IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HUVEPHARMA EOOD and HUVEPHARMA, INC., Plaintiff, v. ASSOCIATED BRITISH FOODS, PLC, AB VISTA, INC., PGP INTERNATIONAL CORPORATION, ABITEX CORPORATION, AB ENZYMES, INC., and AB ENZYMES GMBH, Defendants.	Civil Action No. 18-129-RGA
HUVEPHARMA EOOD and HUVEPHARMA, INC., Plaintiffs, v. E.I. DUPONT DE NEMOURS AND COMPANY, DUPONT INDUSTRIAL BIOSCIENCES, USA LLC, DANISCO USA INC., and DANISCO US INC., Defendants.	Civil Action No. 18-914-RGA

MEMORANDUM OPINION

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ANDREWS, U.S. DISTRICT JUDGE:

Presently before the Court is the issue of claim construction of multiple terms in U.S. Patent Nos. 6,451,572 ("the '572 patent"), 7,026,150 ("the '150 patent"), 7,312,063 ("the '063 patent), 7,829,318 ("the '318 patent"), 8,455,232 ("the '232 patent"), and 8,993,300 ("the '300 patent"). The Court has considered the Parties' Joint Claim Construction Briefs. (C.A. No. 18-129, D.I. 62; C.A. No. 18-914, D.I. 65).[1] At the parties' request, the Markman hearings in these actions were combined. (D.I. 55). The Court heard oral argument on June 6, 2019. (Hr'g Tr.).

I. LEGAL STANDARD

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). "'[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324) (alteration in original). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977–80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (internal quotation marks omitted).

"[T]he words of a claim are generally given their ordinary and customary meaning. . . . [Which is] the meaning that the term would have to a person of ordinary skill in the art in question

[1] Unless otherwise stated, all docket item references in this opinion will refer to Civil Action No. 18-129.

at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312–13 (citations and internal quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314.

When a court relies solely upon the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court's construction is a determination of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The court may also make factual findings based upon consideration of extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317–19 (internal quotation marks omitted). Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

"A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GMBH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (citation and internal quotation marks omitted).

II. BACKGROUND

Plaintiffs Huvepharma EOOD and Huvepharma, Inc. brought suit against Defendants Associated British Foods, PLC, AB Vista, Inc., PGP International Corporation, ABITEC Corporation, AB Enzymes, INC., and AB ENZYMES GmbH ("the ABF Defendants") on January 23, 2018 asserting infringement of the '572 patent, the '150 patent, the '063 patent, the '318 patent, the '232 patent, and the '300 patent ("the Asserted Patents"). (D.I. 1). Plaintiffs brought suit against Defendants E.I. Du Pont de Nemours and Company, DuPont Industrial Biosciences USA, LLC, Danisco USA, Inc., and Danisco US Inc. ("the DuPont Defendants") on June 20, 2018 asserting the '150 patent, the '063 patent, and the '232 patent. (C.A. 18-914, D.I. 1). The Asserted Patents share a common specification and are related to "a method of producing phytase in yeast by introducing a heterologous gene which encodes a protein or polypeptide with phytase/acid phosphatase activity into a yeast strain and expressing that gene." ('150 patent, col. 2:57-60).

The parties have three common disputed terms. (D.I. 62 at 13, 52, 69; C.A. 18-914, D.I. 65 at 13, 51, 67). Plaintiffs and the ABF Defendants dispute an additional term in claims 8-9 of the '300 patent. (D.I. 62 at 72). Plaintiffs and the DuPont Defendants dispute an additional term in claims 1 and 28 of the '150 patent, claim 1 of the '063 patent, and claim 1 of the '232 patent. (C.A. 18-914, D.I. 65 at 69). Claims 1 and 2 of the '150 patent and claims 1 and 6-8 of the '300 patent are representative.

Claims 1 and 2 of the '150 patent read as follows:

1. A method of producing phytase in yeast comprising:
   providing a heterologous polynucleotide from non-yeast organism which encodes a protein or polypeptide comprising either a PhyA phytase or an *AppA phytase*;
   expressing the protein of polypeptide in a yeast; and

isolating the expressed protein or polypeptide, wherein said protein or polypeptide catalyzes the release of phosphate from phytate and has increased thermostability as compared to that of said protein or polypeptide expressed in a non-yeast host cell.

2. The method according to claim 1, wherein the heterologous polynucleotide is an isolated *appA polynucleotide*.

('150 patent, cls. 1-2) (disputed terms italicized). Claims 1 and 6-8 of the '300 patent read as follows:

1. A method of producing a phytase in fungal cells, the method comprising:
providing a polynucleotide encoding an *Escherichia coli phytase*;
expressing the polynucleotide in the fungal cells; and
isolating the expressed *Escherichia coli phytase* wherein the *Escherichia coli phytase* catalyzes the release of phosphate from phytate.

6. The method of claim 1 wherein the fungal cells are cultured in a growth medium.

7. The method of claim 6 wherein the *Escherichia coli phytase* is secreted from the fungal cells into the growth medium.

8. The method of claim 7 wherein the *Escherichia coli phytase* is *purified from the growth medium*.

('300 patent, cls. 1, 6-8) (disputed terms italicized).

III. CONSTRUCTION OF DISPUTED TERMS

1. "a phytase from *Escherichia coli*" / "*Escherichia coli* phytase" ('063 patent, cl. 1; '232 patent, cls. 1, 3-4; '300 patent, cls. 1, 7-9, 11-12)

a. *Plaintiffs' proposed construction*: "any phytase derived from *Escherichia coli*"

b. *ABF Defendants' proposed construction*: "a phytase isolated from wild type *Escherichia coli*"

c. *DuPont Defendants' proposed construction*: "the phytase encoded by the appA polynucleotide (as defined below)"

d. *Court's construction*: "any phytase derived from *Escherichia coli*"

Plaintiffs assert that Defendants' constructions of this term are contrary to the intrinsic evidence and improperly narrow the claim scope. (D.I. 62 at 31-42, 40-41; C.A. 18-914, D.I. 65

at 19-21). Defendants argue that there is both lexicography and prosecution history disclaimer that require this term to be construed in a narrow manner. (D.I. 62 at 20-24; C.A. 18-914, D.I. 65 at 22-26). The DuPont Defendants assert that the prosecution history disclaims any claim scope beyond that of an AppA phytase. (C.A. 18-914, D.I. 65 at 24-26). The ABF Defendants propose a slightly broader construction and argue that the claim language and specification support a claim scope that only reaches phytase isolated from "wild-type" *E. coli*, meaning naturally-occurring *E. coli*. (D.I. 62 at 13, 19).

First, the patentee did not act as a lexicographer in defining this term. "It is not enough for a patentee to simply disclose a single embodiment or use a word in the same manner in all embodiments, the patentee must 'clearly express an intent' to redefine the term." *Thorner v. Sony Comput. Entertainment Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012). Here, the specification does not "clearly express an intent" to redefine the term to be limited to AppA phytase. In fact, the specification indicates that these terms should not be interpreted the same way; several embodiments use the term "*E. coli* AppA phytase," rather than "AppA phytase" or "phytase from *E. coli*." ('063 patent, col. 25:6-8; 26:29-30; 28:19-21). Similarly, the specification does not "clearly express an intent" to redefine the term to be limited to "wild-type" *E. coli*.

Second, I agree with Plaintiff that there is not prosecution history disclaimer. Defendants assert that the patentee disclaimed all phytases other than the AppA phytase during prosecution of the '150 patent and that the disclaimer should flow to the other patents,[2] which are children of the '150 patent. (D.I. 62 at 21-22; C.A. 18-914, D.I. 65 at 21, 48-49). Even if there was disclaimer in the '150 application, that disclaimer does not "flow" to the '062, '232 and '300 patents. The prosecution history for the '063 patent makes clear that the applicant successfully traversed the

[2] This does not include the '572 patent, which is the parent of the '150 patent.

examiner's written description rejection where it argued "that the disclosure of the AppA phytase is sufficient to support all phytases from *Escherichia coli*." (C.A. 18-914, D.I. 66 at 417-18). After the patentee made this argument, the examiner's written description objection was withdrawn, and the claims were allowed. (C.A. 18-914, D.I. 66 at 433.009). Similar exchanges occurred in the prosecution of the '232 patent (C.A. 18-914, D.I. 67 at 512-13, 517-18, 548) and the '300 patent (*id.* at 560-61, 570-71, 590, 595 ("[T]he experiments reported in the present application using AppA are representative of *E. coli* phytases generally and that the host strain does not significantly alter the biochemical characteristics of the expressed phytase.")).

Third, the language of the claims themselves supports Plaintiffs' construction. Accepting the DuPont Defendants' construction would cause claims 1 and 2 of the '232 patent to have the same claim scope. The doctrine of claim differentiation "is based on the common sense notion that different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope." *Anderson Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1369 (Fed. Cir. 2007) (internal quotations omitted). While claim differentiation "can not broaden claims beyond their correct scope," *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1480 (Fed. Cir. 1998), the specification and prosecution history indicate that the terms "*Escherichia coli* phytase" and "AppA phytase" are intended to have different meanings and scope. Therefore, the claim language, the specification, and the prosecution history support Plaintiffs' construction.

Thus, based on the intrinsic evidence, I construe the term "a phytase from *Escherichia coli*" / "*Escherichia coli* phytase" to mean "any phytase derived from *E. coli*."

2. "appA polynucleotide" ('572 patent, cls. 1, 4-5, 9; '150 patent, cls. 2, 28, 33-34, 39; '318 patent, cls. 1, 4-5)

a. *Plaintiffs' proposed construction*: "any nucleotide sequence derived from an appA gene of *Escherichia coli* that encodes a protein or polypeptide with phytase activity"

b. *ABF Defendants' proposed construction*: "the gene originally defined as *E. coli* periplasmic phosphohydrolase gene, which contains 129[9] nucleotides and is identified by GenBank accession number M58708"

c. *DuPont Defendants' proposed construction*: "the polynucleotide having 1,299 nucleotides and corresponding to nucleotides 188 to 1486 of the appA gene of *E. coli* (GenBank accession number M58708)"

d. *Court's construction*: "any nucleotide sequence derived from an appA gene of *Escherichia coli*"

Defendants assert that the term "appA polynucleotide" should be construed as the polynucleotide identified by GenBank accession number M58708 because of lexicography and prosecution disclaimer. (D.I. 62 at 58-60; C.A. 18-914, D.I. 65 at 56-58). Plaintiffs oppose this narrow construction and argue that the patentee did not engage in lexicography or prosecution disclaimer. (D.I. 62 at 53-56; C.A. 18-914, D.I. 65 at 63-64). Plaintiffs also argue that Defendants' proposed constructions would read out preferred embodiments, specifically "Example 10" of the patent specification. (C.A. 18-914, D.I. 65 at 55, 61).

The general rule of claim construction is that "[t]he words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history." *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012). Two exceptions exist: "1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Id.*

First, the patentee has not engaged in lexicography. "To act as its own lexicographer, a patentee must clearly set forth a definition of the disputed claim term other than its plain and

ordinary meaning." *Id.* (internal citations and quotations omitted). To disavow claim scope, "[t]he patentee may demonstrate intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Id.* at 1366 (quoting *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002)). Defendants point to the following sentences of the specification as lexicography: "Another preferred heterologous gene is the appA gene of *E. coli*. The gene, originally defined as *E. coli* periplasmic phosphoanhydride phosphohydrolase (appA) gene, contains 1,29[9] nucleotides (Gen[]Bank accession number: M58708)." ('150 patent, col. 5:66-6:2). However, this language does not "clearly set forth a definition of the disputed claim term." *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002). The GenBank accession number M58708 contains entries for various mutants and variants, all referred to as an appA gene. (C.A. 18-914, D.I. 67 at 605-07). Thus, there is no lexicography here.

Second, the patentee has not clearly disavowed claim scope beyond the GenBank sequence. The specification repeatedly makes clear that the claimed method may require or use a modified gene. *See* '150 patent, col. 9:1-3 ("the present invention is not restricted to any specific type of leader sequence or signal peptide"); col. 23:9-10 ("to construct the signal peptide of PhyA gene with the coding region of appA gene"); col. 23:62-66 ("Transforming INVScl with the construct of pYES2-Sphy-appA (led by the signal peptide of PhyA) produced extracellular phytase activity in the supernatant that was 2,000-fold greater than those of the wild type or of the transformant containing appA gene plus its own signal peptide."). The adjustments or modifications made in the patent occur within the 1,299 nucleotide sequence. (*Id.* at col. 23:9-10, 62-66). Thus, the specification clearly contemplates the use of a gene or polynucleotide that

does not contain the exact 1,299 nucleotide sequence disclosed in the primary entry of Genbank accession number M58708.

Third, Plaintiffs' construction was not disclaimed in prosecution. Defendants point to portions of the prosecution history where the examiner rejected claims under 35 U.S.C. ¶ 112 for lack of written description as contradicting Plaintiffs' construction of this term. (C.A. 18-914, D.I. 65 at 58). The examiner objected to the scope of claims because the specification only provided two representative species of "a heterologous polynucleotide from a non-yeast organism," the appA polynucleotide and the phyA polynucleotide. (C.A. 18-914, D.I. 66 at 340-41). The examiner found that these two polynucleotide species could not support all non-yeast organism polynucleotides encoding proteins or polypeptides with phytase activity. (*Id.* at 376-77). In response, the patentee amended the claim to specify that the protein or polypeptide encoded by the heterologous polynucleotide was "either a phyA phytase or an AppA phytase." (*Id.* at 387). However, this does not equate to a disclaimer of all possible appA polynucleotides. Rather, it is only a clear disclaimer of the broader category of any polynucleotide from a non-yeast organism. Therefore, the patentee did not disclaim the claim scope covered by Plaintiffs' construction.

Finally, the Example 10 embodiment provides further support for Plaintiffs' construction. While the parties agree that claim 1 of the '150 patent contains a "providing" step and an "expressing" step, they disagree as to which step the various subsections of Example 10 would fall under. Plaintiffs argue that the "providing" step of the claimed method encompasses the following subsections of Example 10: Gene and Protein ('150 patent, col. 22:36-61); Host and Vector (*id.* at col. 22:62-64); and Construction of the Expression Vector (*id.* at col. 22:65-23:23). Under Plaintiffs' reading of the claim and specification, only the "Expression" subsection of

Example 10 (*Id.* at col. 22:24-29) would fall under the "expressing" step of the claim. Therefore, Plaintiffs argue, the Defendants' construction of "appA polynucleotide" would read out Example 10, an embodiment of the claims. Defendants disagree. They argue that the "Host and Vector" and "Construction of the Expression Vector" subsections fall under the "expressing" step of the claim, rather than the "providing" step. Therefore, Defendants argue, their construction of "appA polynucleotide" does not read out this embodiment.

Regardless of how Example 10 is read as to which activity is characterized as the providing step and which is the expressing step, it indicates that the invention encompasses more than just the 1,299 nucleotide sequence identified at Genbank accession number M58708. A person of ordinary skill in the art thus would understand after reading the specification that "appA polynucleotide" refers to the sequences (including mutants and variants) found at Genbank accession number M58708 as well as other modified polynucleotides which code for phytase activity. Therefore, I construe "appA polynucleotide" to mean "any nucleotide sequence derived from an appA gene of *Escherichia coli.*"

3. "AppA phytase" / "*Escherichia coli* AppA phytase" / "*E. coli* AppA phytase" ('150 patent, cl. 1; '232 patent, cl. 2; '300 patent, cl. 2)

a. *Plaintiffs' proposed construction*: "any phytase derived from an appA gene of *Escherichia coli*"

b. *ABF Defendants' proposed construction*: "a phytase isolated from wild type *Escherichia coli* encoded by the appA polynucleotide"

c. *DuPont Defendants' proposed construction*: "the phytase encoded by the appA polynucleotide (as defined above)"

d. *Court's construction*: "any phytase encoded by an appA polynucleotide"

Plaintiffs argue that the specification and prosecution history do not support Defendants' narrow constructions. (D.I. 62 at 69-70; C.A. 18-914, D.I. 65 at 67-68). Defendants assert that

the specification and prosecution history require a narrow construction of the term, though they differ on the purported scope of the term. (D.I. 62 at 70-71; C.A. 18-914, D.I. 65 at 68-69).

The parties agree that an "AppA phytase" as described in the claims has a clear relationship to an "appA polynucleotide" as used in the claims. The parties' dispute mirrors the previous term "appA polynucleotide." (D.I. 62 at 69-71). For the reasons explained above, I do not find there to be lexicography or disclaimer requiring or supporting Defendants' narrow constructions. However, Plaintiffs' use of "derived from" to describe the relationship between the phytase and the polynucleotide is not supported by the specification or claim language. The specification repeatedly makes clear that the overexpression of the AppA phytase is the result of the coding sequence in the appA polynucleotide. ('150 patent, col. 2:58-60; 3:12-14; 5:12-14, 51-52; 10:9-12, 22-23). Therefore, "encoded by" is a more accurate description of the relationship between the phytase and the polynucleotide. Thus, I construe the term "AppA phytase" to mean "any phytase encoded by an appA polynucleotide."

4. "purified from the growth medium" ('300 patent, cls. 8-9)

a. *Plaintiffs' original proposed construction*: Plain and ordinary meaning, e.g., "increasing purity of the *Escherichia coli* phytase"

b. *Plaintiffs' supplemental proposed construction*: Plain and ordinary meaning, e.g. "removed from the growth medium with increased purity or concentration"

c. *ABF Defendants' original proposed construction*: "removed from the growth medium at a ratio of at least 80% pure"

d. *ABF Defendants' supplemental proposed construction*:[3] "separated from any other materials in the growth medium, including other proteins and cellular materials"

c. *Court's construction*: "separated from any other materials in the growth medium, including other proteins and cellular materials"

[3] Defendants propose this construction without waiving previously raised indefiniteness arguments. (D.I. 65 at 2 n.3).

Plaintiffs argue that this term should be given its plain and ordinary meaning. (D.I. 62 at 72). Defendants assert that the term must be construed to have a quantitative limitation to avoid indefiniteness. (*Id.* at 75-76). Plaintiffs oppose Defendants' construction because it improperly imports limitations from a preferred embodiment into the claims. (*Id.* at 72).

I agree with Plaintiffs. The intrinsic evidence does not support importing a purity limitation from a preferred embodiment into the claim language. The specification states, "The protein or polypeptide of the present invention is *preferably* produced in purified form (*preferably* at least about 80%, more *preferably* 90%, pure) by conventional techniques." ('150 patent, col. 7:17-20 (emphasis added)). It is improper to import limitations into the claims from a preferred embodiment. *Phillips*, 415 F.3d at 1323. Defendants argue that Plaintiffs' construction will cause the claim term to be indefinite. (D.I. 62 at 75-76). I disagree. "[B]readth is not indefiniteness." *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1367 (Fed Cir. 2017).

However, Plaintiffs' original proposed construction is not a helpful construction to understand the term. Thus, at oral argument, I asked the parties to submit supplemental claim construction briefing. (Hr'g Tr. at 121:8-21). Plaintiffs continue to propose a construction of plain and ordinary meaning but have altered their expression of that meaning to "removed from the growth medium with increased purity or concentration." (D.I. 65 at 1). Defendants have proposed an alternative construction which they argue comports with statements that Plaintiffs made in the claim construction briefing. (*Id.*). In the original claim construction briefing, Plaintiffs argued that "a person of ordinary skill would understand [this term] to mean the act of separating the desired protein from any unwanted materials in the growth medium, including other proteins and cellular materials." (D.I. 62 at 72). Defendants have essentially adopted this statement to be their construction of this term.

I agree with Defendants' supplemental construction. The specification repeatedly uses the term "purify" in a context that indicates the intention is to remove the phytase protein from other proteins and cells. *See* '300 patent, col. 16:20-23 ("Because phytase protein was secreted into the medium in such a high level, it should be easy to purify . . . ."); col. 18:14-16 ("Most importantly, enzyme proteins produced by *S. cerevisiae* are easily purified, because it secretes only a few proteins."); col. 28:56-59 ("Because the expressed protein represented almost the only visible band in the supernatant, it would be convenient to collect the enzyme product without the need for a tedious purification."). Thus, the specification's use of the term "purify" repeatedly indicates that the goal of the invention is to collect phytase protein on its own, rather than in combination with the yeast cells or the growth medium.

Therefore, I construe the term "purified from the growth medium" to mean "separated from any other materials in the growth medium, including other proteins and cellular materials."

5. "isolating the expressed protein or polypeptide" ('150 patent, cls. 1, 28; '063 patent, cl. 1, '232 patent, cl. 1)

a. *Plaintiffs' proposed construction*: Plain and ordinary meaning, e.g., "separating the expressed protein or polypeptide from a host or host cells"

b. *DuPont Defendants' proposed construction*: "Separating the expressed protein or polypeptide from host cells, cell debris and other proteins such that the expressed protein or polypeptide is at least 80% pure"

c. *Court's construction*: Plain and ordinary meaning, e.g., "separating the expressed protein or polypeptide from a host or host cells"

Plaintiffs argue that the Court should construe the term "isolating the expressed protein or polypeptide" to have its plain and ordinary meaning, "separating the expressed protein or polypeptide from a host or host cells." (C.A. 18-914, D.I. 65 at 70). The DuPont Defendants agree that this term captures the concept of separating the expressed protein or polypeptide but argue

that the specification supports both the addition that the protein must be separated from cell debris and other proteins as well as a numerical purity limitation. (*Id.* at 72-73).

First, the intrinsic evidence does not support importing a purity limitation from a preferred embodiment into the claim language. The specification states, "The protein or polypeptide of the present invention is *preferably* produced in purified form (*preferably* at least about 80%, more *preferably* 90%, pure) by conventional techniques." ('150 patent, col. 7:17-20 (emphasis added)). It is improper to import limitations into the claims from a preferred embodiment. *Phillips*, 415 F.3d at 1323. The DuPont Defendants argue that Plaintiffs' construction will cause the claim term to be indefinite. (C.A. 18-914, D.I. 65 at 73-74). I disagree. "[B]readth is not indefiniteness." *BASF Corp.*, 875 F.3d at 1367. Moreover, a person of ordinary skill in the art would be able to understand what the claim term requires without the numerical limitation. It requires separating the expressed protein or polypeptide from a host or host cells. This is a binary proposition; either the POSA engages in a separation step or they do not.

Second, the intrinsic evidence does not support requiring the protein or polypeptide to be separated from more than the host or host cells. The specification provides two identified alternatives for obtaining the protein or polypeptide. First, "the protein or polypeptide . . . is secreted into the growth medium of recombinant host cells." ('150 patent, col. 7:21-23). Second, "[a]lternatively, the protein or polypeptide . . . is produced but not secreted into growth medium. In such cases, to isolate the protein, the host cell carrying a recombinant plasmid is propagated, lysed by sonication, heat, or chemical treatment, and the homogenate is centrifuged to remove cell debris." (*Id.* at col. 7:23-28). The term "isolating the expressed protein or polypeptide" encompasses both alternatives. (*Id.* at cl. 1, 6, 7, 28, 31). Therefore, to import the limitations from the second alternative method would improperly read in limitations from a single embodiment.

Therefore, I construe the term "isolating the expressed protein or polypeptide" to have its plain and ordinary meaning, "separating the expressed protein or polypeptide from a host or host cells."

IV. CONCLUSION

Within five days the parties shall submit a proposed order consistent with this Memorandum Opinion suitable for submission to the jury.