

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
MARSHALL DIVISION**

ALLERGAN SALES, LLC, AND	§	
QUALICAPS CO., LTD.,	§	
	§	Case No. 2:15-CV-01471-JRG (Lead)
<i>Plaintiffs,</i>	§	
	§	
	§	
v.	§	
	§	
TEVA PHARMACEUTICALS USA, INC.;	§	
	§	
<i>Defendant.</i>	§	

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ALLERGAN SALES, LLC, AND	§	
QUALICAPS CO., LTD.,	§	
	§	Case No. 2:15-CV-01740-JRG (Member)
<i>Plaintiffs,</i>	§	
	§	
	§	
v.	§	
	§	
MYLAN PHARMACEUTICALS, INC.,	§	
MYLAN LABORATORIES LIMITED,	§	
AND MYLAN, INC.	§	
	§	
<i>Defendants.</i>	§	

**CLAIM CONSTRUCTION OPINION AND ORDER**

In these consolidated patent infringement lawsuits, Allergan Sales, LLC (“Allergan”) and Qualicaps Co., LTD. (“Qualicaps”) allege that Teva Pharmaceuticals USA, Inc. (“Teva”), Mylan Pharmaceuticals, Inc., Mylan Laboratories Limited, and Mylan, Inc. (collectively “Mylan”) are seeking FDA approval to market and sell a generic version of Allergan’s branded Delzicol drug product in violation of U.S. Patent No. 6,649,180 (“the ’180 patent”). Before the court is the matter of claim construction. The parties submitted technology tutorials and claim construction briefs, and the Court held a claim construction hearing on August 30, 2016.

## BACKGROUND

The '180 patent was filed April 13, 2000, issued November 18, 2003, and is scheduled to expire April 13, 2020. *See* '180 patent, Dkt. 1-2; 35 U.S.C. § 154(a)(2). The background of the patent describes problems with hard gelatin capsules used in the pharmaceutical and health food fields. *Id.* at 1:10-11. Gelatin capsules are films formed from gelatin, a plasticizer, opacifying agent, dye, pigment, and other ingredients. *Id.* at 1:12-14. The capsules are made by dipping a pin (or mold) into an aqueous solution of the capsule forming ingredients, drawing the pin out of solution, allowing the solution adhering to the pin to dry, and, once the solution forms a hard shell, separating the shell from the pin. *Id.* at 1:15-20; 4:54-5:4. The shell is then cut to size and mated with a complementary shell to form a capsule. *Id.* at 4:67-5:4.

Gelatin capsules made in this way are affected by residual water content. *Id.* at 1:21-34. A capsule with too little water is not flexible enough to withstand the stress encountered when the capsule is filled with drug. *Id.* at 1:22-24. Problems associated with too little water may worsen over time as a capsule dries and loses water during storage, resulting in contraction of the capsule. *Id.* at 1:24-26. A capsule may contract to the point where the shell cap disengages from the shell body. *Id.* To prevent these problems, maintaining a water content of about 13 to 15% by weight is optimal. *Id.* at 1:26-28.

Such a relatively high amount of water content limited the use of gelatin capsules to certain drugs. *Id.* at 1:28-35. A hygroscopic or water-absorbing drug, for example, would draw too much water from the capsule, thus leading to problems associated with drying. *Id.* Gelatin capsules worked best with hydrophobic or non-water-absorbing drugs. *Id.*

It was known in the prior art that capsules made from cellulose ether compositions were more versatile. *Id.* at 1:38-42. Capsules made of hydroxypropyl methyl cellulose (HPMC) were

known to maintain sufficient strength even with low water content while otherwise performing similarly to conventional gelatin capsules. *Id.* at 1:47-50. HPMC capsules could be manufactured using the dipping method. *Id.* 1:50-52.

Capsules made from cellulose ether compositions nevertheless had their own problems. Chief among them was the tendency of the gelling agent to precipitate out of the capsule film during long-term storage, causing cloudiness and making the capsule “unpleasant to look at it.” *Id.* at 1:53-56, 2:1-6. When a polysaccharide such as HPMC was used in combination with potassium chloride or calcium chloride as a gelling aid, for example, residual potassium or calcium ions would precipitate out onto the film surface as water content dropped during long-term storage. *Id.* at 1:57-67.

The purpose of the invention claimed in the '180 patent is “to provide a novel and improved cellulose ether film of a composition comprising a cellulose ether as a base, a gelling agent, and a gelling aid, which prevents the gelling aid from precipitating out and maintains a favorable outer appearance during long-term storage.” *Id.* at 2:9-15. The inventors’ discovery, according to the patent, is that precipitation of the gelling aid can be prevented with a cellulose ether that has no more than 37.6% cellulosic alkyl or hydroxyalkyl groups substituted in place of cellulosic hydroxyl groups. *Id.* at 2:26-32. By limiting the amount of cellulosic alkyl or hydroxyalkyl groups, the inventors believed that there were enough hydrophilic hydroxyl groups to ensure the film held enough water, thus preventing potassium or calcium from precipitating. *Id.* at 2:41-49.

The '180 patent has one independent claim (claim 1), and it recites:

A hard capsule formed of a film composition comprising a hydroxypropyl methyl cellulose as a base, a gelling agent, and a gelling aid, wherein said hydroxypropyl methyl cellulose has a content of hydroxypropoxyl groups of at least 4% by weight of the hydroxypropyl methyl cellulose and a content of methoxyl groups

and hydroxypropoxyl groups combined of 23 to 37.6% by weight of the hydroxypropyl methyl cellulose.

*Id.* at 6:38-45. In other words, the HPMC used in the film composition has at least 4% by weight hydroxypropoxyl groups (a type of hydroxyalkyl group), and the combined amount of hydroxypropoxyl and methoxyl groups is 23 to 37.6% by weight. *Id.* at 6:38-45, 2:62-3:7. The other claim at issue for purposes of claim construction is claim 4, which depends from claim 1 and specifies, “the content of methoxyl and hydroxypropoxyl groups combined is 29 to 37% by weight of the hydroxypropyl methyl cellulose.” *Id.* at 6:55-58.

### DISCUSSION

The ultimate claim construction inquiry is a question of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-91 (1996)). “It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). “[T]here is no magic formula or catechism for conducting claim construction.” *Id.* at 1324. Instead, the court is free to attach the appropriate weight to appropriate sources “in light of the statutes and policies that inform patent law.” *Id.*

“[T]he words of a claim are generally given their ordinary and customary meaning . . . [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Id.* at 1312-13 (internal citations and quotation marks omitted). “[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent.” *Id.* at 1321 (internal quotation marks omitted). The patent specification “is always highly relevant to

the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While “the claims themselves provide substantial guidance as to the meaning of particular claim terms,” the context of the surrounding words of the claim must be considered. *Phillips*, 415 F.3d at 1314. Furthermore, “[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent . . . .” *Id.* (internal citation omitted).

It is likewise true that “[d]ifferences among claims can also be a useful guide . . . . For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.” *Id.* at 1314-15 (internal citation omitted). This “presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim.” *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that “the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316. It bears emphasis that “[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.” *Hill–Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (quoting *Liebel–Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)) (internal quotation marks omitted).

In addition to the specification, a court “should also consider the patent’s prosecution history.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff’d*, 517 U.S. 370 (1996). The prosecution history, which is “intrinsic evidence,” “consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent.” *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.” *Id.*

In some cases, “the district court will need to look beyond the patent’s intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period.” *Teva*, 135 S. Ct. at 841. Extrinsic evidence “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries “endeavor to collect the accepted meanings of terms used in various fields of science and technology.” *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful “to ensure that the court’s understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.” *Id.* Nonetheless, courts must not lose sight of the fact that “expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence.” *Id.* Overall, while extrinsic evidence “may be useful” to the court, it is “less reliable” than intrinsic evidence, and its consideration “is unlikely to result in a reliable

interpretation of patent claim scope unless considered in the context of the intrinsic evidence.” *Id.* at 1318-19.

Finally, “[t]he 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.” *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that “a claim interpretation that would exclude the inventor’s device is rarely the correct interpretation.” *Osram GmbH v. Int’l Trade Comm’n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (quoting *Modine Mfg. Co. v. U.S. Int’l Trade Comm’n*, 75 F.3d 1545, 1550 (Fed. Cir. 1996)).

### **Construction of Disputed Terms**

#### **1. “hard capsule”**

<b>Plaintiffs’ Proposed Construction</b>	<b>Defendants’ Proposed Construction</b>
“a hard shell suitable for use in a pharmaceutical dosage form”	“a rigid casing within which a pharmaceutical formulation can be placed”

The parties propose slightly different constructions of the term “hard capsule,” but it is not clear from the briefs that there is any meaningful dispute. Neither party argued this term during the claim construction hearing. *See* Hr’g Tr. at 5:11-16, Dkt. 112. Defendants do not appear to disagree with Plaintiffs’ proposal, except to note that “the parties agree that the rigid casing or hard shell is distinct from the compounds placed inside that casing or shell.” Dkt. 106 at 35. Plaintiffs do not contend otherwise.

The Court construes “hard capsule” as “a hard shell capable of containing a pharmaceutical product or food product.” As the parties agree, the pharmaceutical or food product is distinct from the capsule itself. The phrase “pharmaceutical product” is intended to be coextensive, and no broader than, the parties respective proposals of “pharmaceutical dosage form” and “pharmaceutical formulation” because the Court understands these phrases to have roughly the

same meaning. In addition to a pharmaceutical product, however, the patent discloses that the capsule can contain a food product, such as a nutritional supplement, and thus “food product” is included in the construction. *See* ’180 patent at 5:18-21. As for the choice between “hard shell” and “rigid casing,” the Court adopts Plaintiffs’ proposal simply because the patent repeatedly uses the term “shell.” *See, e.g., id.* at 5:2, 5:19, 6:26. The phrase “rigid casing,” by contrast, does not appear in the patent.

## 2. “hard capsule formed of a film”

<b>Plaintiffs’ Proposed Construction</b>	<b>Defendants’ Proposed Construction</b>
“a hard shell suitable for use in a pharmaceutical dosage form, formed of a film”	“a rigid casing within which a pharmaceutical formulation can be placed”

The parties dispute what it means to be “formed of a film.” Plaintiffs argue that the claims are directed to a “film” that is a manufacturing precursor to the “hard capsule.” Such a construction, according to Defendants, would transform the phrase “formed of a film” into a product-by-process limitation, and would allow the gelling agent to be present during the forming step but absent from the final product. Dkt. 106 at 31. Defendants suggest that “formed of a film” simply means “the claimed hard capsule has thin walls and can be filled with a pharmaceutical formulation.” *Id.*

The Court construes “hard capsule formed of a film” to mean that the “hard capsule is a film,” with “hard capsule” retaining the same construction as explained above. Other than the word “formed,” the claims of the ’180 patent do not include any limitation indicative of a process in which the hard capsule is prepared from a precursor film. The absence of such process limitations suggests that the word “film” should be interpreted as a structural characteristic of the hard capsule, as opposed to a characteristic of a precursor used to make the hard capsule. *See Regents of Univ. of Minnesota v. AGA Med. Corp.*, 717 F.3d 929, 937 (Fed. Cir. 2013) (discussing when process-like terms can be structural).



The specification supports this conclusion. Plaintiffs are correct that the specification uses the term “film” to describe how the capsules are made from the precursor cellulose ether film. *See, e.g.,* ’180 patent at 4:55-59 (“When hard capsules are formed from the cellulose ether film of the invention, for example, the film can be prepared in the form of capsule shells by a well-known dipping method as in the manufacture of conventional gelatin capsules.”); *id.* at 1:6-7 (“This invention relates to a cellulose ether film suited for use in forming pharmaceutical and food hard capsules.”). But the specification also repeatedly describes the hard capsule, i.e., the final product, as a “film,” even after long-term storage, indicating that the “hard capsule” is a film. *See, e.g. id.* at 1:24-26 (“Also, as the water content decreases by drying during storage, the film contracts to undesirably loosen the cap-to-body engagement.”); *id.* at 1:62-67 (“During long-term storage of these cellulose ether film capsules, the water content of the film can be lowered owing to the storage environment or the water absorption of the fill. Then the potassium or calcium ion as the gelling aid will re-form potassium chloride or calcium chloride which precipitates out on the film surface.”); *id.* at 2:3-6 (“Especially in the case of colorless clear film, the precipitates develop as cloud and sometimes, cloud spots rather than uniform cloud, exacerbating the outer appearance of capsules noticeably.”).

The difficulty in construing the term “formed of a film” results from the way in which the parties present their dispute. The claims, after all, do not simply recite “a hard capsule formed of a film.” Rather, they recite “a hard capsule formed of a film *composition*” comprising certain ingredients. *See id.* at 6:38-40 (emphasis added). The question the parties raise is whether the hard capsule is made *from a film* that includes the composition ingredients, on the one hand as Plaintiffs suggest, or whether the hard capsule is made from a composition *that can be formed into a film*, i.e., a hard capsule, as Defendants’ suggest.

The latter construction is most consistent with the intrinsic record. In claim 1, the word “film” modifies the word “composition,” which suggests that claim 1 is directed to more than a hard capsule “formed of a composition.” Otherwise, the word “film” is superfluous. Two reasonable interpretations nevertheless follow. First, the word “film” could be specifying that the precursor composition is in a film-like state. Certain passages in the specification arguably support this interpretation. *See, e.g.*, ’180 patent at 4:55-59, 1:6-7. Moreover, the dependent claims recite a “hard capsule formed of a film of claim 1,” as opposed to a “hard capsule formed of a film *composition* of claim 1.” Second, and by contrast, “film” could be referring to something that can be created from the composition, i.e., the composition is capable of forming a film. Such an interpretation is consistent with the claim language. If claim 1 was meant to specify a hard capsule formed of a *film*, rather than a hard capsule formed of a *film composition*, the drafter could have omitted the word “composition.” While the dependent claims inject some uncertainty into this conclusion by referring to a “capsule formed of a film,” the specification’s repeated characterization of the hard capsule as a “film” resolves the uncertainty. *See, e.g., id.* at 1:24-26, 1:62-67, 2:3-6.

The extrinsic testimony of Defendants’ expert, Dr. Jarosz, does not compel a different conclusion. Dr. Jarosz testified that “the hard capsule is made from the film composition.” Dkt. 1073 at 106:2-5. In contrast to Plaintiffs’ argument, Dr. Jarosz does not truncate the phrase by ignoring the word “composition.” Accordingly, Dr. Jarosz’s testimony is consistent with the conclusion that the hard capsule is a film made from a composition comprising the claimed ingredients, i.e., a capsule made from a film-forming composition.

To be clear, the claims are product-by-process claims in one important sense. The hard capsule is defined by the ingredients used to make it (the film composition ingredients). The

Court’s construction simply clarifies that it is not necessary for the hard capsule to be formed from a film. In sum, the word “film” modifies “composition” to specify that the composition can be formed into a film, which is a characteristic of the “hard capsule.”

### 3. “gelling agent”

<b>Plaintiff’s Proposed Construction</b>	<b>Defendant’s Proposed Construction</b>
<p>No Construction Necessary</p> <p>To the extent this Court finds that a construction is necessary:</p> <p>“An agent that can gel a film composition comprising hydroxypropyl methyl cellulose as a base”</p>	<p>“a substance that increases the amount of gelation, as compared to water”</p> <p>As this term/construction is entirely functional, this term is either indefinite or governed by 35 U.S.C. § 112(6). If governed by 35 U.S.C. § 112(6), then</p> <p><u>Function</u>: increasing the amount of gelation;</p> <p><u>Structure</u>: carrageenan, tamarind seed polysaccharide, pectin, curdlan, furcellaran, gellan gum, and mixtures thereof.</p>

The parties dispute whether the term “gelling agent” is definite or alternatively governed by 35 U.S.C. § 112, ¶ 6, and whether the “gelling agent” can be water. The definiteness issue is easily resolved. The term “gelling agent” describes the function of the agent in the film composition (gelation), and the specification provides examples, including “carrageenan, tamarind, seed polysaccharide, pectin, curdlan, furcellaran, gellan gum, and mixtures thereof.” ’180 patent at 3:60-62. In light of the specification, a person of ordinary skill in the art would understand the term with “reasonable certainty.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014).

Whether the term “gelling agent” is a functional term governed by § 112, ¶ 6, or whether the “gelling agent” can be water, are closely related but more difficult questions. In Plaintiffs’ favor is the absence of the word “means” from the term, which gives rise to a presumption, albeit no longer a strong one, that the term is not governed by § 112, ¶ 6. *See Williamson v. Citrix Online*,

*LLC*, 792 F.3d 1339, 1349, 1347 n.3 (Fed. Cir. 2015) (en banc in relevant part). The “essential inquiry,” however, “is not merely the presence or absence of the word ‘means’ but whether the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure.” *Id.* at 1348. To determine whether a claim recites sufficient structure, “it is sufficient if the claim term is used in common parlance or by persons of skill in the pertinent art to designate structure, even if the term covers a broad class of structures and even if the term identifies the structures by their function.” *TecSec, Inc. v. Int’l Bus. Machs. Corp.*, 731 F.3d 1336, 1347 (Fed. Cir. 2013) (internal quotation marks and citations omitted).

The parties’ experts agree that the term “gelling agent” is not defined by the specification, but they also agree that the specification describes certain examples, and both experts appear to understand what those examples mean. *See* Dkt. 100-2; Dkt. 106-2. Otherwise, the expert testimony on the meaning of the term “gelling agent” is largely conclusory—Plaintiffs’ expert says he understands the term, *see* Dkt. 100-2 ¶¶ 30-33, while Defendants’ expert says the opposite, *see* Dkt. 106-2 ¶¶ 24-27. The question that remains is whether the term “gelling agent” defines a sufficiently definite class of structures, and if so, what is the class. The answer resolves both the § 112, ¶ 6 dispute and the dispute regarding whether the “gelling agent” can be water.

Plaintiffs’ expert acknowledges that the class of structures disclosed in the specification as “gelling agents” (for example, carrageenan, pectin, curdlan, and gellan gum) are “members of a class of compounds known as hydrocolloids.” Dkt. 100-2 ¶ 39. It is true that the examples are nothing more than that; the patent makes this clear by specifying that the “gelling agent used *may* be selected from” the examples. ’180 patent at 3:60-62 (emphasis added). Other than these examples and the term “gelling” in the claims, however, there is no further guidance. The patent does not define a common characteristic of the gelling agent, other than require that the agent gel

the film composition. The examples provided in the specification, by contrast, have a common characteristic, according to Plaintiffs' expert.

This leaves at least two options. One is to leave the class of "gelling agents" broadly defined, confined only by the word "gelling." Though undoubtedly broad, this class arguably connotes sufficient structure by reference to a function. *See TecSec*, 731 F.3d at 1347. Plaintiffs' expert testimony on this point is largely conclusory, but it provides some support for idea that "gelling" sufficiently confines the claims. *See* Dkt. 100-2. The other option is to define the "gelling agent" by reference to the class of structures described in the specification. This is not to say *limit* the claims to those specific examples. Rather, borrowing from the familiar canon of statutory interpretation *noscitur a sociis*, "gelling agent" could be construed to mean "hydrocolloid" because the examples described in the specification are all hydrocolloids, as Plaintiffs' expert admits. *See* Dkt. 100-2 ¶ 39; *see also Graham Cty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 281 (2010) ("The interpretive maxim *noscitur a sociis* [means] 'a word may be known by the company it keeps . . . .'" (internal citation omitted)). This option undoubtedly avoids § 112, ¶ 6 by confining the claims to a specific class of structures. Yet the option leads to a similar result as construction under § 112, ¶ 6 (in effect) by limiting "gelling agent" to the class of structures defined in the specification and their hydrocolloid equivalents.

The issue is a close one because it requires the Court to strike a balance between Defendants' entitlement to understand the scope of "gelling agent" and Plaintiffs' entitlement to the reasonable scope of the claimed invention. On the one hand, there is not strong evidence that a person of ordinary skill in the art would understand the scope of the term "gelling agent" by itself. Indeed, the parties' dispute about whether water can be a "gelling agent" is telling because it is not immediately apparent how water can be a gelling agent, and water is unlike the

hydrocolloid examples disclosed in the specification. To temper any overreach, there are non-limiting examples described in the specification that all share a common characteristic, and perhaps the claims should be limited to gelling agents possessing that characteristic.

On the other hand, “[t]hat a word may be known by the company it keeps is . . . not an invariable rule, for the word may have a character of its own not to be submerged by its association.” *Russell Motor Car Co. v. United States*, 261 U.S. 514, 519 (1923). The term “gelling agent” itself at least confines the claims to a particular function, and the function restricts the type of substance that can meet the gelling agent limitation. More important, the “gelling agent” is not the point of alleged novelty, nor is the combination of the gelling agent with the other film composition ingredients. The alleged point of novelty is that the HPMC used in the film composition that has at least 4% by weight hydroxypropoxyl groups and a combined amount of hydroxypropoxyl and methoxyl groups from 23 to 37.6% by weight. ’180 patent at 6:38-45, 2:62-3:7. Accordingly, the Court construes “gelling agent” according to its plain and ordinary meaning as a “a substance that gels the film composition.”

Armed with this construction, whether water can be a “gelling agent” reduces to a fact question. It is true that the specification does not describe water as a gelling agent. Nor is there evidence that water is a hydrocolloid, unlike every example gelling agent described in the specification. Water may be a gelling agent, however, if it “gels the film composition.” Any overreach is therefore left for the merits of Plaintiffs’ infringement contentions. The record that exists at this point does not support the conclusion that as a matter of claim construction, water does not “gel the film composition.” That is a question for summary judgment or trial.

4. “gelling aid”

<b>Plaintiff’s Proposed Construction</b>	<b>Defendant’s Proposed Construction</b>
“Any substance(s) that can promote gelation by the gelling agent.”	<p>“a substance that promotes gelation by the gelling agent”</p> <p>As this term/construction is entirely functional, this term is either indefinite or governed by 35 U.S.C. § 112(6). If governed by 35 U.S.C. § 112(6), then</p> <p><u>Function</u>: promoting gelation by the gelling agent;</p> <p><u>Structure</u>: potassium ion, calcium ion, ammonium ion, and various organic compounds.</p>

The parties’ dispute surrounding the term “gelling aid” mirrors the “gelling agent” dispute, and the Court’s analysis is the same. “Gelling aid” is construed according to its plain and ordinary meaning as “a substance that can promote gelation by the gelling agent.” The term “gelling aid” itself is confined with reasonable certainty by the claim language as something that aids gelling, and this limitation is made clear in the specification. *See, e.g.*, ’180 patent at 4:18-31. Although the term is broad, sufficient structure is provided by reference to the function, and thus the term is not be governed by § 112, ¶ 6. *See TecSec*, 731 F.3d at 1347.

## CONCLUSION

The Court construes the disputed terms as follows:

<b>Disputed Term</b>	<b>Construction</b>
“hard capsule”	“a hard shell capable of containing a pharmaceutical product or food product”
“hard capsule formed of a film”	“hard capsule is a film,” with “hard capsule” retaining the same construction as above
“gelling agent”	<p>plain and ordinary meaning, which is “a substance that gels the film composition”</p> <p>(not governed by § 112, ¶ 6, and not indefinite)</p>

<b>Disputed Term</b>	<b>Construction</b>
“gelling aid”	plain and ordinary meaning, which is “a substance that can promote gelation by the gelling agent”  (not governed by § 112, ¶ 6, and not indefinite)

The Court understands that one or more parties have amended infringement or invalidity contentions on the basis of the Court’s preliminary claim construction chart distributed during the claim construction hearing. The Court does not consider the constructions set forth herein to be substantively different from the preliminary constructions. Accordingly, and because discovery is now closed, the Court’s preliminary claim construction chart can be considered “the Court’s Claim Construction Ruling” under Local Patent Rule 3-6(a)(1)-(2) for purposes of this case only. Any substantive changes to contentions or expert reports, i.e., any amendments that do more than make minor changes necessary to conform the language of the preliminary constructions to the language of the constructions set forth herein, require leave of Court.

**SIGNED this 12th day of July, 2017.**

  
 ROY S. PAYNE  
 UNITED STATES MAGISTRATE JUDGE