IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HORATIO WASHINGTON DEPOT TECHNOLOGIES LLC, Plaintiff, v. TOLMAR, INC., TOLMAR PHARMACEUTICALS, INC., and TOLMAR THERAPEUTICS, INC. Defendants.	C.A. No. 17-1086-LPS

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MEMORANDUM OPINION

December 26, 2018
Wilmington, Delaware

STARK, U.S District Judge:

Plaintiff Horatio Washington Depot Technologies, LLC ("Horatio") sued Defendants TOLMAR, Inc., TOLMAR Pharmaceuticals, Inc., and TOLMAR Therapeutics, Inc. (together, "Tolmar"), alleging that Tolmar infringes Horatio's U.S. Patent Nos. 5,932,547 ("the '547 patent"), 6,124,261 ("the '261 patent"), and 6,235,712 ("the '712 patent"). (D.I. 1) The patents-in-suit describe stable non-aqueous formulations that include a peptide and a polar aprotic solvent.[1] (*See* '547 patent, Abstract) These formulations may be used, for example, to treat prostatic cancer. ('547 patent, 2:29-46)

Presently before the Court are the parties' disputes over the meaning of certain terms in the asserted claims. The parties submitted technology tutorials (D.I. 67, 68) and claim construction briefs (D.I. 62, 66, 70, 72). Tolmar also filed objections to Horatio's technology tutorial. (D.I. 69) The Court held a claim construction hearing on October 22, 2018. (D.I. 79 ("Tr."))

I. LEGAL STANDARDS

The ultimate question of the proper construction of a patent presents an issue 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) (citation and internal quotation marks omitted). "[T]here is no magic formula or catechism for conducting claim construction."

[1] The patents share substantially identical specifications. For simplicity, the Court cites to the '547 patent's specification.

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 also 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) (internal quotation marks omitted).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *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 [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. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999).

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) (internal quotation marks omitted).

II. CONSTRUCTION OF DISPUTED TERMS[2]

All three patents-in-suit are entitled "Non-Aqueous Polar Aprotic Peptide Formulations." The asserted claims relate to "stable non-aqueous formulation[s]" comprising a "peptide compound," such as luteinizing hormone-releasing hormone (LHRH), and a "polar aprotic solvent," methods for preparing these formulations, and methods for treating prostatic cancer

[2] The Court will adopt the parties' agreed-upon constructions.

using these formulations. ('547 patent, cl. 1; '261 patent, cl. 3, 4; '712 patent, cl. 1, 8) According to the specification, using non-aqueous polar aprotic solvents results in more physically and chemically stable peptide formulations than "standard" formulations, which "consist of dilute aqueous solutions." ('547 patent, 4:14-36) The specification states that this increased stability "mak[es] possible the delivery of peptides in long term implantable devices that would not otherwise be feasible." ('547 patent, 4:48-56)

A. "[stable] non-aqueous formulation"[3]

Horatio plain and ordinary meaning
Tolmar "solution having a non-water-based solvent system"
Court "solution having a non-water-based solvent system"

The parties agree that "stable" is expressly defined in the specification (*see* '547 patent, 3:12-13, 5:4-7) and agree that the use of the term in the preamble is limiting, but they disagree as to the meaning of "non-aqueous formulation." (*See* D.I. 62 at 14; D.I. 66 at 3) The dispute centers on whether a "formulation" can be, as Horatio contends, a depot, suspension, or dispersion or whether, as Tolmar contends, a "formulation" must be a solution. (D.I. 62 at 14-15; D.I. 72 at 2)

The Court will adopt Tolmar's construction because the specification repeatedly and consistently characterizes the claimed formulation as a solution. "[W]hen a patent 'repeatedly and consistently' characterizes a claim term in a particular way, it is proper to construe the claim

[3] The term "stable non-aqueous formulation" appears in claim 1 of the '547 patent, claims 3 and 4 of the '261 patent, and claims 1 and 8 of the '712 patent.

term in accordance with that characterization." *GPNE Corp. v. Apple Inc.*, 830 F.3d 1365, 1370 (Fed. Cir. 2016) (internal citations omitted). Here, for example, the patent states:

- "The present invention provides stable non-aqueous formulations ***which are solutions*** of peptide compounds in polar aprotic solvents." ('547 patent, 3:19-21) (emphasis added)
- "The present invention is drawn to the unexpected discovery that ***dissolving*** peptide compounds in non-aqueous polar aprotic ***solvents*** results in stable formulations." (*Id.*, 4:14-16) (emphasis added)
- "In contrast [to standard formulations], in the present invention, peptides formulated in non-aqueous ***solutions*** . . . were shown to be chemically and physically more stable than those formulated in water." (*Id.*, 4:32-36) (emphasis added)
- "***A major part of the invention is that non-aqueous solutions*** containing peptide compounds in polar aprotic solvents ***are*** chemically and physically ***stable at high temperatures for long periods of time. Such formulations*** are stable even when high concentrations are used." (*Id.* 8:34-38) (emphasis added)

The specification describes the invention as "drawn to the unexpected discovery that dissolving peptide compounds in non-aqueous polar aprotic solvents results in stable formulations," and discloses observations of the stability of more than a dozen solutions, but never suggests that the discovered stabilizing effect would be present in depots or suspensions. (*See generally* '547 patent, 4:14-56, 5:55-8:42, 7:1-34)

Horatio is correct that a characterization may not be limiting "where the references to [the] limitation as being the 'invention' are not uniform, or where other portions of the intrinsic evidence do not support applying the limitation to the entire patent." (D.I. 72 at 3) (quoting

Absolute Software, Inc. v. Stealth Signal, Inc., 659 F.3d 1121, 1136 (Fed. Cir. 2011)) But Horatio fails to identify any evidence that supports its reading of the claimed formulations to include depots, suspensions, or dispersions. Nor does Horatio point to any intrinsic evidence suggesting that a claimed formulation would be "stable" if it was not a solution. Contrary to Horatio's contentions (*see* D.I. 72 at 3-4), the specification's use of the word "formulation" to describe the invention does not, in itself, broaden the meaning of the term "formulation" in the phrase "stable non-aqueous formulation." As Tolmar correctly notes (D.I. 70 at 16), while "formulation" is sometimes used in the patents to refer to depots and suspensions, the patents only characterize the inventive "stable non-aqueous formulation" as a solution.

B. "leuprolide," "LHRH," nafarelin," and "goserelin"[4]

	"leuprolide"	**"LHRH"**	**"nafarelin"**	**"goserelin"**
Horatio	"The peptide compounds themselves, as well as analogs, derivatives, agonists, antagonists and salts thereof, as well as peptides and/or peptide compounds which have D-amino acids, modified, derivatized or nonnaturally occurring amino acids in the D- or L-configuration and/or peptomimetic units as part of their structure."			
Tolmar	"an LHRH agonist having the structure 5-oxo-Pro1-His2-Trp3-Ser4-Tyr5-D-Leu6-Leu7-Arg8-Pro9-NHEt, and not salts thereof"	"a naturally occurring hormone that is a decapeptide with the structure pGlu-His-Trp-Ser-Tyr-Gly-Leu-Arg-Pro-Gly-NH2, and not salts thereof"	"the specific LHRH-related compound, nafarelin, itself, and not salts thereof"	"the specific LHRH-related compound, goserelin, itself, and not salts thereof"
Court	"an LHRH agonist having the structure 5-oxo-Pro1-His2-Trp3-Ser4-Tyr5-D-Leu6-Leu7-Arg8-	"a naturally occurring hormone that is a decapeptide with the structure pGlu-His-Trp-Ser-Tyr-Gly-Leu-Arg-	"the specific LHRH-related compound, nafarelin, itself, and not salts thereof"	"the specific LHRH-related compound, goserelin, itself, and not salts thereof"

[4] The term "leuprolide" appears in claim 4 of the '547 patent and claims 4, 12, and 13 of the '712 patent. The terms "LHRH," "nafarelin," and "goserelin" appear in claim 4 of the '547 patent and claim 4 of the '712 patent.

	Pro9-NHEt, and not salts thereof"	Pro-Gly-NH2, and not salts thereof"		

The parties disagree as to whether each of four peptides recited in the claims, "leuprolide," "LHRH," "nafarelin," and "goserelin" (together, "the recited peptides"), should be construed to include just the respective peptide itself, or also to include other peptides that are related in function and/or structure. (D.I. 62 at 10-12; D.I. 66 at 6-7)

Tolmar's constructions reflect the plain and ordinary meaning of the respective peptides. *See Poly-Am, L.P. v. API Indus., Inc.*, 839 F.3d 1131, 1136 (Fed. Cir. 2016) (stating that construction should depart from plain and ordinary meaning only when patentee acts as lexicographer or disavows claim scope during prosecution). The asserted patents do not explicitly define any of the recited peptides, and the patentee did not disavow the scope of the recited peptides during prosecution.

Horatio contends that "at least four times" the patents "broadly describe" the recited peptides as including salts of those peptides. (D.I. 66 at 6-7) None of the passages cited by Horatio defines any of the recited peptides. ('547 patent, 5:13-29, 6:1-21) Rather, these passages define the terms "peptide," "peptide compound," and "LHRH-related compound," provide examples of "peptides" and "peptide compounds," and state that "peptide compounds" can be used in the form of salts. (*Id.*) That the recited peptides are peptide compounds and LHRH-related compounds does not necessarily extend all characteristics of "peptides," "peptide compounds," and "LHRH-related compounds" to the specific, recited peptides.

Claim differentiation, which creates a "presumption that each claim in a patent has a different scope," *AllVoice Computing PLC v. Nuance Communications, Inc.*, 504 F.3d 1236, 1248 (Fed. Cir. 2007), further undermines Horatio's construction. For example, claim 1 of the '547 patent recites a "peptide compound . . . wherein said peptide compound is an LHRH-related

compound." Claim 4 of the '547 patent claims "[t]he formulation of claim 1 wherein said peptide compound is selected from the group consisting of leuprolide, LHRH, nafarelin and goserelin." The patent defines LHRH-related compound as follows:

> luteinizing hormone releasing hormone (LHRH) and its analogs and pharmaceutically acceptable salts. Octa-, nona- and decapeptide LHRH agonists and antagonists are included in the term LHRH-related compounds, as is native LHRH. Particularly preferred LHRH-related compounds include LHRH, leuprolide, goserelin, nafarelin, and other known active agonists and antagonists.

('547 patent, 5:22-29) All of the recited peptides are LHRH agonists. Horatio's construction of each recited peptide includes not only the peptide itself but also all analogs, agonists, antagonists, and salts. Thus, under Horatio's construction, claim 4 of the '547 patent is essentially coterminous with claim 1 of that patent. For the same reasons, under Horatio's construction, claim 4 of the '712 patent is essentially coterminous with claim 1 of that patent.

C. "dissolving"[5]

Horatio "mixing together, dissolving, or attempting to dissolve to form a mixture or suspension"
Tolmar "mixing together to form a single-phase homogenous mixture"[6]
Court "mixing together to form a solution"

The parties' constructions of "dissolving" follow from their competing constructions of "formulation." Horatio contends that a "formulation" can be a solution, depot, dispersion, or suspension (D.I. 62 at 14-15), so it construes "dissolving" to include mixing together to form a mixture or suspension (*id.* at 7-9). Tolmar contends that a "formulation" can only be a solution

[5] The term "dissolving" appears in claim 1 of the '712 patent.

[6] This is the construction Tolmar advocated for at the hearing. (*See* Tr. at 27)

(D.I. 62 at 14-16), and so construes "dissolving" with respect only to forming a solution, that is, a single-phase homogenous mixture. (D.I. 62 at 16-19)

The Court's construction of "dissolving" – "mixing together to form a solution" – follows from its construction of "formulation." As explained above, the claimed formulations are solutions. Thus, because claim 1 of the '712 patent recites "preparing a . . . formulation" by "dissolving" an "LHRH-related peptide compound" in a "polar aprotic solvent," the step of "dissolving" creates a solution.

Horatio contends that because the patents describe formulations as variously being "suspensions," "solutions," "mixtures," and attempted solutions, the term "dissolving" should not be limited solely to solutions. (D.I. 66 at 8; D.I. 72 at 8-9) But the suspensions described by the patents as formulations are prior art, not the claimed invention. (*See* '547 patent, 2:64-3:6)

D. "LHRH antagonist"[7]

Horatio "LHRH-related peptide compound"
Tolmar "an LHRH analog that inhibits and does not stimulate the release of LH after administration"
Court "an LHRH analog that inhibits and does not stimulate the release of LH after initial administration"

Horatio contends that the use of "LHRH antagonist" in the claims is a mistake made in prosecution that the Court should correct. (D.I. 66 at 9-14; D.I. 72 at 10-11) In its briefing, Horatio argued that its correction satisfies the two-part test laid out in *Novo Indus., L.P. v. Micro Molds Corp.*, 350 F.3d 1348, 1354 (Fed. Cir. 2003). (D.I. 66 at 9-14) However, during the Markman hearing, Horatio contended that the *Novo* test does not apply here because the asserted

[7] The term "LHRH antagonist" appears in claims 8 and 12 of the '712 patent.

patents are expired and therefore, unlike the patent in *Novo*, cannot be corrected by the Patent Office. (Tr. at 43-45) Horatio now insists that *Phillips* is the appropriate standard under which to interpret the claims. (Tr. at 45) In the alternative, Horatio maintains its original argument that the Court should correct the claim term under *Novo*. (*Id.*)

Horatio does not cite any authority for its proposition that the *Novo* test does not apply to expired patents. (*Id.*) Nor does Horatio cite authority establishing that the PTO will not correct an expired patent that is being litigated.[8] In any case, even were the Court were to apply *Phillips*, the Court is not persuaded that one of skill in the art would construe "LHRH antagonist" in the way Horatio suggests. The record does not consistently make clear whether LHRH is an agonist or antagonist; a POSA might find the claim indefinite

Generally – and here – a district court may only correct an "obvious minor typographical [or] clerical" error in a patent if (1) "the correction is not subject to reasonable debate based on consideration of the claim language and the specification" and (2) "the prosecution history does not suggest a different interpretation of the claims." *Novo*, 350 F.3d at 1354. Horatio's proposed correction of "LHRH antagonist" is not proper because its appropriateness would be subject to reasonable debate. It is true, as Horatio contends, that as a result of the mistake, claims 12 and 13 are "nonsensical" because they characterize leuprolide, an LHRH agonist, as an "LHRH antagonist." (D.I. 66 at 12) But, as Tolmar points out (D.I. 70 at 9), there are multiple possible reasonable corrections: "LHRH antagonist" could be interpreted as "LHRH agonist" or "LHRH analog." Both of these alternative constructions would also fix the scientific inaccuracy that exists in claims 12 and 13 as written, as even Horatio seems to acknowledge. (*See* Tr. at 49-50)

[8] As Horatio only first made this argument at the hearing, neither party provided briefing pertaining to it.

("[A] correction of 'LHRH antagonist' to 'LHRH agonist' would also remedy [the purported] error and bring claims 8 to 10 and 12 to 15 into agreement.")

The Court is not persuaded that anything in Tolmar's construction of "LHRH-antagonist" prevents "LHRH-agonist" from being construed in a scientifically accurate manner. Accordingly, the Court will largely adopt Tolmar's construction, which is a scientifically accurate definition of an LHRH antagonist. However, the Court will clarify in its construction that an LHRH antagonist's inhibitory effect occurs "after ***initial*** administration."

E. "implantable drug delivery device" and "implantable drug delivery system"[9]

	"implantable drug delivery device"	**"implantable drug delivery system"**
Horatio	"a drug delivery device that can be inserted into a subject and release a drug or drugs into the subject"	"a drug delivery system that can be inserted into a subject and release a drug or drugs into the subject"
Tolmar	"a preformed device which can be inserted, as is, into a subject and control the release of a drug into the subject"	"a preformed system which can be inserted, as is, into a subject and control the release of a drug into the subject"
Court	"a drug delivery device that can be inserted into a subject and release a drug or drugs into the subject"	"a drug delivery system that can be inserted into a subject and release a drug or drugs into the subject"

Horatio contends that these terms cover both pre-formed device/system injections and *in situ* depot injections. (D.I. 66 at 14-15) Tolmar counters that the terms cover only pre-formed device/system injections. (D.I. 62 at 19-20)

The Court agrees with Horatio that *in situ* depot injections are within the plain meaning of the terms "implantable drug delivery device" and "implantable drug delivery system." The intrinsic evidence does not disturb this interpretation.

[9] The term "implantable drug delivery device" appears in claim 11 of the '712 patent. The term "implantable drug delivery system" appears in claim 15 of the '712 patent.

Tolmar points out that the patents provide several examples of "implantable devices," all of which are pre-formed. (*See* D.I. 62 at 19-20) (citing '547 patent, 8:61-67, 2:47-53) Tolmar also notes that the patents criticize prior art depot formulations. (D.I. 70 at 19-20) But excluding depot injections from the construction is not supported because the patents do not show a "clear intention" by the patentee, using words of "manifest exclusion or restriction," to limit "implantable drug delivery device" and "implantable drug delivery system" solely to pre-formed devices and systems. *See Hill-Rom*, 755 F.3d at 1372. Nothing in the patents suggests that a depot is not an "implantable device" nor that the inventive stable non-aqueous formulations could not be delivered by a depot.

F. "leuprolide is administered daily"[10]

The parties disputed the construction of "leuprolide is administered daily" in their claim construction briefing (D.I. 62, 66, 70, 72) but now agree that the term should be given its plain and ordinary meaning (D.I. 75). The Court will adopt this construction.

III. CONCLUSION

The Court will construe the disputed terms as explained above. An appropriate Order follows.

[10] The term "leuprolide is administered daily" appears in claim 13 of the '712 patent.

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ORDER

At Wilmington, this **26th** day of **December, 2018**:

For the reasons set forth in the Memorandum Opinion issued this date,

IT IS HEREBY ORDERED that the claim terms in this case are construed as follows:

Claim Term	**Court's Construction**
"[stable] non-aqueous formulation"	"solution having a non-water-based solvent system" The phrase "stable non-aqueous formulation" is limiting when found in the preamble.
"leuprolide"	"an LHRH agonist having the structure 5-oxo-Pro1-His2-Trp3-Ser4-Tyr5-D-Leu6-Leu7-Arg8-Pro9-NHEt, and not salts thereof"
"LHRH"	"a naturally occurring hormone that is a decapeptide with the structure pGlu-His-Trp-Ser-Tyr-Gly-Leu-Arg-Pro-Gly-NH2, and not salts thereof"
"nafarelin"	"the specific LHRH-related compound, nafarelin, itself, and not salts thereof"

"goserelin"	"the specific LHRH-related compound, goserelin, itself, and not salts thereof"
"dissolving"	"mixing together to form a solution"
"LHRH antagonist"	"an LHRH analog that inhibits and does not stimulate the release of LH after initial administration"
"implantable drug delivery device"	"a drug delivery device that can be inserted into a subject and release a drug or drugs into the subject"
"implantable drug delivery system"	"a drug delivery system that can be inserted into a subject and release a drug or drugs into the subject"
"leuprolide is administered daily"	plain and ordinary meaning
"stable [non-aqueous formulation]"	The term "stable" means "at least about 65% chemically and physically stable peptide compound remains after two months at 37° C. (or equivalent conditions at an elevated temperature)."
"stable at 37° C. for at least 3 months"	"at least about 65% chemically and physically stable peptide compound remains after three months at 37° C. (or equivalent conditions at an elevated temperature)"
"which does not contain components containing added water"	"wherein the at least one polar aprotic solvent does not contain components containing added water"
"which exhibits bacteriostatic, bactericidal or sporicidal activity without the use of a conventional bacteriostatic, bactericidal or sporicidal agent"	"wherein the at least one polar aprotic solvent exhibits bacteriostatic, bactericidal or sporicidal activity without the use of a conventional bacteriostatic, bactericidal or sporicidal agent"

UNITED STATES DISTRICT JUDGE