IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE RESEARCH FOUNDATION OF STATE UNIVERSITY OF NEW YORK; NEW YORK UNIVERSITY; GALDERMA LABORATORIES INC.; AND GALDERMA LABORATORIES, L.P.,	:	
Plaintiffs,	:	
v.	:	C.A. No. 09-184-JJF-LPS
MYLAN PHARMACEUTICALS, L.P.	:	
Defendant.	:	

REPORT AND RECOMMENDATION
REGARDING CLAIM CONSTRUCTION

Plaintiffs, The Research Foundation of State University of New York ("SUNY"), New York University ("NYU"), Galderma Laboratories, Inc. ("GLI"), and Galderma Laboratories L.P. ("GLLP") (collectively, "Plaintiffs"), hold all substantial rights in four patents which cover a tetracycline class drug that GLLP markets under the brand name "Oracea®." GLLP also holds a New Drug Application on Oracea® brand doxycycline capsules and is the exclusive distributor of Oracea® in the United States. Defendant Mylan Pharmaceuticals, Inc. ("Mylan") submitted an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval for the commercial use, manufacture, and sale of generic doxycycline capsules prior to the expiration of the patents-in-suit. Plaintiffs subsequently brought this ANDA patent infringement action. The matter has been referred to me for purposes including claim construction. (Docket Item ("D.I.") 50) Below I provide my recommended construction of the disputed claim terms.

BACKGROUND

A. Procedure

On March 19, 2009, Plaintiffs brought this action against Mylan for infringement of U.S. Patent Nos. 7,232,572 ("the '572 patent"), 7,211,267 ("the '267 patent"), 5,789,395 ("the '395 patent"), and 5,919,775 ("the '775 patent"). (D.I. 1) Mylan filed its answer and counterclaim on April 16, 2009. (D.I. 14) After the parties briefed their positions on claim construction, I conducted a Markman hearing on March 23, 2010. *See* March 23 Hearing Transcript (D.I. 133) (hereinafter "Tr.").

1. The Patents-In-Suit

The patents-in-suit are divisible into two related pairs: the "Ashley patents," which are the '267 and '572 patents (also referred to as the "Ashley '267" and the "Ashley '572") and the "Amin patents," which are the '395 and '775 patents (also referred to as the "Amin '395" and the "Amin '775").[1] The Ashley patents are directed to methods of treating acne and rosacea with tetracycline compounds. The Amin patents are directed to methods of using tetracycline compounds to inhibit production of nitric oxide ("NO"), a mediator of rosacea.

A key feature of the inventions is that the tetracycline compounds achieve a therapeutic result through non-antimicrobial mechanisms. Specifically, tetracycline compounds with antimicrobial activity are either administered in such low doses that zero or minimal antimicrobial activity results or they are modified at the molecular level to eliminate all or substantially all antimicrobial activity.

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[1]The patents are found in the record as follows: Ashley '572 (D.I. 1 Ex. A); Ashley '267 (D.I. 1 Ex. B); Amin '395 (D.I. 1 Ex. C); and Amin '775 (D.I. 1 Ex. D).

a. The Ashley Patents

The Ashley '267 patent, entitled "Methods of Treating Acne," was granted by the U.S. Patent and Trademark Office ("PTO") on May 1, 2007. The Ashley '572 patent, entitled "Methods of Treating Rosacea," is a continuation of the '267 patent and issued on June 19, 2007. Both patents claim priority to an application filed April 5, 2002. The '267 patent contains thirty-one claims, only the first of which is independent. The '572 patent contains twenty-six claims, of which only claims 1 and 20 are independent. The "Background of the Invention" sections are identical in both Ashley patents.

b. The Amin Patents

The Amin '395 patent, entitled "Method of Using Tetracycline Compounds for Inhibition of Endogenous Nitric Oxide Production," was granted on August 4, 1998. The Amin '775 patent, entitled "Method of Inhibiting Expression of Inducible Nitric Oxide Synthase With Tetracycline," issued on July 6, 1999 and was a divisional of the '395 patent application. The '395 patent contains sixteen claims, three of which are independent. The '775 patent contains ten claims, of which only the first is independent. The Amin patents are nearly identical; only the Abstracts and claims differ.

DISPUTED TERMS

The parties initially presented ten disputed claim terms. (D.I. 53; D.I. 55) However, by the conclusion of the Markman hearing, they had agreed upon the proper construction of what they had labeled the "condition characterized by" and the "amount" terms. (Tr. at 79-80, 90-91, 104) I include the parties' agreed-upon constructions as part of my Recommended Constructions

at the conclusion of this Report and Recommendation.

The remaining disputed terms are:

(a) ***"tetracycline compound" terms***

i. "***tetracycline compound***" (Amin '395 patent, claim 1; Amin '775 patent, claim 1; Ashley '572 patent, claim 1)

ii. "***antibiotic tetracycline compound***" (Ashley '267 patent, claims 1, 12, 16-17, 23; Ashley '572 patent, claims 1, 4-6, 11)

iii. "***the tetracycline compound has substantially no antibiotic activity***" (Amin '395 patent, claims 2 and 14; Amin '775 patent, claim 2).

(b) "***minimum antibiotic serum concentration***" (Ashley '267 patent, claim 12; Ashley '572 patent, claim 4).

(c) "***chronic inflammatory condition***" (Amin '395 patent, claim 13).

Representative claims, showing the disputed claim terms, are reproduced below, with the disputed terms highlighted:

> 1. A method for inhibiting nitric oxide production in a mammal system, comprising providing to the mammalian system an amount of a ***tetracycline compound*** sufficient to cause a decrease in the amount of nitric oxide produced endogenously by the mammalian-system.
>
> 2. The method according to claim 1, wherein ***the tetracycline compound has substantially no anti-microbial activity*** in the mammal system.
>
> 13. The method according to claim 11,[2] wherein the medical condition is a ***chronic inflammatory condition***.

[2]Claim 11 reads: "A method for treating a mammal having a medical condition characterized by excess endogenous production of nitric oxide, comprising administering to the mammal an amount of a tetracycline compound sufficient to inhibit endogenous nitric oxide production in the mammal."

(Amin '395 patent, claims 1-2, 13)

> 1. A method of treating acne in a human in need thereof comprising administering orally or intravenously to said human an ***antibiotic tetracycline compound*** in a sub-antibacterial amount that reduces lesion count, said amount being 10-80% of the antibacterial effective amount, wherein the ***tetracycline compound*** is administered long term, without administering a bisphosphonate compound.
>
> 12. A method according to claim 1, wherein said tetracycline compound is an antibiotic tetracycline compound administered in an amount which results in a serum concentration which is 10-80% of the ***minimum antibiotic serum concentration***.

(Ashley '267 patent, claims 1, 12)

LEGAL STANDARDS

"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). Construing the claims of a patent presents a question of law. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977-78 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370, 388-90 (1996). "[T]here is no magic formula or catechism for conducting claim construction." *Phillips*, 415 F.3d 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." *Liebel-Flarsheim Co. v.*

Medrad, Inc., 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotation marks omitted), *aff'd*, 481 F.3d 1371 (Fed. Cir. 2007).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman*, 52 F.3d at 980. 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.*

A court also may rely on "extrinsic evidence," which "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 ordinary 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). Thus, if possible, claims should be construed to uphold validity. *See In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984).

CONSTRUCTION OF DISPUTED TERMS

A. "tetracycline compound" terms

1. *"tetracycline compound"*

The parties agree that the term "tetracycline compound" includes both antibiotic and non-antibiotic tetracycline compounds. (D.I. 62 at 6; D.I. 53 at 13) The parties disagree, however, as to whether the term requires construction. Plaintiffs do not believe this term needs to be construed by the Court because one of skill in the art would understand its plain and ordinary meaning. (D.I. 53 at 11; D.I. 64 at 2) In the alternative, if the Court is to construe "tetracycline compound," Plaintiffs propose "a compound within the class of which tetracycline is the parent compound and is characterized by a unique four-ring structure." (D.I. 64 at 2; *see also* Tr. at 34.) Mylan proposes, instead, that "tetracycline compound" should be construed as "an antibiotic or non-antibiotic compound that has, or is a derivative of, the general [four-ring structure of

tetracycline]. Non-antibiotic tetracycline compounds are structurally related to the antibiotic tetracyclines, but have had their antibiotic activity substantially or completely eliminated by chemical modification." (D.I. 55 at 7)

I agree with Plaintiffs to the extent they contend that "tetracycline compound" should be construed according to its plain and ordinary meaning. I do not agree, however, that construing the instant term according to its "plain and ordinary meaning" to a person having ordinary skill in the art means that no construction is necessary. Instead, as Mylan argues, I conclude that construction is necessary to reduce confusion – which is particularly important here given the presence of many similar but not identical "tetracycline" claim terms – and to eliminate any ambiguity as to whether the term "antibiotic tetracycline compounds" includes "non-antibiotic compounds" (it does not).

Plaintiffs' proposed alternative construction is consistent with the patent specification. Accordingly, I recommend that the Court construe "tetracycline compound" as "a compound within the class of which tetracycline is the parent compound and is characterized by a unique four-ring structure."[3] Mylan's concern that "antibiotic tetracycline compounds" should not be construed to include "non-antibiotic compounds" will be dealt with in connection with construction of the remaining "tetracycline compound" terms.

2. ***"antibiotic tetracycline compound"***

Plaintiffs assert that the meaning of "antibiotic tetracycline compound" is clear on its face and requires no construction. (D.I. 53 at 13) Mylan, relying on its proposed construction of "tetracycline compound," proposes that the Court construe "antibiotic tetracycline compound" as

[3]The four-ring structure of tetracycline is depicted in the Ashley patents at col. 1 lines 58-65 and the Amin patents at col. 3 lines 11-18.

"a tetracycline compound that has not had its antibiotic activity substantially or completely eliminated by chemical modification." (D.I. 55 at 10) Mylan stresses that the term "antibiotic tetracycline compound" requires a construction clarifying that "antibiotic tetracycline compounds" do not include "non-antibiotic tetracycline compounds."[4] (D.I. 62 at 8)

I recommend that the Court construe this term according to its plain meaning. The parties are in agreement that the term "tetracycline compound" includes both antibiotic and non-antibiotic tetracycline compounds. Plaintiffs also agree with Mylan that the term "antibiotic tetracycline compounds" excludes "non-antibiotic tetracycline compounds." (Tr. at 26, 29-30) To eliminate any risk of confusion on this point, I recommend that the Court construe "antibiotic tetracycline compound" as "a compound having antibiotic activity within the class of which tetracycline is the parent compound and is characterized by a unique four-ring structure."

3. *"the tetracycline compound has substantially no anti-microbial activity"*

Plaintiffs construe the term "the tetracycline compound has substantially no anti-microbial activity" to mean "the tetracycline compound has been modified chemically to reduce or eliminate its antibacterial activity, or the tetracycline compound possesses antibacterial activity but is employed in an amount which has substantially no antibacterial effect." (D.I. 53 at 16) Mylan, on the other hand, construes the term "the tetracycline compound [that] has substantially no anti-microbial activity" to mean "a non-antibiotic tetracycline compound." (D.I. 55 at 11) I recommend that the Court adopt Plaintiffs' proposed construction.

During the Markman hearing, Mylan agreed to the portion of Plaintiffs' construction

[4]The Ashley patents state: "[n]on-antibiotic tetracycline compounds are structurally related to the antibiotic tetracyclines, but have had their antibiotic activity substantially or completely eliminated by chemical modification." (Ashley '267 patent, col. 5 lines 4-7)

relating to a "tetracycline compound that has been modified chemically to reduce or eliminate its antibacterial activity" because, in its view, that phrase is synonymous with Mylan's proposed construction, i.e., a "non-antibiotic tetracycline compound." (Tr. at 53-55) Mylan does not agree, however, that the claim term also encompasses tetracycline compounds with antibacterial activity that are employed in an amount which has substantially no antibacterial effect. (Tr. at 59) Instead, according to Mylan, the language of the claims mandates a construction that excludes tetracycline compounds having antimicrobial activity because "it is the compound (and not the amount of the compound as [P]laintiffs argue) that 'has substantially no antimicrobial activity.'" (D.I. 55 at 11)

The disputed claim term is found in (among other places) claim 2 of the Amin '395 patent, which reads: "The method according to claim 1, wherein ***the tetracycline compound has substantially no anti-microbial activity*** in the mammal system" (emphasis added). Read in full, and in the context of the entire patent including the specification, I find that it refers to a functional limitation of the tetracycline compound as it is administered to a mammal, rather than a physical characteristic of the compound itself. This conclusion is supported by the multiple references in the patent specification indicating that a preferred embodiment of the Amin patents' invention is the administration of an antibiotic compound in an amount that does not have antibiotic effect. For example, the Amin '395 patent states:

> Preferably, the tetracycline compound is provided in an amount which has little or no antimicrobial activity. . . . Accordingly, the method can beneficially employ a tetracycline compound which has been modified chemically to reduce or eliminate its antimicrobial properties. . . .
>
> The invention can also use tetracycline compounds which possess antibacterial activity. However, such compounds are preferably employed in an

amount which has substantially no anti-bacterial effect but which is effective for inhibiting iNOS activity in the involved tissue.

(Amin '395 patent, col. 8 lines 24-43)

Mylan's construction would improperly read out of the claims at issue a preferred embodiment. While "[i]t is often the case that different claims are directed to and cover different disclosed embodiments," Federal Circuit case law "generally counsels against interpreting a claim term in a way that excludes the preferred embodiment from the scope of the invention." *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1383 (Fed. Cir. 2008). This is especially true when the term "has multiple ordinary meanings consistent with the intrinsic record," as is the case here. *Id.*

Accordingly, I recommend that the Court construe the term "the tetracycline compound has substantially no anti-microbial activity" to mean "the tetracycline compound has been modified chemically to reduce or eliminate its antibacterial activity, or the tetracycline compound possesses antibacterial activity but is employed in an amount which has substantially no antibacterial effect."

B. ***"minimum antibiotic serum concentration"***

Plaintiffs propose that the term "minimum antibiotic serum concentration" means "the lowest concentration known to exert a significant antibiotic effect based on steady-state pharmacokinetics." (D.I. 53 at 27) Mylan proposes that the term instead means "the lowest concentration known to significantly inhibit the growth of microorganisms, e.g., bacteria." (D.I. 55 at 22) I largely agree with Mylan.

Plaintiffs misapprehend that the minimum antibiotic serum concentration refers to a

number calculated from the concentration of a given compound in a subject's blood measured over long term administration. Instead, as Mylan explains, the minimum antibiotic serum concentration is the lowest concentration of a given compound known to exert a significant antibiotic effect. (Tr. at 98-99) In other words, the minimum antibiotic serum concentration is not a measure of the serum antibiotic level (i.e., the antibiotic level in the blood), but is instead a characteristic of the tetracycline compound. It is a constant; and it is measured in a laboratory, not in a patient's body. The concept of steady-state pharmacokinetics (and with it the dispute as to the time at which one measures the serum concentration in a human's blood) is not relevant to construction of this disputed claim term.

The patent specification provides a definition, stating: "The minimum antibiotic serum concentration is the lowest concentration known to exert a significant antibiotic effect." ('267 patent, col. 6 lines 14-16) Thus, I recommend that the Court construe "minimum antibiotic serum concentration" as "the lowest concentration known to exert a significant antibiotic effect." This language is slightly different from that proposed by Mylan.

C. ***"chronic inflammatory condition"***

Plaintiffs assert that the meaning of the term "chronic inflammatory condition" is plain to one skilled in the art and, therefore, needs no construction. (D.I. 64 at 27) Mylan, on the other hand, proposes that the term be construed to mean "a condition characterized by inflammation which persists for days or weeks or longer." (D.I. 55 at 15)

The '395 patent, in which this claim term is found, distinguishes between acute and chronic inflammation as follows:

> Acute inflammation is generally of relatively short duration, lasting for from about a few minutes to about one to two days. Its main characteristics are increased blood flow, exudation of fluid and plasma proteins (edema) and emigration of leukocytes, predominantly neutrophils.
>
> Chronic inflammation is of longer duration, e.g., days to weeks or even longer, and is associated histologically with the presence of lymphocytes and macrophages and with proliferation of blood vessels and connective tissue.

('395 patent, col. 7 lines 35-44) As can be seen, the patent distinguishes between acute and chronic conditions based on their general duration, but does so broadly, in a manner that allows for the possibility of overlap (e.g., inflammation lasting two days may be a lengthy acute condition or a short chronic condition). The patent further identifies non-temporal characteristics of acute inflammation and analogous associations of chronic inflammation.

Because the parties dispute the meaning of "chronic inflammatory condition" and their dispute is not immaterial, it is appropriate for the Court to construe this term. *See generally O2 Micro Intern. Ltd. v. Beyond Innovation Technology Co., Ltd.,* 521 F.3d 1351, 1361-62 (Fed. Cir. 2008). Given the portion of the specification quoted above, a proper construction of this disputed claim term should account for not just the temporal aspect of a chronic condition, but also its physical associations.

Accordingly, I recommend that the Court construe "chronic inflammatory condition" to mean "an inflammatory condition lasting for days to weeks or longer, and is associated histologically with the presence of lymphocytes and macrophages and with proliferation of blood vessels and connective tissue."

RECOMMENDED CONSTRUCTIONS

For the reasons given above, I recommend that the Court construe the disputed claim terms as follows:

(1) The term "tetracycline compound," as used in claim 1 of the Amin '395 and '572 patents and claim 1 of the Ashley '572 patent, be construed as "a compound within the class of which tetracycline is the parent compound and is characterized by a unique four-ring structure."

(2) The term "antibiotic tetracycline compound," as used in claims 1, 12, 16-17, and 23 of the Ashley '267 patent and in claims 1, 4-6, and 11 of the Ashley '572 patent, be construed as "a compound having antibiotic activity within the class of which tetracycline is the parent compound and is characterized by a unique four-ring structure."

(3) The term "the tetracycline compound has substantially no antibiotic activity," as used in claims 2 and 14 of the Amin '395 patent and claim 2 of the Amin '775 patent, be construed as "the tetracycline compound has been modified chemically to reduce or eliminate its antibacterial activity, or the tetracycline compound possesses antibacterial activity but is employed in an amount which has substantially no antibacterial effect."

(4) The term "minimum antibiotic serum concentration," as used in claim 12 of the Ashley '267 patent and claim 4 of the Ashley '572 patent, be construed as "the lowest concentration known to exert a significant antibiotic effect."

(5) The term "chronic inflammatory condition," as used in claim 13 of the Amin '395

patent, be construed as "an inflammatory condition lasting for days to weeks or longer, and is associated histologically with the presence of lymphocytes and macrophages and with proliferation of blood vessels and connective tissue."

Additionally, I recommend that the Court adopt the following constructions that have been agreed upon by the parties:

(1) The term "a condition characterized by increased [endogenous] nitric acid production," as used in claim 5 of the Amin patents, be construed as "a disease or condition which may be linked to the increased endogenous production of nitric oxide by inducible nitric oxide synthase by cells such as leukocytes (e.g., neutrophils and macrophages) and other cells."

(2) The term "a condition characterized by an abnormally high level of activity of inducible nitric oxide synthase," as used in claim 9 of the Amin patents, be construed as "a disease or condition which may be linked to the increased endogenous production of nitric oxide substantially over usual levels by inducible nitric oxide synthase by cells such as leukocytes (e.g., neutrophils and macrophages) and other cells."

(3) The term "a medical condition characterized by excess endogenous production of nitric oxide," as used in claim 11 of the Amin '395 patent, be construed as "a disease or condition which may be linked to normally or abnormally increased endogenous production of nitric oxide by inducible nitric oxide synthase by cells such as leukocytes (e.g., neutrophils and macrophages) and other cells."

(4) The terms "the antibacterial effective amount" and "the antibiotic amount," as

used in claim 1 of the Ashley patents, be construed as "an amount that significantly inhibits the growth of microorganisms, e.g., bacteria."

(5) The term "sub-antibacterial amount," as used in claim 1 of the Ashley '267 patent, be construed as "an amount that does not significantly inhibit the growth of microorganisms, e.g., bacteria," and the term "an amount that ... has substantially no antibiotic activity," as used in claim 1 of the Ashley '572 patent, be construed as "an amount that is effective to treat the papules and pustules of rosacea but does not significantly inhibit the growth of microorganisms, e.g., bacteria."

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections **of no longer than ten (10) pages within fourteen (14) days after being served with a copy of this Report and Recommendation.** Fed. R. Civ. P. 72(b). The failure of a party to object to legal conclusions may result in the loss of the right t ode novo review in the district court. *See Henderson v. Carlson,* 812 F.2d 874, 878-79 (3d Cir. 1987); *Sincavage v. Barnhart*, 171 Fed. Appx. 924, 925 n.1 (3d Cir. 2006). **A party responding to objections may do so within fourteen (14) days after being served with a copy of objections; such response shall not exceed ten (10) pages. No further briefing shall be permitted with respect to objections without leave of the Court.**

The parties are directed to the Court's Standing Order In Non-*Pro Se* Matters For Objections Filed Under Fed. R. Civ. P. 72(b), dated November 16, 2009, a copy of which is available on the Court's website, www.ded.uscourts.gov/StandingOrdersMain.htm.

Dated: May 12, 2010
Wilmington, Delaware

Honorable Leonard P. Stark
UNITED STATES MAGISTRATE JUDGE