IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| IBSA INSTITUT BIOCHIMIQUE, S.A., ALTERGON, S.A., and IBSA PHARMA INC.,<br><br>Plaintiffs,<br><br>v.<br><br>TEVA PHARMACEUTICALS USA, INC.,<br><br>Defendant. | Civil Action No. 1:18-cv-00555-RGA |

MEMORANDUM OPINION

Jack B. Blumenfeld and Brian P. Egan, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, DE; Jeffrey J. Oelke (argued), Ryan P. Johnson (argued), Laura T. Moran, and Eric M. Majchrzak, FENWICK & WEST LLP, New York, NY; Erica R. Sutter, FENWICK & WEST LLP, Mountain View, CA.

Attorneys for Plaintiffs.

John W. Shaw, Karen E. Keller, and Nathan R. Hoeschen, SHAW KELLER LLP, Wilmington, DE; J.C. Rozendaal (argued), Kristina Caggiano Kelly (argued), Michael Joffre, and Deirdre M. Wells, STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C., Washington, DC.

Attorneys for Defendant.

August 16, 2019

**ANDREWS, U.S. DISTRICT JUDGE:**

Presently before me is the issue of claim construction of multiple terms in U.S. Patent No. 7,723,390 ("'390 Patent"). (D.I. 70). I have considered the Parties' Joint Claim Construction Brief and supplemental submissions. (*Id.*; D.I. 97, 98). I heard oral argument on June 27, 2019. (D.I. 94 ("Tr.")).

## I. LEGAL STANDARD

### *A. Claim Construction*

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (citation omitted). "'[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324) (alteration in original). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979-80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315.

"[T]he words of a claim are generally given their ordinary and customary meaning. . . . [This 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. "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321. "In some cases, the ordinary meaning of claim language

as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314.

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

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

*B. Indefiniteness*

"[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014); *see also* 35 U.S.C. § 112 ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the

inventor . . . regards as the invention."). A patent claim is sufficiently definite if it is "precise enough to afford clear notice of what is claimed, thereby apprising the public of what is still open to them." *Nautilus*, 572 U.S. at 909 (cleaned up).

"Indefiniteness is a question of law" to which the general principles of claim construction apply. *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1370 (Fed. Cir. 2017). A claim term "is indefinite if its language 'might mean several different things and no informed and confident choice is available among the contending definitions.'" *Media Rights Techs., Inc. v. Capital One Fin. Corp.*, 800 F.3d 1366, 1371 (Fed Cir. 2015) (quoting *Nautilus*, 572 U.S. at 911 n.8).

## II. BACKGROUND

The patent-in-suit relates generally to pharmaceutical compositions for thyroid hormones. ('390 Patent at 1:6-7). The patent descends from an Italian priority application. (*See* D.I. 71-1, Exh. O (Italian application); *see also* D.I. 71-1, Exh. P (February 11, 2019 translation of Italian application)).

The specification discusses only the T3 and T4 thyroid hormones. (*See* '390 Patent at 1:11-16). The body also produces T1 and T2 thyroid hormones. (Tr. at 13:15-20). The numbers (one through four) refer to the number of iodine atoms attached to the base molecule, thyronine. (*Id.*).

The Parties dispute the proper construction of terms in claims 1, 7, and 8:

> 1. A pharmaceutical composition comprising *thyroid hormones or their sodium salts* in the form of either:
>
> > a) a soft elastic capsule consisting of a shell of gelatin material containing a liquid or *half-liquid* inner phase comprising said *thyroid hormones or their salts* in a range between 0.001 and 1% by weight of said inner phase, dissolved in gelatin and/or glycerol, and optionally ethanol, said liquid or *half-liquid* inner phase being in direct contact with said shell without any interposed layers, or

b) a swallowable *uniform soft-gel matrix* comprising glycerol and said *thyroid hormones or their salts* in a range between 0.001 and 1% by weight of said matrix.

7. The pharmaceutical composition according to claim 1, having an *outer coating which simplifies ingestion.*

8. The pharmaceutical composition according to claim 1, wherein the material of *the capsule contents or the swallowable uniform soft-gel matrix includes a plasticizer to control its hardness*.

('390 Patent, claims 1, 7, 8 (disputed terms italicized)).

## III. CONSTRUCTION OF DISPUTED TERMS

### 1. "thyroid hormones or their [sodium] salts"

a. *Plaintiffs' proposed construction*:

Plain and ordinary meaning: "one or more thyroid hormones or their [sodium] salts"

b. *Defendant's proposed construction*:

Plain and ordinary meaning: multiple thyroid hormones or sodium salts of multiple thyroid hormones

c. *Court's construction*:

"one or more thyroid hormones or their [sodium] salts"

The Parties agree that this claim covers compositions that contain more than one type of thyroid hormone.[1] (*See* D.I. 70 at 3-20). They disagree, however, whether the claim covers compositions that contain only one type of thyroid hormone. (*Id.*).

Defendant argues that "hormones," a plural noun, necessarily means that the claim requires more that one type of hormone. (*Id.* at 5). Thus, it argues, the plain and ordinary

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[1] The analysis for "hormones" and "their [sodium] salts" is the same. Thus, while I discuss only hormones, the conclusions I reach apply equally to both terms.

meaning is "beyond dispute" and controls the outcome of this claim construction. (*Id.*). I disagree.

The meaning of hormones, in the context of the claim alone, is not so clear. First, if the term is construed only with reference to the language of the claim, there is nothing to indicate to a POSA that the applicant meant multiple types of hormones as opposed to multiple hormone molecules. The Parties do not dispute that, in the overall context of the Patent, the claim is clearly referring to types of hormones. (Tr. at 13:2-6). That understanding, however, is not ascertainable merely by reading the claim. Second, although a plural noun is often used to refer to more than one thing, the plural is also used to capture the singular in everyday speech. To use a modified example of what I suggested during oral argument, when driving through Montana, I have seen signs saying, "Beware of rattlesnakes." (*See id.* at 16:22-17:9). When I saw this, I understood that a single rattlesnake was something to be wary of. The plural is used to capture the singular. Another example (this time adopting the golf theme presented by Defendant during argument), on a golf course there are often signs that say something to the effect of, "Watch for flying golf balls." That sign, of course, means to watch for one or more flying balls—it is using the plural to capture the singular. Thus, I find that the meaning of "hormones" is not readily determined from the claim alone.

Plaintiffs argue that the specification would indicate to a POSA that, in the context of the '390 Patent, "hormones" means one or more. (D.I. 70 at 3-5; 12-17). They support their position by citing multiple instances in the specification where the applicant described his invention as containing, "thyroid hormones, in particular T3 and/or T4." (*Id.*; *see also* '390 Patent at 2:57-63, 4:7-9, 6:13-18, 9:21-27). They also point out that Defendant's construction

requires an undisclosed additional thyroid hormone and reads out most of the embodiments described in the specification:

> The '390 patent contains 36 example compositions, but not a single example composition contains T3 or T4 combined with another hormone. Five of the 36 example compositions contain T3 and T4, while the other 31 example compositions contain either T3 or T4, mirroring the "T3 and/or T4" language from the specification. In fact, no other thyroid hormone is mentioned anywhere in the specification.

(D.I. 70 at 12 (citation omitted)). Defendant responds that the "and/or" language of the specification, and the absence of any embodiment with a hormone other than T3 or T4, does not indicate that a third hormone cannot be present in the composition. (*Id.* at 7-10). At argument, however, Defendant was unable articulate a reason why, based on the disclosure in the specification, the applicant would have claimed compositions that contain only more than one hormone. (Tr. at 14:13-16:9).

I do not find Defendant's position persuasive. It is not reasonable to construe "hormones" as excluding the majority of embodiments of the invention. Nor is it reasonable to read the claims as requiring an undisclosed third hormone when just one of the disclosed hormones is present in the composition. Thus, I find that a POSA reading the specification would conclude, based on the examples in the specification and the repeated use of "thyroid hormones, in particular T3 and/or T4," that "hormones" in the claim refers to one or more hormones.[2]

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[2] Other courts have construed plural nouns as encompassing the singular when, in the context of the patent, such a construction was appropriate. *See, e.g.*, *Yodlee, Inc. v. Plaid Techs., Inc.*, 2016 WL 204372, at *6 (D. Del. Jan. 15, 2016) (construing "list of addresses" as covering a list with just one address); *Flash Seats, LLC v. Paciolan, Inc.*, 2010 WL 184080, at *8-9 (D. Del. Jan. 19, 2010) (construing "asks" as "one or more asks"); *see also Versa Corp. v. Ag-Bag Int'l Ltd.*, 392

Accordingly, I will construe "thyroid hormones or their [sodium] salts" as "one or more thyroid hormones or their [sodium] salts."

**2. "half-liquid"**

a. *Plaintiffs' proposed construction*:

Plain and ordinary meaning: semiliquid, i.e., having a thick consistency between solid and liquid

b. *Defendant's proposed construction*:

Indefinite.

Alternatively, "a non-solid, non-paste, non-gel, non-slurry substance"

c. *Court's construction*:

Indefinite.

The Parties agree that the intrinsic record does not define "half-liquid." (D.I. 70 at 24). They disagree, however, whether the term is amenable to construction.

Plaintiffs argue for a "plain and ordinary meaning" construction based on their position that "half-liquid" is synonymous with "semi-liquid." (*Id.* at 21-24). The intrinsic record does not, however, support such an understanding. Plaintiffs argue that a POSA would understand that the two terms are synonymous based on (1) the Italian priority application's use of "semiliquido," (2) the '390 Patent's specification's use of "half-liquid" in a manner that is

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F.3d 1325, 1330 (Fed. Cir. 2004) ("[I]n context, the plural can describe a universe ranging from one to some higher number, rather than requiring more than one item."). This indicates that there is no one correct method of claiming a singular. Thus, I do not find Defendant's argument that "a" or "an" is understood in patent law to mean "one or more" to be probative of the proper construction of this claim term. (*See* D.I. 70 at 11). The fact that other patents may use "a" or "an" to communicate "one or more" is not a proper consideration for construing "hormones" in the context of the '390 Patent.

consistent with a POSA's understanding of "semi-liquid," and (3) uses of the term "half-liquid" in extrinsic evidence.

The Italian priority application is minimally probative of the meaning of half-liquid. Plaintiffs argue that a POSA would understand, based on the Italian priority application's use of "semiliquido," that half-liquid means semi-liquid.[3] (*Id.* at 21; *see also* D.I. 71-1 , Exh. O at IBSATIR-00000576, -579-81). To support their argument, Plaintiffs rely on extrinsic evidence, that is, they commissioned a professional translation of the priority application. (*See* D.I. 71-1, Exh. P (2019 English translation of Italian priority application)). Plaintiffs' retranslation of the Italian priority application is not, however, good evidence of what the applicant meant by "semiliquido." A comparison of Plaintiffs' translation of the Italian application's "Field of Invention" and "Prior Art" sections against those portions of the '390 Patent's specification quickly reveals that the applicant and the translator regularly interpret words and phrases differently. (*Compare* '390 Patent at 1:6-4:51, *with* D.I.71-1, Exh. P at 2-11). The inconsistency between the two translations is likely because translation requires the translator to use judgment. I must assume the applicant used his judgment, and knew what he meant to communicate, when he translated the Italian priority application into English for the purpose of filing a U.S. patent application. That translation is significantly more probative of what the applicant meant than a litigation-inspired translation done in 2019. The best evidence of what the applicant meant are the words he chose. Thus, I do not give the Italian priority application, or Plaintiffs' translation of that application, any weight in claim construction.

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[3] I am quite sure that, for purposes of claim construction, a POSA is not required to be fluent in Italian, and thus I am dubious that Italian-language materials, even if part of the intrinsic record, inform a POSA's understanding of what the patent claims.

The specification's use of "half-liquid" similarly does not support redefining that term as semi-liquid. Plaintiffs argue that the applicant's citation to pharmaceutical references that use the term "semi-liquid" means he understood half-liquid as meaning semi-liquid. (D.I. 70 at 21-23). I do not agree with Plaintiffs' conclusion. It seems more likely to me that the applicant's citation to references that use the term "semi-liquid," coupled with his choice to use the term "half-liquid," indicates that he was aware of the term of art and chose not to use it.

The prosecution history provides additional support for the conclusion that the applicant understood "semi-liquid" and "half-liquid" to have different scopes. During prosecution, the applicant proposed a set of claims that included the term "semi-liquid":

> 20. (New) Pharmaceutical composition comprising thyroid hormones or their salts in soft elastic capsules consisting of a shell of gelatin material and containing a liquid or *half-liquid* inner phase or in swallowable uniform soft-gel matrices of gelatin, wherein the inner phase of the soft elastic capsule and the swallowable uniform soft-gel matrix comprise ethanol, glycerol, or mixtures thereof.
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> . . .
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> 24. (New) The composition according to claim 20, wherein soft elastic capsule includes an inner phase consisting of a paste or a gel comprising gelatin and a liquid or *semi-liquid* vehicle consisting of ethanol, glycerol or a mixture thereof.

('390 Patent File History: Response to Office Action (April 12, 2005) at 3 (D.I. 71-1, Exh. C at IBSATIR-00000776) (emphasis added); *see also* '390 Patent File History: Examiner's Amendment (Jan. 12, 2010) at 3 (D.I. 71-1, Exh. N at IBSATIR-00001016 (allowing original claim 20 to issue as claim 1))). The applicant later amended the application to remove proposed claim 24.[4] ('390 Patent File History: Response to Office Action (Oct. 26, 2006) at 3 (D.I. 71-1,

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[4] Had proposed claim 24 issued, guiding principles of claim construction would have strongly favored "half-liquid" and "semi-liquid" having distinct meanings. *See Amgen Inc. v. Sandoz*

Exh. E at IBSATIR-00000838)). I view this prosecution history as evidence that the applicant did not mean "semi-liquid" when he used the term "half-liquid." He was clearly aware of the term and could easily have used "semi-liquid" in claim 1, the independent claim. He, however, chose not to. He chose to eliminate "semi-liquid" from the claims entirely. Thus, the specification and prosecution history indicate the opposite of Plaintiffs' proposition. Far from showing that the applicant understood the two terms as synonymous, the record indicate that the applicant knew the term "semi-liquid" and intentionally chose not to use it.

The extrinsic evidence identified by Plaintiffs is minimally probative and unpersuasive. Plaintiffs look first to an 1896 definition of "semiliquid" to support their argument that "half-liquid" is a synonym. (D.I. 70 at 30-31). A late 19th-century edition of Webster's International Dictionary defines "semiliquid" as "half liquid; semifluid." (D.I. 71-1, Exh. HH at 1308). I do not find this evidence persuasive as to the meaning of "half-liquid" in the context of the '390 Patent. The purpose of claim construction is to determine the meaning of claim terms to a POSA at the time of the invention. It is important to focus on language at the time of invention because language evolves over time. Thus, a dictionary entry from more than a century prior to the relevant date, defining a term other than the claim term, carries essentially no weight in determining the meaning of the term.

Plaintiffs further point to a handful of patents as support for their argument that a POSA understands the term "half-liquid." They argue, "The cited patents use the term 'half-liquid'

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*Inc.*, 923 F.3d 1023, 1031 (Fed. Cir. 2019) ("[D]ifferent claim terms are presumed to have different meanings." (quoting *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1382 (Fed. Cir. 2008)).

without providing any express definition, refuting [Defendant's expert's] claim that one would have been necessary to understand it." (D.I. 70 at 29). I do not find this argument persuasive. The extrinsic patents identified by Plaintiff are not persuasive evidence of what "half-liquid" means in the context of the '390 Patent. The four pre-priority date patents identified by Plaintiff each describe pharmaceutical compositions in "half-liquid bases." (*See* D.I. 71-1, Exh. Z at 8-9 (Plaintiff's expert's summary of the patents; D.I. 71-1 Exhs. AA-DD (patents identified by Plaintiff)). Notably, the '390 Patent does not mention a "half-liquid base." Plaintiff, however, does not address that issue. It is my opinion that, if a term was not used in the art outside of patents and was used in patents only in combination with another term, it is exceedingly unlikely that the term was a term of art at the relevant date.

Plaintiffs also look to their expert for support of their position that "half-liquid" is a term of art meaning "semi-liquid." (*Id.* at 29-30). Plaintiffs' expert's opinion is, however, drawn exclusively from his review of the patents and dictionary definition that I discuss above. (*See* D.I. 71-1, Exh. Z at ¶¶19-22). He admitted during his deposition that he is not aware of any other support in the art for understanding "half-liquid" to mean "semi-liquid." (D.I. 86 at 164:11-165:12). Thus, as I do not find the sources that Plaintiffs' expert relies on to be anything more than unconvincing data points, I do not give his opinion on this matter any weight.[5]

In sum, the intrinsic record indicates that the applicant knowingly chose not to use the term "semi-liquid" and the extrinsic record provides no support for a conclusion that the term

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[5] Plaintiffs' expert's declaration is, of course, extrinsic evidence. In essence, the expert's ultimate opinion about the meaning of "half-liquid" is a legal opinion, which is outside his area of expertise. That is why expert opinions on claim construction are usually worthless.

"half-liquid" is identical in scope to "semi-liquid." Thus, I will not adopt Plaintiffs' position that "half-liquid" means "semi-liquid."

As the record does not support construing "half-liquid" to mean "semi-liquid," I must consider whether the record discloses a reasonably certain meaning for "half-liquid."

I start with the language of the claim itself. From the claim, a POSA would understand that "half-liquid" does not mean liquid. (*See* '390 Patent, claim 1 (claiming a "a liquid *or* half-liquid inner phase" (emphasis added)). A POSA would also understand, based on the applicant's use of the word "liquid," that a half-liquid is not a solid. It is not clear from the claims, however, what manner of substance qualifies as a half-liquid.

I next look to the specification for guidance on the meaning of "half-liquid." The '390 Patent specification includes "half-liquid" in a list that includes pastes and gels. ('390 Patent at 7:65-8:2 ("In particular, said soft capsule contains an inner phase consisting of a liquid, a half-liquid, a paste, a gel, an emulsion or a suspension comprising the liquid (or half-liquid) vehicle and the thyroid hormones together with possible excipients in suspension or solution."). A POSA would understand that this language is meant to indicate that a half-liquid is not, or at least is not necessarily, a gel or a paste. A half-liquid is some category of matter that is not identical to those that may be classified as gel or paste.

The prosecution history is the final piece of intrinsic evidence that I consider when construing a claim term. During the '390 Patent's prosecution, the applicant distinguished at least one type of gel and one type of slurry from the claimed "half-liquid." To overcome an obviousness rejection, the applicant stated that the invention claimed in the '390 Patent "is not a ***macromolecular*** gel-**lattice** matrix." ('390 Patent File History: Response to Office Action (April 23, 2008) at 4-5 (D.I. 71-1, Exh. I at IBSATIR-00000938-39) (emphasis in original)). In

response to another obviousness rejection, the applicant clarified that a liquid or half-liquid is not a "high concentration slurry." ('390 Patent File History: Response to Office Action (Nov. 19, 2008) at 6 (D.I. 71-1, Exh. K at IBSATIR-00000964)). The full scope of the applicant's disclaimers is not clear from my review of the intrinsic record, but it is clear that the applicant disclaimed some portion of the claim's scope that might otherwise qualify as a half-liquid.

Turning now to extrinsic evidence of the meaning of "half-liquid," the record reflects that the Parties' experts do not know what manner of substance meets the half-liquid limitation of the claim. When asked how a person could know that something is not a half-liquid inner phase, Plaintiffs' expert responded that he didn't know. (D.I. 86 at 50:7-14). He also testified that some slurries and some gels may be half-liquid but could not articulate a boundary. (*Id.* at 99:4-18; 123:16-124:4; 129:10-130:2). In his declaration, Plaintiffs' expert notes that the distinction between the disclaimed macromolecular gel-lattice matrices and high concentration slurries is nuanced. (D.I. 71-1, Exh. Z at ¶ 25). He does not, however, attempt to characterize which substances are half-liquid. (*See id.*).

Defendant's expert's strikingly short declaration states that "half-liquid" does not have a meaning in the art and that the specification does not clarify the term's meaning. (D.I. 71-1, Exh. Y at ¶¶ 18-20). Although his declaration is brief, I do credit Defendant's expert's testimony as he has a great deal of relevant personal experience and education in pharmaceuticals. (*Id.* at ¶¶ 2-8). On balance, considering Plaintiffs' expert's difficulty articulating the boundaries of "half-liquid," I think that, almost by default, Defendant's expert's opinion that half-liquid is not a well-known term in the art must be right.

Taken together, the record is unclear on the meaning of "half-liquid." The intrinsic record teaches us a few things that are not a half-liquid by outlining some of the boundaries of the claim

term. The intrinsic and extrinsic records are, however, devoid of any indication of what defines a half-liquid. There is nothing to put a POSA on notice of what a half-liquid is. This ambiguity renders it impossible for a POSA to know, with reasonable certainty, whether they are dealing with a half-liquid within the meaning of the claim. Thus, I find that "half-liquid" is indefinite as a matter of law.

**3. "uniform soft-gel matrix"**

a. *Plaintiffs' proposed construction*:

Plain and ordinary meaning: "homogeneous soft-gel matrix"

b. *Defendant's proposed construction*:

"composition containing active drug particles uniformly dispersed in an unencapsulated gel matrix"

c. *Court's construction*:

"composition containing active drug particles uniformly dispersed in a single phase with no outer shell that can be distinguished from the bulk of the soft-gel matrix, except for external additive layers like enteric layers or layers facilitating swallowing"

The Parties' dispute on this term is the narrow question of how to properly capture the language used by the applicant in the specification and prosecution history. The Parties agree uniform means uniformly dispersed. (Tr. at 68:13-21). The Parties also agree that external additive layers, like enteric layers or layers to facilitate swallowing, fall within the scope of the term. (*See* Tr. at 79:12-18, 80:11-14). They further agree that the outer layer must have a reason for being there—a defined purpose consistent with the purposes described in the specification. (*See id.* at 77:4-9, 79:4-8).

The intrinsic record provides two indications of the meaning of "uniform soft-gel matrix." First, the specification describes "uniform soft-gel matrix" as "constituted of a single

phase and . . . not provided (except for putative external additive layers like enteric layers or layers facilitating the swallowing) with an outer shell which could be distinguished from the bulk of the soft-gel matrix." ('390 Patent at 9:28-32). Second, to overcome an obviousness rejection during the prosecution of the Patent, the applicant explained that the "uniform soft-gel matrix" embodiment:

> is made up of a single, uniform, gelatinous phase. Thus, in [the] embodiment . . . there is neither a discernible capsule filling as such (as in Veronesi [U.S. Patent No. 5,814,338]), nor an "outer" gelatine layer or an "inner" silicon layer (see claim 1 of Veronesi). Stated in other words, a Veronesi-type multilayer texture is clearly excluded by the very wording "uniform softgel matrix" which appears in claim 1.

('390 Patent File History: Response to Office Action (Oct. 26, 2006) at 5 (D.I. 71-1, Exh. E at IBSATIR-00000840)). Together, the intrinsic record indicates that the distinction between a soft-gel capsule and a soft-gel matrix with an additive layer is the nature of the outer coating. A capsule is filled with the active drug while an additive layer is applied to a fully formed soft-gel matrix. Whether something is a capsule versus an additive layer is, however, a factual question that a POSA can opine on.

The specification clearly sets out what the applicant meant by "uniform soft-gel matrix." The prosecution history does not clearly change or add to that meaning. Thus, I will construe "uniform soft-gel matrix" according to the specification as "composition containing active drug particles uniformly dispersed in a single phase with no outer shell that can be distinguished from the bulk of the soft-gel matrix, except for external additive layers like enteric layers or layers facilitating swallowing"

**4. "outer coating which simplifies ingestion"**

a. *Plaintiffs' proposed construction*:

No construction necessary.

b. *Defendant's proposed construction*:

"additional outer layer that reduces the friction between the capsule and the patient's esophagus"

c. *Court's construction*:

None.

"[T]here no real dispute as to the scope of this claim." (D.I. 70 at 50). It is not clear how the Parties understanding of the term differs, if at all. The Parties only clear dispute is whether "outer coating which simplifies ingestion" should be construed. I find that no construction is necessary.

The plain language of the claim does not lend itself to Defendant's construction. That is, it is not clear that "simplifies ingestion" should be limited to a reduction in friction between the capsule and a patient's esophagus. It is also not clear that "outer coating" requires something "additional" to the outer surface of the capsule described in claim 1.

The specification describes one purpose of an "outer layer," but that description is not lexicography for the term "outer coating." The detailed description of the invention explains:

> Besides (or instead of) possible enteric layers, the capsules or swallowable uniform soft-gel matrices according to the present invention can also be provided with additional outer layers which simplify ingestion, i.e. consisting of excipients which reduce the friction between the capsule and the patient's esophagus.

('390 Patent at 6:49-55). Defendant argues that its construction merely copies the specification's discussion of "layers which simplify ingestion" to clarify an otherwise ambiguous claim term.

(D.I. 70 at 48). I do not find Defendant's argument persuasive. It is true that the use of an "i.e." phrase can be strong evidence of an applicant's characterization or definition of her invention. *See SkinMedica, Inc. v. Histogen Inc.*, 727 F.3d 1187, 1200 (Fed. Cir. 2013) ("[A] patentee's use of 'i.e.' signals an intent to define the word to which it refers." (citation omitted)). Where, as here, the applicant uses "i.e." to define a different term than the one that appears in the claim, the importance of such definitional language is less clear. It is not clear from this passage that the applicant meant to disclaim all ingestion-assisting *coatings* (as opposed to *layers*) other than those that help with swallowing. Thus, I will not construe this term as limited in that way. Instead, I find that no construction of this term is necessary.

**5. "the capsule contents or the swallowable uniform soft-gel matrix includes a plasticizer to control its hardness"**

a. *Plaintiffs' proposed construction*:

No construction necessary.

b. *Defendant's proposed construction*:

Indefinite.

c. *Court's construction*:

Plain and ordinary meaning.

Defendant argues that this term is indefinite. The crux of its argument is this: "It is unclear how a liquid or half-liquid can be 'hard,' how someone can 'control [the] hardness' of a liquid or half-liquid, or how someone would test to determine if they are 'control[ling] [the] hardness' of a liquid or half-liquid." (D.I. 70 at 52 (alterations in original)). Defendant does note, citing Wikipedia, that "hardness" in the context of a liquid typically relates to mineral content. (*Id.* at 56). Defendant does not, however, cite any expert testimony or reliable evidence

to support its position that hardness has no other meaning or couldn't mean mineral content in the context of the claim. (*See* Tr. at 98:6-15 (explaining that Defendant's expert did not address "hardness")). Defendant's position, appealing to "common sense," does not meet the clear and convincing evidence standard for finding indefiniteness.

As neither Party proposes a construction for this term, I will construe it as having its plain and ordinary meaning. I express no opinion at this time on whether the plain and ordinary meaning makes logical sense in the context of this patent.

## IV. CONCLUSION

Within five days the parties shall submit a proposed order consistent with this Memorandum Opinion.