IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

NUTECH VENTURES, **Plaintiff,** **vs.** **SYNGENTA SEEDS, INC., and TRENTON AGRI PRODUCTS LLC,** **Defendants.**	**CASE NO. 8:12CV289** **MEMORANDUM AND ORDER**

This matter is before the Court on the parties' Joint Claim Construction Statement (Filing No. 75). Plaintiff and Counterclaim Defendant NuTech Ventures ("NUTech") has sued Defendants and Counterclaim Plaintiffs Syngenta Seeds, Inc. ("Syngenta") and Trenton Agri Products LLC ("Trenton") (collectively "Defendants") alleging that the Defendants have infringed U.S. Patent No. 6,506,592 B1 (the "'592 Patent"). The parties collectively have requested that the Court construe certain terms in the '592 Patent.

BACKGROUND

I. General Patent Overview

The '592 Patent is titled "Hyperthermophilic Alpha-Glucosidase Gene and Its Use," and generally relates to plant matter that has been genetically transformed so that it produces an enzyme not naturally produced in the plant. (Filing No. 1-1, summary; Filing No. 85 at 2.) The patent application was filed on August 18, 1999, and claims priority to a provisional application that was filed a year earlier. The '592 Patent issued on January 14, 2003, and includes nine claims directed to a "method of converting plant substrate." Dr. Paul Blum ("Dr. Blum"), a professor and researcher at the University of Nebraska in Lincoln, Nebraska, developed the technology used in the '592 Patent, and

NUTech owns the ‘592 Patent. NUTech claims that the Defendants’ use of a bio-engineered corn called Enogen relies on technology from the ‘592 Patent to convert the starch in corn into smaller sugars during ethanol production.

II. General Scientific Overview

The ‘592 Patent relates to reactions that occur during a chemical process called hydrolysis. Carbohydrates can be considered a group of sugar molecules joined by chemical bonds. Carbohydrates, such as starch, store energy. When the chemical bonds in a group of sugar molecules are broken, the starch can be processed for use in different industries, such as the production of ethanol. The chemical bonds between sugar molecules in starch are called “glycosidic bonds.” To convert starch into sugars, the chemical bonds between the sugar molecules are broken by water through hydrolysis.

The natural hydrolysis reaction can be very slow, so ethanol producers add proteins to the process called “enzymes” to act as catalysts to speed up the reactions. Enzymes are proteins that function as catalysts in biochemical reactions by acting on one or more starting plant materials called “substrates.” Environmental conditions, such as temperature and pH, can greatly affect the activity of an enzyme. In general, the activity of an enzyme increases with temperature because molecules move and interact more quickly at higher temperatures. Temperature also affects the integrity and stability of enzymes. Increased temperature can cause the protein structure of an enzyme to weaken, which can hinder its ability to catalyze reactions. Depending on their structure and other characteristics, some enzymes are only active at moderate temperatures, whereas other related enzymes catalyzing the same reactions are capable of activity at

relatively high temperatures. The thermophilicity of an enzyme relates to the ability of the enzyme to catalyze reactions at relatively high temperatures.

While active enzymes can convert plant material to products such as ethanol, continued activity at times may not be desirable. For this reason, cells of living organisms have evolved to regulate enzyme activity. For example, cells can regulate when and where an enzyme is produced. Those skilled in the art can take advantage of natural regulatory mechanisms in living cells to design recombinant enzymes to catalyze desired activity. For example, those skilled in the art can engineer the cellular location and activity of enzymes to control when certain processes occur.

III. Invention Background

The claims in the ‘592 Patent involves a specific type of enzymes called “glycosyl hydrolases” that aid in breaking glycosidic bonds during hydrolysis. NUTech claims that, prior to the invention, companies typically added enzymes at some point during the hydrolysis process to speed up production. This is because industrial hydrolysis involved not only adding water and enzymes to a mixture of plant material, but also heating the mixture to a very high temperature. Thus, the enzymes had to be heat resistant to perform their function at high temperatures. Enzymes that can resist heat and perform their function at high temperatures are called “thermostable” enzymes. Purchasing and storing thermostable enzyme additives is expensive and represents a significant cost in the starch hydrolysis process.

In the ‘592 Patent, Dr. Blum claims to have identified and cloned a glycosyl hydrolase derived from an organism that grows in locations that experience high temperatures. Dr. Blum also developed a bioengineered plant containing glycosyl

hydrolases from these organisms. Because the organisms could survive in high temperatures, the glycosyl hydrolases derived from the organisms were thermostable, and could survive at high temperatures. Further, the enzymes were already located in the bioengineered plants, so companies would not have to purchase, store, and then add the enzyme additives to convert the starch in the plant material. Because of their hyperthermophilic origin, the enzymes would not significantly interfere with the plants' normal metabolism, and were not toxic to the plants even when the enzymes were found inside the same cells as the plant substrate.

IV. Patent Prosecution History

Dr. Blum originally filed a provisional patent application in 1998, and a formal patent application in 1999. The United States Patent and Trademark Office ("USPTO") spent over three years reviewing the application before a patent was issued in 2003. Both parties' arguments reference the prosecution history to aid their respective claim constructions. By reviewing the prosecution history, the Court does not prejudge infringement or validity of the '592 Patent. However, this information is useful for background, and can be considered in interpreting terms.[1]

The parties agree that, generally in the 1990s, the method in the industry was to add separately produced enzymes to plant material for use in hydrolysis. The '592

[1] The Court cannot prejudge infringement or validity in the *Markman* ruling. *See PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1355 (Fed. Cir. 1998) ("Claims are often drafted using terminology that is not as precise or specific as it might be. As long as the result complies with the statutory requirement to 'particularly point[ ] out and distinctly claim[ ] the subject matter which the applicant regards as his invention,' . . .that practice is permissible. That does not mean, however, that a court, under the rubric of claim construction, may give a claim whatever additional precision or specificity is necessary to facilitate a comparison between the claim and the accused product. Rather, after the court has defined the claim with whatever specificity and precision is warranted by the language of the claim and the evidence bearing on the proper construction, the task of determining whether the construed claim reads on the accused product is for the finder of fact.").

Patent states that "[a] variety of industries, such as food and chemical, employ hydrolases for the production of glucose, sucrose and other sugars," and that "[h]igh value is placed on thermostability and thermoactivity of enzymes for use in the bioprocessing of starch . . . ." (Filing No. 1-1 at 1:25–30.) The '592 Patent also notes that "the current method used in the industry" in the 1990s was "to add separately produced commodity enzymes to plant material." (*Id*. at 3:1–2.)

The USPTO Examiner originally rejected Dr. Blum's pending claims as obvious. The USPTO explained that the original application lacked reference to previously published papers on related subjects, and thus failed to disclose the prior art. Much of the prosecution history concerned a 1992 article entitled "Production of Active Bacillus Licheniformis Alpha-Amylase in Tobacco and Its Application in Starch Liquiefaction" written by Jan Pen and others (the "Pen Article").[1] The USPTO noted that the Pen Article concerned a tobacco plant with enzymes that had the characteristic of being less active at lower temperatures and highly active at high temperatures. Accordingly, the USPTO rejected the application as obvious considering the prior art.

Dr. Blum responded to the USPTO by differentiating the enzymes described in the Pen Article from the enzymes in his application. Br. Blum explained that in the Pen Article, the plant substrate was located inside the plant cells, and the enzyme was outside the plant cells. Thus, the enzyme and the plant substrate were separated into different cellular compartments, and were brought together for the processing through homogenization. In contrast, the Dr. Blum argued that his invention used a "hyperthermophilic" glycosyl hydrolase. According to Dr. Blum's application, his

[1] The Pen Article appears in multiple filings. References to the Pen Article in this Memorandum and Order will be to its first appearance at Filing No. 83-6.

invention did not require separation of the plant substrate from the enzymes, because the activity of the enzyme was not detectable at normal plant growth temperatures. The USPTO Examiner initially rejected this argument because the patent itself did not specifically state that the enzyme and the plant material could coexist in the cells. Specifically, the USPTO noted that the claims in the application "did not specifically require nonsequestered localization of the transgenic enzyme in the plant." (Filing No. 86-5 at ECF 82.)

Dr. Blum responded by amending the '592 Patent's claims to include the phrase "wherein the glycosyl hydrolase is located with the substrate in tissue of the plant." (*See* Filing No. 1-1 at ECF 40.) Dr. Blum distinguished his invention from the prior art mentioned in the Pen Article by explaining that "[s]ince enzyme and substrate are present in different cellular compartments [in the method of the Pen Article], no degradation of the substrate occurs during growth. The enzymatic reaction is initiated . . . when by homogenation the enzyme and the substrate are brought together." (Filing No. 86-5 at ECF 101.) In contrast, Dr. Blum stated that "[s]uch separate localization is not required in the method of the present invention." (*Id*.) Based on this amendment, the USPTO withdrew its rejection, and allowed the patent to issue.

The claim issued as independent Claim 1[2] in the '592 Patent. Claims 2-9 of the '592 Patent all depend on Claim 1. The parties' claim construction dispute relates to Claim 1 and dependent Claim 9 in the '592 Patent. Claim 1 states:

[2] Prior to the final amendment, the text of what is now Claim 1 was referred to as "claim 25."

> A method for converting plant substrate, comprising heating said substrate in the presence of recombinant hyperthermophilic glycosyl hydrolase, wherein said substrate comprises extract of plant transformed with said recombinant hyperthermophilic glycosyl hydrolase, and wherein the glycosyl hydrolase is localized with the substrate in tissue of the plant.

(Filing No. 1-1 at 41:53-59.) Claim 9 states:

> The method of claim 1, wherein said substrate is heated at a temperature of between about 65° C. and about 85° C.

(*Id.* at 42:62-63.)

V. Procedural Background

NUTech filed its Complaint on August 15, 2012, alleging that the Defendants infringed the '592 Patent through use of a bio-engineered corn called Enogen in the ethanol production process. It is alleged that Enogen is a transgenic corn that has been bioengineered to express an "alpha-amylase," which allows it to be thermostable and active during the high temperatures required for starch hydrolysis in ethanol production (specifically during the dry-grind that occurs during ethanol production). NUTech alleges that Syngenta modified Enogen corn so it produces a specific type of enzyme derived from an organism that grows at very high temperatures, which is then used in the process of converting starch into smaller sugars during the production of ethanol. When using Syngenta's Enogen corn, ethanol plants no longer need to purchase and separately add a commodity enzyme that breaks down starch during ethanol production. Enogen corn can also reduce the amount of water and energy required to make ethanol. NUTech argues that the '592 Patent discloses and claims the use of a genetically modified plant that produces an enzyme such as the one found in Enogen.

VI. Disputed Terms and Phrases:

The parties have identified four terms that appear in the '592 Patent's nine claims to be construed by the Court. Three of the terms come from Claim 1, and the fourth comes from Claim 9. The disputed terms and the parties' proposed construction are reproduced below from Ex. A to the parties' Joint Claim Construction Statement (Filing No. 75-1):

Term/Phrase	NUTech	Defendants
"hyperthermophilic"	"an organism capable of growth above 70° C, or proteins derived from such an organism"	Term encompassed by the phrase "hyperthermophilic glycosyl hydrolase"
"hyperthermophilic glycosyl hydrolase"[3]	"'glycosyl hydrolase' derived from organisms capable of growth above 70° C"	"glycosyl hydrolase that is capable of activity at temperatures above 70° C and has undetectable activity at temperatures supporting plant growth"
"said substrate comprises extract of plant transformed with said recombinant hyperthermophilic glycosyl hydrolase"	"the 'plant substrate'[4] includes extract of plant that has been transformed with the recombinant 'hyperthermophilic glycosyl hydrolase'"	"said substrate is endogenous to the plant transformed with said recombinant hyperthermophilic hydrolase and is not separately added or mixed"
"wherein the glycosyl hydrolase is localized with the substrate <u>in tissue of the plant</u>"	"wherein the glycosyl hydrolase and substrate of the transformed plant are located inside the same cell tissue of the transformed	"wherein the glycosyl hydrolase is located having access to, and thus is capable of acting on, the substrate"

[3] The parties have agreed to the following construction of "glycosyl hydrolase":

"*enzyme, which hydrolyzes substances linked by glycosyl bonds, for example, polysaccharides*"

[4] The only times the term "plant substrate" appears in the parties Joint Claim Construction Statement is in their agreed upon construction of the term and in NUTech's proposed construction of Term #2. The parties' agreed upon construction of "plant substrate" is:

"*plant material that can be acted upon by an enzyme*"

	plant"	Defs. do not believe "in tissue of the plant" needs to be construed.
Claim 9 - "heated at a temperature between about 65° C and about 85° C"	"heated at a temperature between approximately 65° C and approximately 85° C"	"heated at a temperature above about 65° C and not exceeding about 85° C"

CLAIM CONSTRUCTION STANDARD

To determine whether a patent has been infringed, the Court must undertake a two-step analysis. "'First, the [C]ourt determines the scope and meaning of the patent claims asserted.'" *Cordis Corp. v. Boston Scientific Corp.*, 658 F.3d 1347, 1354 (Fed. Cir. 2011) (quoting *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc)). Second, "'the properly construed claims are compared to the allegedly infringing device.'" *Id.* Claim construction is a way "'of elaborating the normally terse claim language in order to understand and explain, but not change, the scope of the claims.'" *Terlep v. Brinkmann Corp.,* 418 F.3d 1379, 1382 (Fed. Cir. 2005) (quoting *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1347 (Fed. Cir. 2000)). It is also "a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement. It is not an obligatory exercise in redundancy." *U.S. Surgical Corp. v. Ethicon, Inc.,* 103 F.3d 1554, 1568 (Fed. Cir. 1997). "[A] sound claim construction need not always purge every shred of ambiguity. The resolution of some line-drawing problems . . . is properly left to the trier of fact." *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 806 (Fed. Cir. 2007) (citing *Abbott Labs. v. Baxter Pharm. Prods.*, Inc., 471 F.3d 1363, 1368 (Fed. Cir. 2006); *PPG Indus. v. Guardian Indus. Corp.*, 156

F.3d 1351, 1355 (Fed. Cir.1998); *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1554 (Fed. Cir. 1996)).

"The 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 at the time of the invention.'" *NTP, Inc. v. Research In Motion, Ltd.,* 418 F.3d 1282, 1293 (Fed. Cir. 2005) (quoting *Phillips v. AWH Corp*., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc)). An inventor may, however, "choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) (citing *Hoechst Celanese Corp. v. BP Chems. Ltd.*, 78 F.3d 1575, 1578 (Fed. Cir. 1996)).

To determine the meaning of a claim term, "the court looks to those sources available to the public that show what a person of ordinary skill in the art would have understood disputed claim language to mean.'" *Phillips*, 415 F.3d at 1314 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys.*, 381 F.3d, 1111, 1116 (Fed. Cir. 2004)). Such "sources include 'the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.'" *Id.* When interpreting any asserted claim, "court[s] should look first to the intrinsic evidence of record," which encompasses "the patent itself, including the claims, the specification and, if in evidence, the prosecution history." *Vitronics*, 90 F.3d at 1583 (citing *Markman*, 52 F.3d at 979). Following this analysis of the intrinsic evidence, extrinsic evidence may be considered only if necessary to determine the "'meaning or scope of technical terms

in the claims.'" *See id.* (quoting *Hormone Research Found.*, *Inc. v. Genentech, Inc.*, 904 F.2d 1558,1562 (Fed. Cir. 1990)). The Court's "primary focus in determining the ordinary and customary meaning of a claim limitation is . . . the intrinsic evidence of record." *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 996 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312-17). The analysis of the intrinsic record begins "with the language of the claims" themselves. *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1341-42 (Fed. Cir. 2001); *see also Phillips*, 415 F.3d at 1314 ("Quite apart from the written description and the prosecution history, the claims themselves provide substantial guidance as to the meaning of particular claim terms."). However, "[t]he claims . . . do not stand alone." *Phillips*, 415 F.3d at 1315. Instead, "they are part of 'a fully integrated written instrument,'" and must be read in view of that fully integrated written instrument. *Id.* (quoting *Markman*, 52 F.3d at 979).

After looking to the language of the claim itself, "[t]he most relevant source [for ascertaining the meaning of a claim] is the patent's specification, which is 'the single best guide to the meaning of a disputed term.'" *MBO Labs. Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1329 (Fed. Cir. 2007) (quoting *Phillips*, 415 F.3d at 1315). "'Usually, it is dispositive[.]'" *Terlep*, 418 F.3d at 1382 (quoting *Phillips*, 415 F.3d at 1314). The specification may indicate "that certain embodiments are preferred." *Electro Med. Sys., S.A. v. Cooper Life Scis., Inc.*, 34 F.3d 1048, 1054 (Fed. Cir. 1994). Nevertheless, "particular embodiments appearing in a specification will not be read into the claims when the claim language is broader than such embodiments." *Id.* The next most relevant source of intrinsic evidence "is the prosecution history, which . . . directly reflects how the patentee has characterized the invention." *Id.* (citing *Phillips*, 415 F.3d

at 1317). "'[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.'" *Terlep*, 418 F.3d at 1382 (quoting *Phillips*, 415 F.3d at 1317); *see also Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1374-75 (Fed. Cir. 2008) (citing *Rexnord*, 274 F.3d at 1343) ("Statements made during prosecution may . . . affect the scope of the claims.").

"In most situations, an analysis of the intrinsic evidence[, including the claims themselves, the remainder of the specification, and the prosecution history,] [ ] will resolve any ambiguity in a disputed claim term." *Vitronics*, 90 F.3d at 1583. However, there may be "instances in which intrinsic evidence is insufficient to enable the court to determine the meaning of the asserted claims, and in those instances, extrinsic evidence . . . may also properly be relied on to understand the technology and to construe the claims." *Id.* at 1584 (citing *Markman*, 52 F.3d at 979). "Extrinsic evidence . . . may be helpful [to ascertain the meaning of a claim term] but is 'less significant than the intrinsic record in determining the legally operative meaning of claim language.'" *MBO Labs*, 474 F.3d at 1329 (quoting *Phillips*, 415 F.3d at 1317). Extrinsic evidence is very broad, and includes basically all evidence but intrinsic evidence. Common forms of extrinsic evidence include dictionaries, reference books on the topic of the art, expert testimony, and "other material not part of the public record associated with the patent." *Id.* Although a court may rely on extrinsic evidence, extrinsic evidence "cannot be used to alter a claim construction dictated by a proper analysis of the intrinsic evidence." *On-Line Tech. v. Bodenseewerk Perkin-Elmer*, 386 F.3d 1133, 1139 (Fed. Cir. 2004); *see*

also Intel Corp. v. VIA Techs., Inc., 319 F.3d 1357, 1367 (Fed. Cir. 2003) (emphasis in original) ("When an analysis of *intrinsic* evidence resolves any ambiguity in a disputed claim term, it is improper to rely on extrinsic evidence to contradict the meaning so ascertained.").

When the Supreme Court decided claim construction is matter of law for the courts rather than an issue of fact for the jury, it noted "the importance of uniformity in the treatment of a given patent[.]" *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390 (1996). It also noted:

> But whereas issue preclusion could not be asserted against new and independent infringement defendants even within a given jurisdiction, treating interpretive issues as purely legal will promote (though it will not guarantee) intrajurisdictional certainty through the application of *stare decisis* on those questions not yet subject to interjurisdictional uniformity under the authority of the single appeals court.

Id. at 391. Therefore, although prior claim construction rulings with respect to the same patent-in-suit may not be binding on the Court, they will generally be "entitled to reasoned deference under the broad principals of *stare decisis* and the goals articulated by the Supreme Court in *Markman*, even though *stare decisis* may not be applicable *per se*." *Maurice Mitchell Innovations, L.P. v. Intel Corp.*, No. 2:04-CV-450, 2006 WL 1751779, at *4 (E.D. Tex. June 21, 2006), *aff'd*, 249 F. App'x 184 (Fed. Cir. 2007).

DISCUSSION

I. Claim 1: "hyperthermophilic" and "hyperthermophilic glycosyl hydrolase"

Term/Phrase	NUTech	Defendants
"hyperthermophilic"	"an organism capable of growth above 70° C, or proteins derived from such an organism"	Term encompassed by the phrase "hyperthermophilic glycosyl hydrolase"

"hyperthermophilic glycosyl hydrolase"	"'glycosyl hydrolase' derived from organisms capable of growth above 70° C"	"glycosyl hydrolase that is capable of activity at temperatures above 70° C and has undetectable activity at temperatures supporting plant growth"

The parties first disagree on whether the term "hyperthermophilic" needs to be construed. Defendants argue the term "hyperthermophilic" is merely an adjective modifying the general subject "glycosyl hydrolase." NUTech argues that the '592 Patent expressly defined both terms. NUTech thus claims that its proposed construction follows the express definition Dr. Blum gave to the term in the '592 Patent. Under NUTech's proposed construction, the phrase "hyperthermophilic glycosyl hydrolase" is understood simply by combining the definitions given in the '592 Patent for the terms "hyperthermophilic" and "glycosyl hydrolase." According to NUTech, the express definition of hyperthermophilic refers to two things: (1) an organism capable of growth above 70° C; and (2) proteins derived from such an organism. A glycosyl hydrolase enzyme is a protein. Thus, "hyperthermophilic glycosyl hydrolase" refers to "glycosyl hydrolase derived from organisms capable of growth above 70° C."

Defendants argue that statements in the specifications and prosecution history demonstrate that the construction of the term "hyperthermophilic glycosyl hydrolase" requires that enzymes have "undetectable activity at temperatures supporting plant growth." For example, Defendants point out that the '592 Patent refers to activity several times. *See, e.g.,* Filing No. 1-1 at 2:54-62 ("The recombinant glycosyl hydrolases expressed in the transgenic plants are nontoxic in plant tissues because the

enzymes are inactive at temperatures supporting plant growth and therefore do not significantly interfere with normal metabolism in the living plant."); 2:64–65 ("When desired, the transgenic plant tissue can be heated to activate the enzymes"); 17:63–64 ("processing milled tissue, at high temperatures to activate the recombinant protein"). Defendants also argue that NUTech repeatedly referenced undetectable activity at plant growth temperatures during the patent prosecution process. (Filing No. 85-6 at ECF 76, 101.) Defendants claim that NUTech's proposed construction does not distinguish whether the enzyme itself is thermostable or active at high temperatures, and thus impermissibly broadens the scope of the claim.

The Court concludes that the appropriate construction should rely on the definitions within the '592 Patent. As stated above, when construing a claim term, the Court looks at the "ordinary meaning in the context of the written description and the prosecution history." *Phillips*, 415 F.3d at 1313. "There are only two exceptions to this general rule: 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." *Thorner v. Sony Computer Entm't Am., LLC*, 669 F.3d 1362, 1365 (Fed.Cir. 2012); *see also SkinMedica, Inc. v. Histogen Inc.*, 727 F.3d 1187, 1195 (Fed. Cir. 2013) ("If the specification reveals 'a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess[,] ... the inventor's lexicography governs.'") (quoting *Phillips*, 415 F.3d at 1316); *Helmsderfer v. Bobrick Washroom Equip*., Inc., 527 F.3d 1379, 1381 (Fed. Cir. 2008) (explaining that inventors' definition of a claim term controls when they "clearly express an intent" to redefine a term used in the claims); *3M Innovative Props. Co. v. Avery Dennison Corp.*,

350 F.3d 1365, 1374 (Fed. Cir. 2003) ("Because 3M expressly acted as its own lexicographer by providing a definition of embossed in the specification, the definition in the specification controls the meaning of embossed, regardless of any potential conflict with the term's ordinary meaning."). For a patentee's lexicography to control construction of a claim term, it must be provided "with reasonable clarity, deliberateness, and precision before it can affect the claim." *Abbott Labs*, 334 F.3d at 1355.

In this case, NUTech has acted as its own lexicographer and has expressly defined the terms "hyperthermophilic" and "glycosyl hydrolase." The parties have agreed that "glycosyl hydrolase" means "enzymes which hydrolyze substances linked by glycosyl bonds, for example, polysaccharides." (Filing No. 1-1 at 6:47-49; Filing No. 75-1 at 1.) The '592 Patent also defines the term "hyperthermophilic" as referring "to an organism capable of growth above 70 degrees C., or proteins derived from such an organism." (Filing No. 1-1 at 6:50-52.) The definitions provided in the '592 Patent are presented clearly, deliberately, and precisely. The definitions do not create opposing meanings for the disputed terms. *See Abbott Labs*, 334 F.3d at 1355 (concluding that the patent provided two alternative definitions for the disputed terms). Though the terms are defined separately, the definition for "hyperthermophilic" is clear that it is an adjective for organisms capable of growth above 70 degrees Celsius, or proteins derived from such organisms. The Court's review of the specification does not suggest that Dr. Blum operated under a different definition during the prosecution history. Further, the Defendants do not dispute the meaning of the phrase "glycosyl hydrolase." Accordingly, the Court can find no reason to disturb Dr. Blum's chosen definitions, and

concludes that Dr. Blum demonstrated specific intent to define the terms in question in the Patent. Using the definitions in the '592 Patent, the claim term "hyperthermophilic glycosyl hydrolase" will be construed to mean "glycosyl hydrolase derived from organisms capable of growth above 70° C."[5]

II. Claim 1: "said substrate comprises extract of plant transformed with said recombinant hypothermophilic glycosyl hydrolase"

NUTech	Defendants
"the 'plant substrate' includes extract of plant that has been transformed with the recombinant 'hyperthermophilic glycosyl hydrolase'"	"said substrate is endogenous to the plant transformed with said recombinant hyperthermophilic hydrolase and is not separately added or mixed"

The parties next dispute the portion of Claim 1 stating "said substrate comprises extract of plant transformed with said recombinant hypothermophilic glycosyl hydrolase." The parties agree that "plant substrate" is "plant material that can be acted upon by an enzyme." However, Defendants argue that the invention is limited to plant substrate that is converted by the method of Claim 1, and therefore must be endogenous to the plant. This is because the claim language does not require separate adding or mixing of enzymes as part of the claim method. Further, Defendants argue that the '592 Patent specifies that the process obviates the need to add commodity enzymes separately to plan material. NUTech argues that Defendants' proposed construction is contrary to the plain language of the Claim. Specifically, NUTech argues that the Claim's use of the word "comprises" demonstrates that the plant substrate must

[5] As stated above, the parties agree on the following construction of the term glycosyl hydrolase: "*enzyme, which hydrolyzes substances linked by glycosyl bonds, for example, polysaccharides.*" Accordingly, the Court will not construe that term further, and when used herein, glycosyl hydrolase shall be construed in the manner agreed to by the parties.

include at least extract of plant that has been transformed with the recombinant hyperthermophilic glycosyl hydrolase.

The parties' dispute principally turns on the breadth of the word "comprises" within Claim 1. NUTech argues that its proposed construction relies on the established meaning of the term "comprises" within patent law. This Court has previously recognized that "'[c]omprising' is a term of art used in claim language meaning that the named elements are essential, but that other elements may be added and still form a construct within the scope of the claim." *GP Indus., LLC v. Bachman*, 8:06CV50, 2008 WL 2037415, at *3 (D. Neb. May 9, 2008) (citing *Genetech, Inc. v. Chiron Corp*., 112 F.3d 495, 501 (Fed.Cir.1997). "A drafter uses the term 'comprising' to mean 'I claim at least what follows and potentially more.'" *CollegeNet, Inc. v. ApplyYourself, Inc*., 418 F.3d 1225, 1235 (Fed.Cir.2005) (quoting *Vehicular Techs. Corp. v. Titan Wheel Int'l, Inc*., 212 F.3d 1377, 1383–84 (Fed.Cir.2000)). For example, in *CollegeNet*, the Federal Circuit construed a patent for online college admission application services. The district court was asked to construe the term "automatically" within Claim 1 of the patent at issue. The district court rejected the defendant's more limited definition that automatically meant a process that occurred without human intervention. *Id*. The Federal Circuit upheld the district court and concluded that "[w]hile claim 1 does not expressly provide for human intervention, the use of 'comprising' suggests that additional, unrecited elements are not excluded. Such elements could include human actions to expressly initiate the automatic [querying, generating, transmitting, or receiving], or to interrupt such functions." *Id*.

Defendants argue that the term "[c]omprising is not a weasel word with which to abrogate claim limitations . . . [or] restore [ ] excluded subject matter." *Spectrum Int'l, Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1380 (Fed. Cir. 1998). In other words, the term "comprising" is not "a talismanic incantation that counteracts a clear disclaimer." *BASF Agro B.V. v. Makhteshim Agan of N. Am., Inc.*, 519 F. App'x 1008, 1017 (Fed. Cir. 2013). Defendants argue that the Claim language requires that the substrate must naturally be part of the plant containing the recombinant hyperthermophilic glycosyl hydrolase. Defendants argue that the '592 Patent provided only examples of converting plant extracts that were the source of both the enzyme and the plant substrate. Further, during the prosecution history, Dr. Blum stated that the invention eliminated the need for separate enzyme and substrate preparation, and focused on the use of plants as production hosts. (*See* Filing No. 86-5 at ECF 51-52.)

The Court concludes that NUTech has not provided a clear disclaimer to negate Claim 1's use of the inclusive term "comprising." It is true that one of the supposed distinguishing factors of the '592 Patent is that the method "obviates the need to add separately produced commodity enzymes to plant material, as is the current method used in the industry." (Filing No. 1-1 at 2:54-3:2, ECF 20-21.) While Claim 1 does not specifically identify any adding or mixing steps within the method, neither the Claim, the specification, nor the prosecution history preclude using the recombinant enzyme in plants transformed through authohydrolysis from being used to convert substrate from other plants. In other words, while the invention obviates the need for storing or adding separately prepared commodity enzymes, it does not preclude adding or mixing plant substrate for transformed plants. The specification explicitly explains that "[e]nzyme

substrates included exogenous polysaccharides of defined composition *and* plant extracts enriched for endogenous polysaccharides." (Filing No. 1-1, '592 Patent at 18:16-18, ECF 28 (emphasis added).) Further, the prosecution history demonstrates Dr. Blum used the term "comprise" in an inclusive manner. *See, e.g.* Filing No. 83-4 at ECF 210 ("In summary, the substrates which are converted by the method of the present invention *comprise* plant extract of plants transformed with recombinant thermostable hydrolase.") (emphasis added); id. at ECF 211 ("However, as made explicit by amendment herein to, claim 25, the plant substrate of claims 25-27, 29-31, 33-34 *comprises* extract of plant transformed with said recombinant thermostable enzyme.") (emphasis added). During the prosecution history, Dr. Blum amended what is now Claim 1 to remove the word "endogenous" and add the language that includes the term "comprises."[6] There is no indication that the '592 Patent disclaimed the language proposed by NUTech to nullify the inclusive language encompassed by the term "comprises."[7] Accordingly, the phrase "said substrate comprises extract of plant transformed with said recombinant hyperthermophilic glycosyl hydrolase" is construed to

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[6] The amendment in its entirety appears below:

> (AMENDED) A method for converting plant [endogenous] substrate comprising heating said substrate in the presence of recombinant thermostable enzyme, wherein said substrate comprises extract of plant transformed with said recombinant thermostable enzyme, and wherein said thermostable enzyme is a hydrolase selected from the group consisting of glycosyl hydrolase, protease, lipase and nuclease.

Filing No. 83-4 at ECF 208-9 (brackets and underlining in original to show deleted and added language, respectively).) Dr. Blum also stated: "Claim 25 has been amended to make explicit that the substrate comprises extract of plant transformed with recombinant thermostable hydrolase." (*Id*. at 208.)

[7] In reaching its conclusion, the Court does not intend to define the limits or scope of the '592 Patent. *See TransAmerica Life Ins. Co. v. Lincoln Nat. Life Ins. Co.*, 550 F. Supp. 2d 865, 904 (N.D. Iowa 2008) (stating that "the court is not required to determine the 'overall scope' of the patent as a first step in claim term construction.") The Court's construction is limited to its conclusion that term "comprises" is inclusive, and that it has not been limited through disclaimer.

mean "the 'plant substrate' includes extract of plant that has been transformed with the recombinant 'hyperthermophilic glycosyl hydrolase.'"

III. Claim 1: "wherein the glycosyl hydrolase is localized with the substrate in tissue of the plant"

NUTech	Defendants
"wherein the glycosyl hydrolase and substrate of the transformed plant are located inside the same cell in tissue of the transformed plant"	"wherein the glycosyl hydrolase is located having access to, and thus is capable of acting on, the substrate"

The parties' next dispute focuses on the "localization" of plant substrate, and the extent to which plant substrate must be sequestered from the hypothermophilic glycosyl hydrolase.[8] NUTech's proposed construction requires that the claimed enzyme and plant substrate be located inside the same cell in tissue of the transformed plant. NUTech essentially argues that the phrase "localized with the substrate" denotes a spatial relationship between the enzyme and the plant substrate. The Defendants argue that the enzyme must act on the substrate to convert it. Thus, according to Defendants, "localized with the substrate" means the glycosyl hydrolase is located with access to the substrate, so that it is capable of acting upon it. Defendants argue that under NUTech's proposed construction, an enzyme could be located within the same cell but in different cell compartments. In such a situation, the enzyme would not have access to the substrate, and the conversion would not occur. NUTech argues that the requirements were not so narrow, and distinguishing between the prior art only required that the enzyme and substrate be located in the same cell.

[8] The Court agrees with Defendants that the phrase "in the tissue of the plant" does not need to be construed.

The Court concludes that the Claim language and the specification are at least ambiguous,[9] and the prosecution history informs the proper construction of the phrase ""wherein the glycosyl hydrolase is localized with the substrate." The parties' dispute focuses in large part on Dr. Blum's attempts to distinguish his invention from the prior art. According to Dr. Blum, the Pen Article "describes sequestering of [a] recombinant bacterial enzyme, extracellularly, by introducing a barrier between the transgene product and the substrate to restrict access of enzyme to plant starch and thereby avoid starch hydrolysis until the harvested seeds are combined with starch from another source and the mixture is homogenized." (Filing No. 86-5 at ECF 75-76.) The Pen Article explained that "[t]he enzyme was properly secreted into the intercellular space." (Filing No. 83-6 at ECF 2.) The Pen Article suggested that "[a]n even more promising approach may be the sequestered localization of an industrial enzyme in a crop where the substrate is also present, thus creating a potential bioconversion. This obviates the need for down-stream processing of the enzymes completely." (*Id*. at ECF 5 (internal marks omitted).) An example of this "promising approach" was "the expression of an

[9] Defendants argue that none of the experiments described in the '592 Patent indicates whether the glycosyl hydrolase and substrate were located in the same cell. However, the specification does indicate that the "hyperthermophilic glycosyl hydrolases" used in the claimed method "are inactive at temperatures supporting plant growth and therefore do not significantly interfere with the normal metabolism in the living plant." (Filing No. 1-1 at 2:60-63, ECF 20.) Thus, according to Defendant, the specification supports a conclusion that "localization" refers to the enzyme's ability to act upon the substrate.

NUTech argues the specification and the preferred embodiment support its construction. Specifically, NUTech argues that Example 5 references enzymes that were not secreted outside the cell, nor were they directed to any particular organelle within the cell, and thus had to be located within the cytoplasm of a plant cell. (*See Id*. at 23:3-24:9, ECF 31; Filing No. 99 at ECF 30-31.) NUTech further explains that the substrates contemplated by the '592 Patent include starch, and starch is a substrate located within a membrane-bound organelle inside a cell called an amyloplast. (*Id*. at ECF 31.) Thus, NUTech claims, the enzymes in Exhibit 5 and the characteristics of starch demonstrate that they are located inside the same cell, but that the amyloplast membrane separates the starch from the cytoplasm.

extracellular [alpha]-amylase in potatoes or corn used for starch production." (*Id*.) Thus, "[s]ince enzyme and substrate are present in different cellular compartments, no degradation of the substrate occurs during growth. The enzymatic reaction is initiated during processing of the crop, when by homogenization the enzyme and the substrate are brought together." (*Id*.)

The USPTO twice rejected Dr. Blum's patent application because it was not satisfied that Dr. Blum had distinguished the prior art as described in the Pen Article. In Dr. Blum's first attempt to distinguish the prior art, he explained that "[t]he method of the present invention . . . bypasses the need to sequester the enzyme outside the cell (the method described by Penn et al.) or otherwise use regulated plant promoters in order to avoid toxicity." (Filing No. 83-5 at ECF 19.) On May 14, 2001, the USPTO Examiner responded that:

> While it is agreed that Pen et al. refers to a sequestered localization of a glycosyl hydrolase, such as amylase in the plant, instant claims do not specifically require nonsequestered localization of the transgenic enzyme in the plant. The above claims are directed to a method irrespective of the localization of the transgenic enzyme in the plant. The above claims are directed to a method of converting endogenous plant substrate wherein said plant is transformed with a recombinant thermophilic enzyme. Thus the transformed plant may or may not have a sequestered localization of the enzyme. Absent any specific indication in the claims regarding nonsequestration of the enzyme in the plant, Pen et al. reference makes the above invention obvious. Hence the above rejection is maintained.

(Filing No. 83-5 at ECF 34-35.)

In other words, the USPTO Examiner did not disapprove of Dr. Blum's interpretation of the prior art, but neither was the Examiner satisfied that the claims specified nonsequestration. Dr. Blum acquiesced to the Examiner by explicitly amending the claim to specify localization of the enzyme with the plant substrate. Dr.

Blum's amendment included the phrase "wherein the glycosyl hydrolase is localized with the substrate in tissue of the plant." (Filing No. 83-5 at ECF 41.) The USPTO accepted Dr. Blum's amendment and allowed the Claim. (*Id*. at ECF 50.)

Dr. Blum's negotiation with the USPTO Examiner is telling in construing the disputed phrase. *See Phillips*, 415 F.3d at 1317 (stating that "the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.") The Court understands the Pen Article's reference to "extracellular" and "intercellular" space to mean outside a cell or between cells. This conclusion is supported by Dr. Blum's explanation to the USPTO Examiner of his understanding of the Pen Article. The Pen Article described a "promising approach" of placing the alpha-amylase extracellularly. (Filing No. 83-6 at ECF 5.) In contrast, Dr. Blum explained that his invention bypassed the need to sequester the enzyme outside the cell. The USPTO did not take issue with Dr. Blum's understanding of the prior art and specifically stated that it was agreed that the approach from the Pen Article "refers to a sequestered localization of a glycosyl hydrolase." (Filing No. 83-5 at ECF 34-35.) Thus, the USPTO implicitly agreed that the sequestration referred to was sequestration outside the cell, and required that Dr. Blum specify nonsequestration in the claims. Accordingly, it is reasonable that the sequestration refers to cellular location, and there is no indication that the term must be limited further. Based on the specification as instructed by the prosecution history, the Court construes the term "wherein the glycosyl hydrolase is localized with the substrate

in tissue of the plant" to mean "wherein the glycosyl hydrolase and substrate of the transformed plant are located inside the same cell."

IV. Claim 9: "heated at a temperature between about 65° C and about 85° C"

Plaintiff NUTech	Defs
"heated at a temperature between approximately 65° C and approximately 85° C"	"heated at a temperature above about 65° C and not exceeding about 85° C"

The Court concludes that the final term in dispute need not be construed. As stated above, claim construction is "a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement. It is not an obligatory exercise in redundancy." *U.S. Surgical Corp.,* 103 F.3d at 1568. "[A] sound claim construction need not always purge every shred of ambiguity. The resolution of some line-drawing problems . . . is properly left to the trier of fact." *Acumed*, 483 F.3d at 806. The disputed temperature range is not terse or technical claim language essential to assist a trier of fact in understanding the technical scope of the claims. *See Terlep,* 418 F.3d at 1382. Accordingly, the Court will not construe the term ""heated at a temperature between about 65° C and about 85° C."

CONCLUSION

The Court has construed the terms "hyperthermophilic glycosyl hydrolase," "said substrate comprises extract of plant transformed with said recombinant hyperthermophilic glycosyl hydrolase," and "wherein the glycosyl hydrolase is localized with the substrate," appearing in Claim 1 of the '592 Patent. For the reasons discussed, the Court has generally adopted the construction proposed by NUTech for each of these terms. the Court

will not construe the term ""heated at a temperature between about 65° C and about 85° C." Accordingly,

IT IS ORDERED:

1. The Court construes the term "hyperthermophilic glycosyl hydrolase," appearing in Claim 1 of the '592 Patent, to mean "glycosyl hydrolase derived from organisms capable of growth above 70° C."
2. The Court construes the term "said substrate comprises extract of plant transformed with said recombinant hyperthermophilic glycosyl hydrolase," appearing in Claim 1 of the '592 Patent, to mean "the plant substrate includes extract of plant that has been transformed with the recombinant hyperthermophilic glycosyl hydrolase."
3. The Court construes the term "wherein the glycosyl hydrolase is localized with the substrate in tissue of the plant," appearing in Claim 1 of the '592 Patent, to mean "wherein the glycosyl hydrolase and substrate of the transformed plant are located inside the same cell."

Dated this 22nd day of November, 2013.

BY THE COURT:

s/Laurie Smith Camp
Chief United States District Judge