has not happened yet. D.I. 120, 17. That interpretation wrongly transforms “comprising” in the ’096 claims to “consisting of” and imports a temporal limitation not found in the claims. *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1345 (Fed. Cir. 2008) (reversing construction that required reduction in “reduced air content cleaning fabric” occurring before fabric was wound, but “winding [wa]s not even explicitly recited in either claim”).

The case law that Motif cites does not support either of its erroneous constructions. D.I. 120, 16-17 (citing *INVISTA N. Am. S.a.r.l. v. M&G USA Corp.*, 951 F. Supp. 2d 604 (D. Del. 2013)² and *Wilson Sporting Goods Co. v. Hillerich & Bradsby Co.*, 442 F.3d 1322 (Fed. Cir. 2006)). *INVISTA* involved construction of “composition” in patents that “repeatedly and only refer[ed] to the claimed composition as a ‘blend.’” 951 F. Supp. 2d at 612. Here, the ’096 patent does not discuss a “blend.” In *Wilson*, the Federal Circuit noted the summary judgment record contained no information about the accused products, thus the appeal “assume[d] many attributes of a proceeding seeking an advisory opinion on [patent scope].” 442 F.3d at 1327. There is no such concern here and Motif’s products are not relevant. *NeoMagic Corp. v. Trident Microsys., Inc.*, 287 F.3d 1062, 1074 (Fed. Cir. 2002) (“It is well settled that claims may not be construed by reference to the accused device.”).

F. Limitations specifying compounds—Terms 7-14

Motif’s construction commits “one of the cardinal sins of patent law—reading a limitation from the written description into the claims.” *Phillips*, 415 F.3d at 1320. Each of

² Motif’s brief erroneously identifies this as a Federal Circuit opinion.

these terms has a clear meaning on its face. Sarnoski, ¶121. Motif’s importation of limitations requiring that these compounds are isolated and added, and that they are added for a *particular purpose*, is improper—particularly as the term “flavor precursor” does not appear anywhere in the ’761 patent.

As with term 22, Motif’s proposed constructions for terms 7-14 insert a requirement that the recited structural component be “added” separately from other ingredients. D.I. 120, 18-19. This ignores the specification of the ’241 and ’096 patents indicating the “[f]lavor precursor molecules . . . *can be derived from ingredients* in the uncooked consumable food product.” ’241 patent, 2:55-64. Furthermore, none of the examples in the ’761 patent recite added sulfur compounds beyond what is included in the plant-based ingredients. Example 16 in the ’306 and ’250 patents likewise does not contemplate isolated sugar or sulfur compounds. ’306 patent, 71:47-73:58. Example 33 of the ’306 and ’250 patents compares three replicas—one without any isolated sugar or sulfur compounds added—to 80:20 ground beef. ’306 patent, 84:15-18. While the additional compounds tended to “beef up” the replicas, the replica without the added compounds was comparable in “flavor quality” and other aspects to the other replicas. Sarnoski, ¶125.

Likewise, during prosecution the Examiner based rejections on the inclusion of sugar and sulfur molecules *contained in a beef source* in the prior art. Ex. 17, IF_0013047. In response, Impossible never argued that these references were inapplicable because the claims required the compounds be separately “added.” Ex. 18. Additionally, in the ’241 patent prosecution, Impossible submitted a declaration reflecting investigation of the amount of sulfur compounds in the corn flour *ingredient* of the Proulx reference and concluded the assembled product contained less than the at least 1.5 mM sulfur compounds required by the claims. Ex. 16, ¶¶5, 9, 27.

Motif misinterprets the '306 patent prosecution history. D.I. 120, 20. There, Impossible overcame a rejection of a claim reciting “at least one sulfur compound” by adding the limitation to the claims to recite *specific* compounds. Ex. 19, IF_0003494-495.

The terms have a plain meaning to a POSA and there is no support for adding a limitation regarding use as a “flavor precursor.” Sarnoski, ¶¶119-131.

G. “aroma”—Terms 23-25

Motif’s arguments regarding terms 23-25 ignore the intrinsic evidence, selectively cite the extrinsic evidence, and are inconsistent with the understanding of a POSA. Sarnoski, ¶¶132-148.

The intrinsic evidence and the literature in the field reflect that the descriptors “beef-*like*” and “meat-*associated*” convey that the product is not animal-based. *Id.*, ¶¶135-136, 144. The prosecution history supplements that straightforward notion with multiple declarations that provide information regarding the compounds that are responsible for a “meaty”/“beefy” aroma. *Id.*, ¶¶139-140; Ex. 20; Ex. 21, ¶14. Additionally, references, including those cited in declarations submitted in the prosecution history and as cited by Motif, discuss compounds that contribute to a “beef-like” or “meat-associated” aroma. Sarnoski, ¶¶139-144.³

Even the extrinsic evidence that Motif relies on—an EU Opposition decision regarding a patent that is not at issue here and applying a legal standard not applicable here—does not support Motif’s argument. In a portion that Motif chose not to discuss, that decision reads:

it has *not been convincingly demonstrated* by the Opponent *that taste and smell of a meat substitute are a subjective perception* only and cannot be assessed with sufficient accuracy by the skilled person working in the field of food science and technology without undue burden. The use of both trained taste panels and/or of high-sensitivity chemical analysis tools, such as GC-MS, was well known to the

³ The case law cited by Motif is inapposite given these facts.

skilled person working in the field of food technology at the effective date of the opposed patent and is furthermore explained in detail in the working examples of the opposed patent itself.

D.I. 120-1, Ex. 23, 10. Thus, Motif’s recycled argument has already failed in its EU Opposition, and it fails here as well. In fact, “beefy” and “meaty” smells are well studied and particular compounds that are associated with these aromas/flavors are well documented, including by Motif’s expert. Sarnoski, ¶¶139-144; Ex. 22.

H. “transcriptional activator”—Terms 18-20

To defend its incorrect constructions, Motif is forced to lump together three *different* claim phrases and treat them as identical. They are not identical, and the differences among them are meaningful, revealing that Motif’s constructions cannot be adopted.

First, terms 19-20 contain the phrase “nucleic acid *encoding*” while term 18 does not. That difference reflects that the terms cover two different molecular components: an Mxr1 transcriptional activator sequence (*i.e.*, a “motif” or “consensus” sequence) to which Mxr1 binds (term 18) and a sequence *encoding* Mxr1 (terms 19-20).

Motif’s argument that the phrase “binding site” is required for term 18 to encompass a binding site is not supported. The Yeast Patents describe enhancing exogenous polypeptide expression via an interaction between Mxr1 and an Mxr1 transcriptional activator sequence. Alper, ¶¶29, 56; Alper Reply, ¶¶6-10. A POSA would understand that term 18 requires an Mxr1 “binding site” without needing to see those particular words. Making this clear, Motif acknowledges that “[t]he specification [] repeatedly describes a Mxr1 nucleic acid sequence that *encodes* Mxr1—not a binding site.” D.I. 120, 25. This is consistent with terms 19-20, which include the word “*encoding*.” In contrast, term 18 does not refer to a nucleic acid sequence that *encodes* Mxr1.

Motif’s construction also renders a dependent claim limitation duplicative. Alper, ¶¶54–

56. Motif’s expert makes the conclusory statement that claim 14 could “refer[] to an embodiment in which more than one Mxr1 transcriptional activator is encoded . . . one native to *P. pastoris* and another that may be of a different origin. Batt, ¶134; D.I. 120, 25. Yet Motif and its expert offer ***no support*** for this hypothesis and no explanation for the resultant incongruity between the ’492 and ’656 patents. Alper Reply, ¶¶6-8.

Second, terms 18 and 20 contain the phrase “from *P. pastoris*” while term 19 does not. Motif offers no justification for ignoring this difference in claim language. Rather, apparently in an effort to exclude any variation or mutant of wild-type *P. pastoris* Mxr1 from the claims, Motif advocates for a contorted analysis including:

- Inserting “from *P. pastoris*” into term 19
- Changing “from *P. pastoris*” in all terms to “endogenous”
- Defining “endogenous” as “native” and concluding that “native” means “wildtype” and excludes any mutant or variant

There is no support for any of these distortions in the intrinsic record.

Motif’s insertion of “native” in place of “from” distorts the claims. Whether an Mxr1 nucleic acid sequence is “native” or “non-native” depends on the genus and species of the host organism and the relevant exogenous nucleic acid. Alper Reply, §III.A.2. Adding the term “native” introduces restrictions that go beyond the claims and specification, which plainly do not require terms 18-20 to be sequences with the same genus and species (*i.e.*, “native” sequences) to the recited yeast cell hosts. *E.g.*, ’656 patent, cls. 1, 26 (referring to exogenous nucleic acid sequences, which may or may not be native to the host cell); 4:5-9; 5:31-37; *see also* Alper, ¶¶58–61; Alper Reply, §III.A.2.

Further, as Motif acknowledges, the Yeast Patents teach variants and mutations resulting from genetic engineering—specifically, nucleotide additions, deletions, or substitutions—of

Mxr1, and do not limit the scope of the invention to wild-type Mxr1. A Mxr1 transcriptional activator “from *P. pastoris*” includes both the wild-type and such variants and mutants. *E.g.*, ’656 patent, Example 15; *see also* Alper Reply, ¶14. Certainly term 19, which does not even contain the “from *P. pastoris*” limitation, encompasses such variants and mutants.

Motif’s contention that the words “variant” or “mutant” must be in the claims to encompass Mxr1 variants and mutants is also wrong. The only words that terms 18 and 20 contain are “from *P. pastoris*”—none of terms 18-20 recite “native,” “wildtype,” “variant,” or “mutant” because all of those embodiments are sufficiently conveyed by the plain language of the claims in the context of the specification.

I. “promoter element”—Term 26⁴

The Yeast Patents provide a POSA with reasonable certainty regarding the meaning of “promoter element” and what “quantum” of a promoter constitutes a “promoter element.” D.I. 106, 15-16; Alper, ¶¶63-67; Alper Reply, §III.B. Motif fails to identify clear and convincing evidence to the contrary, instead resorting to mischaracterizing a POSA as lacking even basic background knowledge, citation to layperson dictionary definitions, and insisting an express definition is somehow required.

1. Motif admitted that “promoter element” has a readily understood plain and ordinary meaning

Motif’s entire argument is based on the declaration of Dr. Batt, who just a few months ago declared that “promoter element” (and every other claim term in the Yeast Patents) has a plain and ordinary meaning to a POSA. Ex. 23, ¶53. Yet, as Dr. Batt recognized in his prior declaration, the Yeast Patents’ shared specification consistently and repeatedly states that the

⁴ Motif’s brief contains no argument supporting Motif’s contention that a “promoter element” must be “endogenous.” D.I. 106-1, Ex. 4, 87.

invention encompasses both an entire promoter or a portion thereof, *i.e.*, a promoter element, that directs or regulates expression. D.I. 106, 15-16; '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[.]”), 6:41-42 (“promoters, or promoter elements therefrom”), 6:59 (same), 7:5-6 (same); *see also* Alper Reply, ¶¶19-23.

2. Motif ignores the context of the intrinsic record

Motif attempts to manufacture confusion about “promoter element” by divorcing it from the context of the claims and the specification. In the parlance of the Yeast Patents, a “promoter element” is a promoter (which is a type of expression element) or portion thereof that can direct or regulate expression of the nucleic acid to which it is “operably linked.” “Expression element” and “operably linked” provide meaningful context for a POSA’s understanding of “promoter element.” *Phillips*, 415 F.3d at 1314 (“[T]he context of the surrounding words of the claim also must be considered in determining the ordinary and customary meaning of those terms.”). Motif’s demand that these claim terms, and their meanings, be ignored in analyzing “promoter element” finds no support in the law. *Id.* at 1314-15 (“[T]he claims themselves provide **substantial** guidance as to the meaning of particular claim terms” and “claims must be read in view of the specification.”); *3M Innovative Props. Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1374 n.5 (Fed. Cir. 2003) (“The only interpretation under which the definition of embossed provided in the specification is nonsensical is [patent challenger]’s.”).

Likewise, Motif’s contention that “promoter” and “promoter element” must be distinct also ignores the context found in the specification and the claims. As Dr. Alper explained, a POSA understands that a promoter includes various sequences (elements) that allow for the promoter to function as a promoter, *i.e.*, promoting expression of a downstream gene. Alper, ¶29; *see also* Alper Reply, ¶¶20-23. Thus, it is those elements of the promoter that are

meaningful in the context of the claims of the Yeast Patents, which encompass a recombinant organism designed for expression of a particular gene encoding a protein. The claims do not exclude the presence of the full promoter—but all that they require is that the promoter element is present.

Motif and Dr. Batt acknowledged this fundamental relationship between “promoter” and “promoter element” in support of Motif’s IPR petitions. In his IPR declarations, Dr. Batt states “[the Yeast Patents] refer[] to/disclose[] several *promoter elements* that can be constructed into the claimed expression system. For example, the [Yeast Patents] provide[]/disclose[] that the AOX1 promoter can be used to direct gene expression in methylotrophic *P. pastoris*.” Ex. 23, ¶44; Ex. 24, ¶41. Likewise, in its IPR petitions, Motif stated “a [POSA] would recognize that the *PEX8* promoter-driven expression of Mxr1 taught in [reference] reflects the methanol-inducible expression of Mxr1 by a *promoter element* (*PEX8*) to which Mxr1 itself binds.” Ex. 25, IF_0014168.

Motif’s complaint that, without testing, a POSA would not know what “quantum” of a promoter would direct or regulate expression does not evidence indefiniteness. D.I. 120, 26; Batt, §XI.A. “Definiteness does not require that a potential infringer be able to determine *ex ante* if a particular act infringes the claims.” *Nevro Corp. v. Bos. Sci. Corp.*, 955 F.3d 35, 40 (Fed. Cir. 2020). There is no dispute here that a POSA “would be able to quickly determine whether” a given sequence in a yeast cell functions to direct or regulate expression of a downstream gene. *Id*; Batt, ¶136, n.2 (“[I]t is also possible to identify ‘elements’ of a promoter with some role in the promoter’s activity.”); Ex. 23, ¶¶138, 149; Alper Reply, ¶¶30–31. Further, Motif’s assertion that there is no structure for “promoter element” plainly contradicts the claim language, *e.g.*, “wherein the methanol-inducible promoter element comprises at least one

sequence to which a Mxr1[] transcriptional activator binds.” ’656 patent, cl. 26. Thus, “promoter element” is not indefinite.

The case law cited by Motif is inapposite. D.I. 120, 25 (citing *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015)). In *Teva*, the claims at issue required a specific molecular weight, and the parties agreed that weight could be measured in several ways “that would typically yield a different result.” *Id.* There are no such facts here. The Yeast Patent claims require only that the claimed organism contain a “promoter element”—the claims do not require that the promoter element drive a specific amount of expression.

3. The Yeast Patent claims are not means-plus-function claims

Motif’s contention that “[i]f ‘promoter element’ were defined purely by function, however, it should be treated as a means-plus-function term” is also wrong. D.I. 120, 27. “The mere fact that the disputed limitations incorporate functional language does not automatically convert the words into means for performing such functions.” *Zeroclick, LLC v. Apple Inc.*, 891 F.3d 1003, 1008 (Fed. Cir. 2018). The Yeast Patent claims do not contain the word “means,” thus, to apply a means-plus-function analysis, Motif has the burden of demonstrating that “promoter element” fails to recite sufficiently definite structure. *Id.* Motif has not met that burden.

Motif does not even attempt to argue that “promoter element” lacks definite structure, instead focusing on the term’s functionality and breadth. Yet, “breadth is not indefiniteness.” *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365-68 (Fed. Cir. 2017). Even where a claim term “is defined in terms of its function” and “does not connote a precise physical structure in the minds of those of skill in the art” it has sufficiently definite structure if the patent “convey[s] to one knowledgeable in the art a variety of structures” embodying the claim term. *Personalized Media Commc’ns, LLC v. ITC*, 161 F.3d 696, 705 (Fed. Cir. 1998). As Motif’s

expert, Dr. Batt stated, the Yeast Patents meet that standard because they refer to “several *promoter elements* that can be constructed into the claimed expression system.” Ex. 23, ¶44; Ex. 24, ¶41.

Motif cites case law that fails to support its argument. In *Zeroclick*, the Federal Circuit reversed a district court finding that claims related to a graphical user interface were means-plus-function claims. 891 F.3d at 1007. The district court’s error implicates the same error in Motif’s argument: “remov[ing] the [claim] terms from their context, which otherwise strongly suggests the plain and ordinary meaning of the terms.” *Id.* at 1008. In context, a POSA “could reasonably discern” the plain and ordinary meaning of the claim terms via conventions in the art at the relevant time. *Id.* Further, the court noted that “the distinction drawn between the graphical user interfaces in the prior art and the improvement to such interfaces in the claimed invention . . . bolster[ed] that conclusion.” *Id.* As in *Zeroclick*, the Yeast Patents draw a distinction between the invention and the prior art, which “fail[ed] to disclose or suggest a methylotrophic yeast cell comprising a [Mxr1] transcriptional activator” and “a methanol-inducible *promoter element* to which the Mxr1 transcriptional activator binds.” D.I. 107-2, Ex. E, IF_0007678. Thus, the file history, together with the specification and claims, demonstrate that the term “promoter element” cannot be a “black box recitation[] of structure” bereft of “additional clarification regarding the structure of the term.” *Zeroclick*, 891 F.3d at 1008; *see also* Alper Reply, §III.B. A POSA would understand the meaning of “promoter element” in the context of the Yeast Patents.

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Dated: July 7, 2023

CERTIFICATE OF COMPLIANCE

I certify that this document complies with Paragraph 13 of Court's Scheduling Order (D.I. 37) because it contains 4,899 words as determined by the word count feature of Microsoft Word (excluding the caption, tables, and signature blocks).

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CERTIFICATE OF SERVICE

I hereby certify that on the 7th day of July 2023, I caused the foregoing document to be served by electronic mail upon the following counsel:

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