

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

**MGP INGREDIENTS, INC.,**

**Plaintiff,**

**v.**

**Case No. 06-2318-JWL**

**MARS, INCORPORATED and  
S&M NUTEC, LLC,**

**Defendants.**

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**MEMORANDUM AND ORDER**

This lawsuit involves the popular Greenies® chew for dogs, which has been sold for years by defendant S&M NuTec LLC (SMN) using, until recently, a formulation containing confidential ingredients supplied by plaintiff MGP Ingredients (MGPI). In April of 2006, defendant Mars, Incorporated (Mars) acquired SMN and developed a purportedly new formulation. MGPI alleges that, in doing so, defendants infringed on MGPI's Greenies® formulation patent, Mars tortiously interfered with MGPI's supply agreement with SMN and their continued business relationship, defendants misappropriated MGPI's trade secrets, and SMN breached its various business contracts with MGPI. MGPI seeks injunctive relief and damages.

This matter is currently before the court in relation to MGPI's patent infringement claim. MGPI owns United States Patent No. 5,665,152 ("the '152 Patent"), which discloses and claims methods of forming grain protein-based articles. The parties have requested that

the court construe certain terms contained in claims 1 and 24 of the ‘152 Patent as a matter of law pursuant to *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995) (en banc), *aff’d*, 517 U.S. 370 (1996). The court has thoroughly considered the information submitted in the parties’ briefs as well as the oral arguments presented at the *Markman* hearing on June 25, 2007, and the court is now prepared to construe the disputed language in claims 1 and 24 of the ‘152 Patent. As a matter of law, the court determines that those claims have meaning and scope as set forth below.

### **LEGAL STANDARDS FOR CLAIM CONSTRUCTION**

Claim construction is governed by the methodology set forth by the Federal Circuit in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc), *cert. denied*, 126 S. Ct. 1332 (2006). It is a bedrock principle of patent law that the claims of the patent define the patentee’s invention. *Id.* at 1312. Thus, claim construction begins with the words of the claim itself. *Id.* The words of a claim should be given their ordinary and customary meaning as understood by a person of ordinary skill in the art in question at the time of the invention. *Id.* at 1312-13. “[T]he claims themselves provide substantial guidance as to the meaning of particular claim terms.” *Id.* at 1314. Both “the context in which a term is used in the asserted claim” and the “[o]ther claims of the patent in question” are useful for understanding the ordinary meaning. *Id.*

The claims do not stand alone, but are part of “a fully integrated written instrument.” *Id.* at 1315. Therefore, they “must be read in view of the specification, of which they are a

part.” *Id.* (quotation omitted). In fact, the specification is “the single best guide to the meaning of a disputed term” and is often dispositive. *Id.* The specification may reveal a special definition given to a claim term, or may reveal the inventor’s intentional disclaimer or disavowal of claim scope. *Id.* at 1316. In both instances, the specification serves to express the correct claim scope as dictated by the inventor. *Id.* The fact that the specification includes limited and specific embodiments is insufficient to define a term implicitly, and it is improper to confine the scope of the claims to the embodiments of the specification. *Id.* at 1323. “The construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.” *Id.* at 1316 (quotation omitted).

The court should also consult the patent’s prosecution history, if in evidence. *Id.* at 1317. Like the specification, the prosecution history “provides evidence of how the PTO and the inventor understood the patent.” *Id.* “Yet because the prosecution 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.” *Id.*

Finally, the court may consult extrinsic evidence such as expert and inventor testimony, dictionaries, and learned treatises. *Id.* These have all been recognized as tools that can assist the court in determining the meaning of particular terminology. *Id.* at 1318. Extrinsic evidence may be helpful to the court in understanding the technology or educating itself about the invention. *Id.* In particular, because technical dictionaries collect accepted

meanings for terms in various scientific and technical fields, they can be useful in claim construction by providing the court with a better understanding of the underlying technology and the way in which one skilled in the art might use the claim terms. *Id.* at 1318. “However, conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court.” *Id.* Extrinsic evidence is less reliable than intrinsic evidence in determining the construction of claim terms, and therefore the court should discount any expert evidence that is at odds with the intrinsic evidence. *Id.*

## DISCUSSION

The Abstract of the ‘152 Patent generally discloses a method of forming solid, non-edible biodegradable, grain protein-based articles. A formulation containing grain protein, starch, water, plasticizer, and reducing agents is heated to create a substantially homogeneous and flowable mixture which can be formed into biodegradable articles. The formulations can be processed in extrusion or injection molding equipment to create solid articles.

The disputed claim terms are set forth in claims 1 and 24 of the ‘152 Patent, both of which are independent claims. Those claims state as follows, with the disputed claim language underlined:

1. A method of forming a biodegradable article comprising the steps of:

[i] providing a formulation comprising from about 20-85% by weight of grain protein, from about 5-75% by weight starch, from about 10-40% by weight plasticizer and at least about 0.01% by weight of a reducing agent operable for cleaving disulfide bonds present in said grain protein; and

[ii] heating said formulation to a maximum temperature of up to about 80° in order to render the formulation substantially homogenous and flowable while avoiding any substantial heat denaturation of said grain protein; and

[iii] molding said heated formulation into a biodegradable article, including the step of substantially denaturing said grain protein during said molding.

....

**24.** A method of forming protein-containing pellets which can be used in injection molding equipment for the production of biodegradable articles, that method comprising the steps of:

[i] providing a formulation comprising from about 20-85% by weight of grain protein, from about 5-75% by weight starch, from about 10-40% by weight plasticizer and at least about 0.01% by weight of a reducing agent operable for cleaving disulfide bonds present in said grain protein; and

[ii] heating said formulation and forming said pellets by extrusion, said heating step being carried out so that the formulation heated to a maximum temperature of up to about 80° C. in the extruder in order to render the formulation substantially homogeneous and flowable, with the avoidance of any substantial heat denaturation of said grain protein in said pellets.

**A. “Biodegradable Article[s]”**

Defendants ask the court to construe the claim term “biodegradable article[s]” to mean *non-edible biodegradable articles*. They contend that this meaning is warranted by the specification language which establishes that the inventors expressly described their invention as a process for making non-edible articles, and also because the inventors added this language to the patent specification during patent prosecution in order to evade the prior art. MGPI, on the other hand, contends that defendants’ proposed meaning is unsupported by the plain language of the claim and, furthermore, that even if the court were to import non-edible into this claim term, the court should further construe the term non-edible to mean *non-edible by humans*.

## 1. Claim Language and Language Contained in the Specification

The court begins with the words used in the claims themselves. Claims 1 and 24 disclose “biodegradable article[s]” without any reference to whether those articles are edible or non-edible. Defendants point out that the patent Abstract discloses “[a] method of forming solid, *non-edible* biodegradable, grain protein-based articles.” <sup>152</sup> Patent, Abstract (emphasis added). The Field of the Invention states that “[t]he present invention is broadly concerned with a method of forming solid, *non-edible* biodegradable articles such as eating utensils, cups, plates, sheet items, packaging, and other convenience products.” *Id.* col. 1, ll. 10-13 (emphasis added). The Description of the Prior Art explains that “[p]etroleum-based synthetic resins have achieved widespread use in the fabrication of a multitude of products . . . such as eating utensils and cups,” *id.* col. 1, ll. 25-28, and acknowledges “a growing concern about the indiscriminate use of petroleum-based synthetic resins, and their accumulation in the environment.” *Id.* col. 1, ll. 33-35. The Summary of the Invention states that “[t]he present invention overcomes the problems outlined above and provides an improved method of forming biodegradable *non-edible* solid articles using essentially completely biodegradable starting materials and avoiding petroleum-based synthetic resin.” *Id.* col. 2, ll. 23-27 (emphasis added). The Preferred Embodiment discusses “solid biodegradable articles” without referring to those articles as non-edible, but it gives an example of a formulation for non-edible items. *Id.* col. 5, at ll. 7-8 (“injection molding of large, flat annular washers”).

The claim terms (which do not contain the “non-edible” limitation) must of course be read in view of the specification (which does). *See Phillips*, 415 F.3d at 1315. But, at the same time, the Federal Circuit has repeatedly warned against importing limitations from the specification into the claims. *Anderson Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1373 (Fed. Cir. 2007); *Varco, L.P. v. Pason Sys. USA Corp.*, 436 F.3d 1368, 1373 (Fed. Cir. 2006); *CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1231 (Fed. Cir. 2005). Recognizing that the distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be a difficult one to apply in practice, *Phillips*, 415 F.3d at 1323; *see also Anderson Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1373 (Fed. Cir. 2007) (“We have . . . recognized the difficulty faced by district courts in trying to walk that tightrope.”), the Federal Circuit has instructed courts to remain focused on “understanding how a person of ordinary skill in the art would understand the claim terms.” *Phillips*, 415 F.3d at 1323. “To avoid importing limitations from the specification into the claims, it is important to keep in mind that the purposes of the specification are to teach and enable those of skill in the art to make and use the invention and to provide a best mode for doing so.” *Id.* 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. *Id.* at 1316. “In other cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor. In that instance as well, the inventor has dictated the correct claim scope, and the inventor’s intention, as expressed in the specification, is regarded as dispositive.” *Id.*

Here, defendants are arguing that MGPI's inventors expressly described their invention as a process for making non-edible articles, disclaiming the use of the claimed process for manufacturing edible items. An inventor's intent to disclaim or disavow the broad scope of a claim must be clear from the specification. *Conoco, Inc. v. Energy & Env'tl. Int'l, L.C.*, 460 F.3d 1349, 1347 (Fed. Cir. 2006). Absent a clear disavowal of claim scope, the patentee is entitled to the full scope of its claim language. *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004). "A patentee may claim an invention broadly and expect enforcement of the full scope of that language absent a clear disavowal or contrary definition in the specification." *Id.*

After careful consideration of the intrinsic record, the court is unpersuaded that the "non-edible" language in the specification of the '152 Patent represents a clear disavowal of the full scope of the claim language. To be sure, the specification's references to "the present invention" as a method of forming articles that are, among other things, "non-edible" are some evidence that the term "non-edible" applies to the invention as a whole. *See Honeywell Int'l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1318 (Fed. Cir. 2006) (claim term "fuel injection system component" was limited to a fuel filter where, among other things, the written description referred to the fuel filter as "this invention" or "the present invention" on at least four occasions); *cf. SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1343 (Fed. Cir. 2001) ("[T]he characterization of the coaxial configuration as part of the 'present invention' is strong evidence that the claims should not be read to encompass the opposite structure."). But, the specification of the '152 Patent does not contain any



additional language that leads the court to believe that the inventors intended to disclaim biodegradable articles produced by the claimed methods simply because those items might happen to be edible. The specification refers to the biodegradable articles with various additional adjectives throughout the specification: the Abstract refers to them as also solid, non-edible, and grain protein-based; the Field of the Invention refers to them as solid and non-edible; the Summary of the Invention refers to them as non-edible and solid; and the Description of the Preferred Embodiment refers to them as nothing more than “solid,” entirely omitting any reference to “non-edible.” Thus, the term “non-edible” is not consistently included throughout the specification. Moreover, despite the fact that the specification describes the articles formed by the patented method as biodegradable, solid, non-edible, and grain protein-based, the inventors notably chose to include in the claim language itself nothing more than the “biodegradable” limitation. *See Ventana Med. Sys., Inc. v. Biogenex Labs., Inc.*, 473 F.3d 1173, 1181-82 (Fed. Cir. 2006) (“When the claim addresses only some of the features disclosed in the specification, it is improper to limit the claim to other, unclaimed features.”).

In support of defendants’ argument in reliance on the language contained in the specification they rely on *Honeywell International, Inc.*, 452 F.3d at 1312, in which the Federal Circuit held that the claim term “fuel injection system component” was limited to a “fuel filter” because the written description used language that led to the conclusion that a fuel filter was the only fuel injection system component that the claims cover. *Id.* at 1318. In that case, the written description referred to the fuel filter as “this invention” or “the

present invention” on four occasions. *Id.* Additionally, the fuel filter was the only component of an electronic fuel injection system that the written description disclosed as having a polymer housing with electronically conductive fibers interlaced therein; the only other fuel component specifically mentioned in the written description, the fuel line, was not required to be made of an electrically conductive polymer material, as the claims required; and the prior art problem addressed by the patented invention was leakage of non-metal fuel filters in electronic fuel injection systems. *Id.*

The applicability of the specification language to the meaning of the claim term “biodegradable” in this case is distinguishable from the specification language at issue in *Honeywell*. In *Honeywell*, the court was confronted with the task of construing the claim language “fuel injection system component,” the meaning of which was unclear from the ordinary and customary meaning of the words used in the claim itself. Thus, the court was entitled to use the specification to resolve the ambiguity concerning the meaning of that claim term. *See Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1326 (Fed. Cir. 2002) (“The specification may assist in resolving ambiguity where the ordinary and accustomed meaning of the words used in the claims lack sufficient clarity to permit the scope of the claim to be ascertained from the words alone.”). But, without a claim term that is susceptible of clarification by the written description, there is no legitimate way to narrow the property right. *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1310 (Fed. Cir. 2005). Thus, “it is manifest that a claim must explicitly recite a term in need of definition before a definition may enter the claim from the written description.” *Renishaw PLC v. Marposs*

*Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998). Here, defendants are not really asking the court to resolve an ambiguity concerning or to clarify the meaning of the claim term “biodegradable.” Instead, they are asking the court to construe the claim language, which says nothing about whether the subject article is edible, based on the extraneous concept of non-edibility as derived from the specification. In asking the court to construe the claim to mean only non-edible articles, defendants are not really asking the court to construe the meaning of any term already existing in the claim, but rather to add a new claim limitation. “That claims are interpreted in light of the specification does not mean that everything expressed in the specification must be read into all the claims.” *Teleflex, Inc.*, 299 F.3d at 1326 (quotation omitted).

To illustrate this point, if the court were to construe the term “biodegradable articles” to be limited to “*non-edible* biodegradable articles,” the court would further have to determine what is meant by “non-edible,” a term which is not even included in the claim language itself. To put the matter in context, this case is about dog chews. If the court were to construe the patented invention to claim a method of forming non-edible items, such a claim construction would not assist with resolution of the parties’ dispute in this lawsuit in the absence of a further determination about whether the term non-edible means non-edible to humans and/or non-edible to dogs. This demonstrates that such a claim construction would be more akin to improperly importing an additional limitation from the specification than it would be to using the specification to interpret the meaning of an existing claim term,

as it would import an entirely new concept into the claim language that is separate and distinct from the concept of biodegradability.

Defendants also rely on the case of *SciMed Life Systems, Inc.*, 242 F.3d at 1337. There, the specification led to the “inescapable conclusion” that the references in the asserted claims to an inflation lumen “separate from” the guide wire lumen must be understood as referring to coaxial lumens rather than side-by-side lumens. *Id.* at 1342. Additionally, the patents distinguished the prior art in part on the ground that it used a disadvantageous dual lumen structure and pointed out the advantages of the coaxial lumens. *Id.* at 1343. The specification described a sleeve structure (for coaxial lumens) and stated that it “is the basic sleeve structure for *all embodiments of the present invention contemplated and disclosed herein.*” *Id.* at 1343 (quoting the patents at issue). The court held that the words “all embodiments of the present invention” broadly and unequivocally made the point that the coaxial lumen configuration was a necessary element of every variant of the claimed invention. *Id.* at 1344; *see also Microsoft Corp. v. Multi-Tech Systems, Inc.*, 357 F.3d 1340, 1348 (Fed. Cir. 2004) (specification led to the “inescapable conclusion” that communications must occur over a telephone line rather than a packet-switched network such as the Internet).

Unlike in *SciMed*, in this case the ‘152 Patent specification contains no such broad and unequivocal language which leads to the inescapable conclusion that the claims should be construed to disclaim edible articles. Mindful that the purpose of the specification is to teach and enable those of skill in the art to make and use the invention and to provide a best mode for doing so, the court believes that one of ordinary skill in the art would understand

that the specification's reference to "non-edible" articles derives from the historical context of the invention. The invention is broadly concerned with an improved method for forming biodegradable articles by avoiding petroleum-based synthetic resins due to problems associated with accumulation of synthetic resins in the environment. The Description of the Prior Art explains that this formerly included non-biodegradable items made from synthetic resins such as eating utensils, cups, plates, and the like. Hence, one of ordinary skill in the art would understand the novelty of the invention to be concerned with a method of forming those types of items so that they are biodegradable. Just because the invention seeks to cure a problem which has historically been associated with such non-edible items does not, however, mean that one of ordinary skill in the art would necessarily interpret the method to exclude the formation of biodegradable items which also happen to be edible. Simply put, the specification would not lead one of ordinary skill in the art to the "inescapable conclusion" that claims 1 and 24 of the '152 Patent exclude methods of forming articles which are edible. In the absence of a clear disavowal of claim scope coverage, then, MGPI is entitled to the full scope of its claim language.

## **2. Prosecution History**

Defendants further contend that limiting the claims to non-edible items is warranted by the prosecution history. "[T]he prosecution history may not be used to infer the intentional narrowing of a claim absent the applicant's clear disavowal of claim coverage." *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004) (quotation omitted); *accord Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1306 (Fed. Cir.

2003). “To be given effect, such a disclaimer must be clear and unmistakable.” *Sunrace Roots*, 336 F.3d at 1306 (quotation omitted); *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325-26 (Fed. Cir. 2003) (the alleged disavowing actions or statements made during prosecution must be both clear and unmistakable).

Here, there is no such clear and unmistakable disavowal of claim scope in the prosecution history. The court has carefully reviewed the relevant prosecution history. Claims 1 and 24 were initially rejected as being anticipated by Mullen. The PTO interview summary notes that they discussed Mullen as the prior art; that “[p]rior art products have gone through denaturation in the extruder”; that “Mullen discloses extruder temperatures/conditions that would denature the product”; and that it was agreed that the inventors of the ‘152 Patent would file a continuation-in-part (C-I-P) patent application “to enhance description of Process of claim one . . . to include step of denaturation of article in mold.” When the PTO ultimately allowed the claims, the stated reasons for allowance were that the prior art “fails to teach or suggest the improvement wherein the grain protein article is denatured only in the molding step.” Thus, the prosecution history reveals that the amendments made to distinguish over Mullen were concerned with denaturation of the grain protein during step [iii] of the claimed method.

Defendants point out that in response to the PTO’s concerns regarding the prior art Mullen patent, in the C-I-P application the inventors inserted the “non-edible” language cited above in the ‘152 Patent specification. Additionally, the remarks to the C-I-P application explain that “[t]he present invention is directed to a method of forming solid, non-edible

biodegradable articles such as eating utensils, sheet items and packaging using grain protein-based formulations.” As defendants point out, the abstract of the Mullen patent refers to edible sausage casings. Specifically, it states as follows: “Films are formed by extruding plastic masses containing particulate silica or silicate and derived from non-heat coagulable simple proteins. The films find value as edible packaging materials and in the form of casings are useful in sausage making and the like.” U.S. Patent No. 3,615,715 to Mullen, Abstract. Notwithstanding this statement in the Mullen abstract, however, it does not appear from the remainder of the written description in the Mullen patent that the invention disclosed by Mullen is necessarily limited to edible materials. Nor is there anything else in the prosecution history of the ‘152 Patent which establishes that the inventors clearly and unmistakably disclaimed edible materials from the scope of the claims. As MGPI points out, although this issue was arguably “teed up” during patent prosecution by virtue of the inventors adding the “non-edible” language to the written description, the inventors did not add this language to the claims and the examiner did not require them to do so in order to evade the prior art. The remarks to the C-I-P application are no more informative than the non-edible language contained in the written specification. In fact, the overall thrust of the remarks appears to be explaining how the step [iii] denaturation limitation was added to distinguish over Mullen. In sum, the prosecution history is ambiguous, at best, concerning why the “non-edible” language was added to the ‘152 Patent specification; it certainly does not support the notion that it was added to the written description to distinguish over Mullen. *See Mars, Inc. v. H.J. Heinz Co., L.P.*, 377 F.3d 1369, 1377 (Fed. Cir. 2004) (“It is

inappropriate to limit a broad definition of a claim term based on prosecution history that is itself ambiguous.” (quotation omitted)). Thus, it would be improper to limit the scope of the claim based on this ambiguous prosecution history.

### **3. Extrinsic Evidence**

Defendants also rely on the opinion of their expert, E. Allen Foegeding, Ph.D., that a person of ordinary skill in the art would understand the term “biodegradable articles” to mean non-edible items. Dr. Foegeding explained in his deposition that “we don’t put the qualifications of ‘biodegradable’ on our biological materials that we eat.” Foegeding Depo. at 79:7-8. He opines that, consequently, the term “biodegradable articles” would be understood to be non-edible, non-food items that will eventually end up in the environment. The court discounts the significance of this extrinsic evidence, as it is far less reliable than the intrinsic evidence which is a matter of public record. Furthermore, his opinion is at odds with the intrinsic evidence as well as the ordinary and customary meaning of the word biodegradable, which is generally associated with the extent to which an item will decompose, not whether the item is edible.

Accordingly, the court rejects defendants’ argument that the claim term “biodegradable article” should be limited to non-edible articles. The court finds that the claim terms “biodegradable article[s]” require no further claim construction.

### **B. Extent to Which the Grain Protein is Denatured**



Defendants’ next proposed claim construction relates to claim language concerning denaturation of the grain protein. They contend that the court should construe the claim term “grain protein” used as the starting material in step [i] of the claimed method to mean *substantially undenatured* and, furthermore, construe substantially undenatured in this context to mean *less than about 10% by weight denaturation of said protein*; construe the claim language in step [ii] “while avoiding any substantial heat denaturation of grain protein” to mean *less than about 10% by weight denaturation* of the previously substantially undenatured grain protein; and construe the claim language in step [iii] “substantially denaturing said grain protein” to mean *the previously substantially undenatured grain protein is denatured such that there is less than about 10% by weight undenatured protein remaining*. MGPI objects to this proposed claim construction on the grounds that it ignores the multifaceted nature of protein denaturation. Specifically, MGPI explains that the claims refer explicitly only to the use of heat denaturation, whereas there are many other types of protein denaturation such as shear,<sup>1</sup> hydrostatic pressure, and chemicals (e.g., extreme pH values, organic solvents and solutes, detergents, etc.). Thus, the parties’ point of disagreement on this issue concerns when, and to what extent, the grain protein is denatured during the steps of the claimed method.<sup>2</sup>

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<sup>1</sup> Shear refers to shaking, kneading, whipping, and the like. Food Chemistry 362 (Owen R. Fennema ed., 3d ed. 1996) (“High mechanical shear generated by shaking, kneading, whipping, etc. can cause denaturation of proteins.”).

<sup>2</sup> Denaturation is a one-way street: undenatured protein can be denatured, but once denatured it cannot be un-denatured to return to its native state.

Claim 1<sup>3</sup> provides, in relevant part, as follows:

A method of forming a biodegradable article comprising the steps of:

[i] providing a formulation comprising from about 20-85% by weight of grain protein . . . and at least about 0.01% by weight of a reducing agent operable for cleaving disulfide bonds present in said grain protein; and

[ii] heating said formulation . . . in order to render the formulation substantially homogeneous and flowable while avoiding any substantial heat denaturation of said grain protein; and

[iii] molding said heated formulation . . . , including the step of substantially denaturing said grain protein during said molding.

‘152 Patent, col. 5, ll. 55-67 to col. 6, ll. 1-3 (emphasis added). The prosecution history establishes that the underlined language was added to distinguish the method claimed in the ‘152 Patent over Mullen. The reasons for allowance state that the prior art (i.e., Mullen) “fails to teach or suggest the improvement wherein the grain protein article is denatured only in the molding step.”

Defendants also direct the court’s attention to language in the specification which speaks to the issue of denaturation of the grain protein. One of the paragraphs in the Description of the Prior Art states as follows:

Grain proteins normally exhibit better moisture resistance than starch, but exhibit significant processing problems such as altered rheology and flow characteristics, especially under conditions of heat denaturation. As a consequence, it can be very difficult to economically process grain protein-based plastics using conventional extrusion and injection molding equipment. These problems are believed to stem in part from the highly branched and

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<sup>3</sup>The parties seem to agree that although step [iii] is expressly included in claim 1 and not claim 24, it may be included in claim 24 because (1) that claim is a “comprising claim,” which means that other steps may be added, and (2) claim 45, which is dependent on claim 24, expressly adds step [iii].

networked structure of grain proteins and their ease of denaturation under normal processing temperatures.

‘152 Patent, col. 1, ll. 67 to col. 2, ll. 9. The Summary of the Invention set forth in the ‘152

Patent continues to address this issue:

Broadly speaking, the method of the invention first comprises the step of providing a formulation especially designed to have flow and rheology properties allowing the formulation to be processed using conventional plastics forming equipment. This formulation is then heated under moderate temperature conditions, usually with shear, to create a substantially homogeneous and flowable formulation. The heated formulation can then be formed into desired articles using injection molding, extrusion or other forming equipment. Very importantly, the formulation is prepared as a substantially homogeneous and flowable product with the avoidance of any substantial heat denaturation of the grain protein (normally less than about 10% by weight denaturation of such protein). Thereafter, during the formation of the desired articles, the substantially undenatured protein is denatured. Thus in the context of injection molding, the preferred temperature conditions of molding assure essentially complete protein denaturation.

*Id.* at col. 2, ll. 28-46 (emphasis added). The language underlined above was added during the prosecution history in connection with the narrowing amendment to distinguish over Mullen. Defendants rely heavily on this specification language to support their claim interpretation.

MGPI contends that the claim language and the portion of the specification cited by defendants speak only in terms of *heat* denaturation, and that defendants have ignored the disclosure of denaturation by the addition of a reducing agent (i.e., a chemical) to the formulation introduced into the extruder as well as the fact that the specification also states that the formulation can be “heated under moderate temperature conditions, *usually with shear . . .*” ‘152 Patent, col. 2, ll. 33-35 (emphasis added). Plaintiffs contend that they made

the narrowing amendment to distinguish Mullen’s high temperatures, which had the practical effect of causing nearly complete heat denaturation in the extruder. They contend that under the ‘152 Patent the only type of “undesirable” denaturation in the extruder is the heat denaturation. MGPI relies on another excerpt from the Summary of Invention which states as follows:

Normally, the reducing agent is simply added to the other components of the formulation prior to or as a part of the extrusion process. Alternately, the reducing agent can be used to preliminarily treat the selected grain protein(s) prior to preparation of the starting formulation. . . . In any case, the reducing agent should be used in an amount to cleave from about 10-100% of the disulfide bonds in the grain protein.

*Id.* at col. 3, ll. 38-47. MGPI contends that this teaches that the grain protein may be pretreated with a reducing agent to denature the protein by severing up to 100% of its disulfide bonds.

After careful consideration of the parties’ arguments on this issue, the court largely agrees with plaintiffs’ characterization of the intrinsic record, which is essentially that the narrowing amendment was made to limit the claim such that the addition of any heat to the formulation in the extruder in step [ii] may be only moderate so as to avoid “substantial *heat* denaturation of said grain protein” (emphasis added), as stated by the claim language. Neither the claim language nor the specification addresses the possibility of denaturation by other means such as pressure or chemicals. The written description indicates that “the reducing agent can be used to preliminarily treat the selected grain protein(s) prior to preparation of the starting formulation.” Thus, this obviously permits the grain to be

denatured in step [i], at least to some extent, by methods other than heat. To the extent that the starting grain protein is denatured in step [i], step [ii] simply prohibits any further substantial denaturation by virtue of heat. In fact, the specification states that the reducing agent can be used to treat the grain protein (i.e., denaturation by using chemicals) prior to step [i]. Defendants infer based on this argument that because the specification states that a reducing agent should be used to cleave from about 10-100% of the disulfide bonds in the grain protein, MGPI is contending that completely denatured protein can be provided for use in the claimed formulation. The court does not understand MGPI to be advocating such a claim construction, however. Instead, the court understands MGPI's argument in this regard to be targeted to explaining why defendants' proposed claim construction is wrong—namely, because it fails to account for other factors which may denature the grain protein throughout the claimed method.

On the other hand, based largely on the “[v]ery importantly” excerpt from the specification added to distinguish over Mullen, the court does agree with defendants to the limited extent that the grain protein in step [i] must be substantially undenatured. But, the “very importantly” language added to the specification to distinguish over Mullen, again, was addressed only to preventing heat denaturation of the grain protein in the extruder, i.e., before step [iii]. Indeed, this tracks with step [ii] of the claim language, which states that the formulation must be heated to render the formulation substantially homogenous and flowable “while avoiding any substantial heat denaturation of said grain protein.” Thus, the court

construes the term “grain protein” in step [i] to mean *grain protein that has not been substantially denatured by heat*.

The remaining aspect of defendants’ proposed claim construction relates to importing the 10% limitation from the specification. It is well settled, however, that “when a claim term is expressed in a general descriptive word, the court will not ordinarily limit the term to a numerical range that may appear in the written description or in other claims.” *Conoco, Inc. v. Energy & Envtl. Int’l, L.C.*, 460 F.3d 1349, 1358 (Fed. Cir. 2006). This is particularly so where, as here, the patentee used numerical ranges and numbers throughout the claims of the patent and notably did not do so with respect to the degree of denaturation.<sup>4</sup> Accordingly, the court finds defendants’ argument in this respect to be without merit. The court, then, rejects defendants’ proposed claim construction concerning importing the less-than-10%-denaturation limitation from the specification. The court finds that the claim terms concerning denaturation of the grain protein require no further construction beyond construing the term “grain protein” in step [i] to mean *grain protein that has not been substantially denatured by heat*.

### **C. Starch**

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<sup>4</sup> Additionally, the parenthetical “(normally less than about 10% by weight denaturation of such protein)” once again follows a reference to “the avoidance of any substantial *heat* denaturation of the grain protein.” Thus, even if the court were to find the less than 10% by weight denaturation limitation to be warranted (which the court does not), that number would apply only to denaturation by virtue of heat, not other factors.

Defendants ask the court to construe the term “starch” in step [i] of the claimed method to mean *a carbohydrate that is granular in form, consisting of two polysaccharides (amylose and amylopectin), whether in native form or modified in order to improve the properties of starch, but the end products of starch hydrolysis are not “starch.”* In essence, defendants ask the court to exclude from the meaning of the term end-product starch hydrolysates, including the syrups and sugars resulting from the breaking down of starch granules and the polysaccharides that form those granules—in other words, any products of a hydrolysis process. To put the matter in context, defendants explain that they use a hydrogenated starch hydrolysate (or “HSH”) product that is a liquid combination of two simple sugar alcohol products (maltitol and sorbitol). Plaintiffs state that they do not dispute that products such as pure maltitol and sorbitol do not fall within the literal claim language, but that the starch in most commercial syrups (HSHs) is only partially hydrolyzed and therefore those syrups still constitute starch or starch equivalents. Thus, plaintiffs contend that the claim term “starch” must be construed, as it is broadly defined in the specification, to include all types of starch.

The court squarely rejects every aspect of defendants’ proposed claim construction. Defendants’ suggestion that the starch must be granular in form is contradicted by the specification. By way of background, starch occurs naturally as discrete particles, or granules. Food Chemistry 191 (Owen R. Fennema ed., 3d ed. 1996). In attempting to give meaning to the term “starch,” the specification states as follows:

[A] variety of starches could be used, such as those taken from the group consisting of corn, wheat, potato, and tapioca starches and mixtures thereof. The starches *can be native or modified by gelatinization or chemical treatment* (e.g., oxidized, acetylated, carboxymethyl, hydroxyethyl, hydroxy-propyl, high amylose, and alkyl-modified starches).

‘152 Patent, col. 2, ll. 66-67 to col. 3, ll. 1-5 (emphasis added). This specification gives meaning to the claim term “starch,” broadly including within its breadth not only native starch, but also starches modified by chemical treatment. Additionally, a starch need not consist of two polysaccharides (amylose and amylopectin), as plaintiff’s counsel explained that there is at least one starch, a waxy maize corn, that exists in its native state that only has amylopectin, not amylose. Thus, excluding all starches which do not consist of two polysaccharides would exclude at least some native starches.

Defendants’ suggestion that all end products of hydrolysis should be excluded from the definition of “starch” is also without merit. Hydrolysis of starch occurs when the granules are depolymerized. Food Chemistry at 199. This generally involves the starch being chemically treated with acid, such as hydrochloric acid or hydrogen chloride gas, or enzymes. *Id.* at 199-200. Thus, the process of hydrolysis, which involves modifying a starch by chemical treatment, falls within the meaning of the claim term “starch.” Consequently, the court rejects defendants’ proposed claim definition that the claim term “starch” should be defined to exclude all end products of starch hydrolysis, as this definition is plainly inconsistent with the intrinsic record.

Beyond this, the parties do not provide the court with any further suggestion about how it should construe the claim term “starch.” A starch can be completely, or only partially,



hydrolyzed. *See generally id.* Plaintiff concedes that the starch hydrolysates maltitol and sorbitol, in their pure form, do not fall within the literal claim language. *See also* ‘152 Patent, col. 3, ll. 16-19 (listing sorbitol and maltitol as among the preferred class of plasticizers). But it is unclear from the record where sorbitol and maltitol fall along the hydrolysis spectrum. They may be starches which have been completely hydrolyzed, and therefore have ceased to be starches. In the absence of more meaningful evidence concerning the impact of hydrolysis and its relation to the various starches listed in the specification, the court will not endeavor to assign a different meaning to this claim term other than the one suggested by defendants, which the court rejects. The parties have presented no evidence from which the court could determine how a person of ordinary skill in the art would understand this claim term to define it more precisely. Thus, the court declines to give further meaning and scope to the claim term “starch,” other than as set forth in the specification. Accordingly, the court defines the claim term “starch” to mean *starch, whether native or modified by gelatinization or chemical treatment.*

**D. “About”**

Finally, the parties dispute the meaning of the term “about,” which is used by the ‘152 Patent to modify ingredient range limitations (“about” 5-75% starch) and temperature limitations (heating said formulation to a maximum temperature of “up to about 80°”). Defendants ask the court to construe the term from “about” 5-75% starch to mean *from 4.75% starch to 78.75% starch* and to construe the 80° limitation to mean *a temperature that*

*may approach, but not exceed, a maximum of 80 °C.* MGPI, on the other hand, contends that the starch limitation should be construed to mean *2-80% by weight starch* and that “to a maximum temperature of up to about 80°” limitation should be read out of step [ii] altogether such that the formulation is heated so as to render the formulation homogeneous and flowable while avoiding heat denaturation of said grain protein.

a. “About 5-75% by Weight Starch”

Defendants contend that the “about” 5-75% starch limitation should be construed by taking 5% of the end-points, which equals 4.75% to 78.75% starch. In support of this argument, they cite Dr. Foegeding’s testimony that a person of ordinary skill in the art would view the fact that a range has already been specified as including the essential levels of tolerance, and that “about” would be viewed by a person of ordinary skill to be in line with a 5% “rule of thumb” that is used in the normal course of practice by such a person and viewed as acceptable in an industrial situation.

MGPI contends that the court should disregard Dr. Foegeding’s opinion as to the meaning of “about” because it is merely a number he pulled out of thin air with no relation to the technology at issue. According to MGPI, defendants are improperly fixated on providing a precise numerical range. MGPI argues that “about” qualifies a range which depends on the formulation and other factors so long as the prime functional goal—a formulation homogeneous and flowable without substantial heat denaturation of the protein—is met. MGPI contends that the lower limit (5%) of the range would lie in the range

of 2% to 3% principally because it is advantageous at times to operate in that zone, and one skilled in the art of extrusion would expect the ‘152 Patent claims to cover that lower range.

The word “about” does not have a universal meaning in patent claims, as its meaning depends upon the technological facts of the case. *Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd.*, 476 F.3d 1321, 1326 (Fed. Cir. 2007). The use of the word “about” avoids a strict numerical boundary, and requires the court to interpret the range in its technological and stylistic context. *Central Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1354 (Fed. Cir. 2007). The court considers how the term was used in the patent specification, the prosecution history, and other claims. *Id.* It is appropriate to consider the effects of varying that parameter, for the inventor’s intended meaning is relevant. *Id.* Extrinsic evidence of meaning and usage in the art may be helpful in determining the criticality of the parameter. *Id.*

The intrinsic evidence points to a broad meaning of the term “about” in the “about 5-75% by weight starch” limitation. The claims themselves set forth broad ranges for the various components of the formulation. The formulation must include 20-85% grain protein, 5-75% starch, and 10-40% plasticizer. These amounts are set forth in essentially rounded numbers at 5% increments. This stands in stark contrast to the “at least about 0.01%” reducing agent, which indicates that the inventors deliberately chose not to be so precise about the relative quantity of the grain protein, starch, and plasticizer ingredients.

The specification also discusses the relative amounts of grain protein, starch, and plasticizer in 5% increments, and every one of those increments is qualified by the word

“about.” *See generally* ‘152 Patent, col. 2-3. For example, the specification refers to about 20-85% grain protein, and states that the formulation will “more preferably” include “from about 30-70% by weight grain protein.” *Id.* col. 2, ll. 49-50. It explains that the grain would normally be provided as a mixture, and when such mixtures are used, typically they would comprise “at least about 50% by weight of the desired grain protein, and more preferably at least about 75% by weight thereof.” *Id.* col. 2, ll. 60-62. As for starch, the specification states that the formulation should include “about 5-75% by weight starch, and more preferably from about 10-70% by weight thereof.” *Id.* col. 2, ll. 65-66. The fact that the preferred 10-70% range is stated more narrowly than the claimed range of about 5-75% indicates that the claimed range truly represents the outer range of the parameter.

Focusing on the principle that “the claims themselves provide substantial guidance as to the meaning of particular claim terms,” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc), *cert. denied*, 126 S. Ct. 1332 (2006), the court returns to the fact that the relative quantities of ingredients are stated in 5% increments. In order to give meaning to these chosen claim terms and their relative degree of precision, the word “about” should not be read to extend the range of the claim downward such that the stated percentage is closer to 0% than it is to 5%, nor should it be extended upward such that the stated percentage is closer to 80% than it is to 75%. The criticality of the claimed range to the invention requires that the claim not be construed so broadly. Accordingly, the court

construes the claim term “about 5-75% by weight starch” to mean *approximately*<sup>5</sup> 5-75% by weight starch, but not less than 2.5% by weight starch nor more than 77.5% by weight starch.

In reaching this conclusion, the court notes that it finds both parties’ expert opinions to be unhelpful in determining the criticality of the parameter. Dr. Foegeding explains that “about” implies a certain limited amount of tolerance of variance for the upper and lower points of the range, generally 5% or less of the endpoints. Thus, his 5% end-point rationale would require the court to construe the claim term to mean 4.75% starch to 78.75% starch. His rationale is that this 5% tolerance is “acceptable in an industrial situation.” Dr. Foegeding does not, however, explain how this 5% end-point sets forth a critical parameter given the relevant technology which is at issue in the ‘152 Patent. The opinion of plaintiff’s expert and the inventor, Dr. Bassi, is equally unhelpful. He proposes a tolerance of “very roughly 10-15% of the overall range.” But, this would not work because it would put the low end of the starch range close to zero. He proposes to remedy this by simply using half of the low end of the tolerance computation, which would make the outer limit of the low end 2%. Ultimately, it appears to the court that the experts have picked rather arbitrary numbers without assisting the court with understanding how a person of ordinary skill in the art would

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<sup>5</sup> “About” is synonymous with “approximately.” See Webster’s Third New International Dictionary, Unabridged 5 (1986); Roget’s II, The New Thesaurus 4 (1988); see, e.g., *Ortho-McNeil Pharm., Inc.*, 476 F.3d at 1328 (finding no error in the district court’s construction of the term “about 1:5” to mean “approximately 1:5, encompassing a range of ratios no greater than 1:3.6 to 1:7.1”).

understand the criticality of the stated parameters. Accordingly, the court construes this claim term, as stated above, based solely on the intrinsic evidence.

b. Heating . . . to a Maximum Temperature of Up To About 80°

Defendants contend that the heating in subparagraphs [ii] of claims 1 and 24 of the ‘152 Patent should be construed to mean *the temperature may approach, but not exceed, a maximum of 80 ° Celsius*. MGPI, on the other hand, argues that the “up to about 80°” limitation should be broadly construed in light of the claim language that the formulation is to be heated so as to render the formulation homogeneous and flowable while avoiding heat denaturation of the grain protein. MGPI’s argument is, essentially, that the court should disregard the 80° limitation entirely so long as this stated purpose of the heating step is accomplished.

Once again, the court begins with the claim language. Step [ii] of claims 1 and 24 require heating the formulation to a maximum temperature of up to about 80° “in order to render the formulation substantially homogeneous and flowable,” avoiding “any substantial heat denaturation of said grain protein.” ‘152 Patent, col. 5, ll. 64-66 & col. 7, ll. 34-36. The specification further explains as follows:

[I]t is important to maintain the temperature of the material within the extruder barrel below about 80° C. to avoid heat denaturation of the protein content of the formulation. . . .

. . . As in the case of extrusion processing, the melt temperature inside the barrel of the injection molder should be maintained to a level of up to about 80° C., and more preferably up to about 65° C. (indeed, it is preferred that the initial formulation and forming steps be carried out so that the formulation experiences a maximum temperature of about 65° C.).

‘152 Patent, Col. 4, ll. 9-13, 16-22 (emphasis added).

The language underlined above was added during patent prosecution in order to distinguish Mullen. The remarks to that amendment explain that “in the extrusion process of the present invention [i.e., step [ii] of the claimed method], time and temperature conditions are carefully maintained so as to avoid any substantial heat denaturation of the grain protein.” The temperature conditions disclosed in Mullen, however, are more predominantly concerned with the minimum temperatures for decomposing the protein which would seem to be more analogous with substantially denaturing the grain protein in step [iii] of the claimed method in the ‘152 Patent. For example, claim 1 of Mullen sets forth a process which includes, among other things, heating the composition to temperatures “of at least about 70° C.” ‘715 Patent, col. 9, ll. 9. Claim 13 discloses a process wherein “the plastic mass is heated to temperatures in the range of about 70° to 190° C.” *Id.* col. 10, ll. 10-11. The specification discusses the same temperatures, *id.* col. 7, ll. 2-3, and the preferred embodiments of the invention set forth temperatures within these parameters, *see generally id.* col. 8 (setting forth temperatures in the three zones of the extruder ranging from 90° in Zone 1 in each of the preferred embodiments, to 110°-125° in Zone II, to 143°-161° in Zone III). Thus, largely because the relevant temperatures disclosed in Mullen are more predominantly concerned with minimum temperatures for denaturing the protein in the extruder, referring to the temperatures set forth in Mullen is really not that helpful in determining a more precise parameter for the “up to about 80°” maximum parameter set forth in the ‘152 Patent.

Dr. Bassi testified in his deposition that denaturation may start at about 75° Celsius. He explained that as the temperature increases, the amount of denaturation is not linear, but rather is “logarithmic like an F16, just goes way up right away.” Bassi Depo. at 162:19-21. He further explained that complete denaturation would occur at at least 120° Celsius. At 88° Celsius, the protein would not be substantially denatured, but the denaturation would be substantial enough “to make a difference in the flow characteristics and its – and it being not very homogeneous.” *Id.* at 164:7-9. He explained that 80° is a guide, but “the most important part is also watching the characteristics of the extrudate.” *Id.* at 169:1-2.

An excerpt from the book Food Chemistry further explains the impact of temperature on denaturation of protein:

Thermal denaturation of monomeric globular proteins is mostly reversible. For example, when many monomeric enzymes are heated above their denaturation temperatures, or even briefly held at 100°C, and then are immediately cooled to room temperature, they fully regain their activities . . . However, thermal denaturation can become irreversible when the protein is heated at 90-100°C for a prolonged period even at a neutral pH.

Food Chemistry, *supra*, at 359.

This evidence clearly does not support defendants’ argument that the court should construe the claim term to impose an 80° cap. Their only evidence in support of that claim construction is Dr. Foegeding’s opinion that a person of ordinary skill in the art would understand that it is critical that the temperature not exceed 80° Celsius in order to maintain the grain protein of the formulation in substantially undenatured form. The court discounts Dr. Foegeding’s proposed 80° cap primarily because his opinion on this issue is too



conclusory and unsupported to assist the court in understanding the relevant technology or educate the court about the nature of the invention.

Viewing the “up to about 80°” limitation in light of the relevant technology, the criticality of this temperature parameter is to heat the formulation so that it is substantially homogeneous and flowable, while avoiding substantial heat denaturation of said protein. Mindful that various other factors can impact the rate and degree of denaturation as well as flow characteristics, the court believes that the claim term “up to about 80°” must be construed with some degree of flexibility. But, at the same time, this limitation must be given some force because the specification explains that the formulation should more preferably be heated to a lower temperature of only up to about 65°. The evidence indicates that heat denaturation can begin to occur as low as 75° and that the amount of denaturation goes up logarithmically thereafter, and that the protein would be denatured enough to make a difference in the composition of the extrudate at 88°. This suggests that the temperature of the formulation most certainly should not reach 88°. This temperature is consistent with other evidence which indicates that denaturation can become irreversible when the protein is heated at 90-100° for a prolonged period, and that the preferred embodiments set forth in Mullen disclose a low-end temperature of 90° in the first zone of the extruder. Thus, it appears that a person of ordinary skill in the art would likely recognize the temperature of 88° to be below the generally accepted temperatures where denaturation becomes substantial. In light of this record, then, the court believes that one of ordinary skill in the art would understand that the temperature of the formulation in step [ii] of the claimed method should

not reach 88°. The court wishes to emphasize that this temperature, of course, continues to be qualified by the remainder of the claim language that the formulation is heated so as to render it substantially homogeneous and flowable while avoiding substantial heat denaturation. Thus, the formulation could be heated beyond this point at a lower temperature. The court is only construing the claim limitation concerning the maximum temperature for heating the formulation in step [ii] of the claimed method. Accordingly, the court construes the claim term “up to about 80°” to mean *up to approximately 80 °, but not to reach 88 °*.

## CONCLUSION

In summary, the court construes the claim terms set forth below as follows:

1. “grain protein” in step [i] of the claimed method means *grain protein that has not been substantially denatured by heat*;
2. “starch” means *starch, whether native or modified by gelatinization or chemical treatment*;
3. “about 5-75% by weight starch” means *approximately 5-75% by weight starch, but not less than 2.5% by weight starch nor more than 77.5% by weight starch*; and
4. “up to about 80°” means *up to approximately 80 °, but not to reach 88 °*.

The court concludes that the remainder of the disputed terms in claims 1 and 24 of the ‘152 Patent do not require further construction in order to determine their meaning and scope.

**IT IS THEREFORE ORDERED BY THE COURT** that claims 1 and 24 of the '152 patent have the meaning and scope set forth above.

**IT IS SO ORDERED** this 5th day of July, 2007.

s/ John W. Lungstrum  
John W. Lungstrum  
United States District Judge