IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MYLAN PHARMACEUTICALS INC.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	Civ. No. 10-892-LPS
	:	
GALDERMA LABORATORIES, INC.; AND GALDERMA LABORATORIES, L.P.; and SUPERNUS PHARMACEUTICALS, INC.,	:	
	:	
Defendant.	:	

OPINION

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March 24, 2011
Wilmington, DE

Stark, U.S. District Judge:

Mylan Pharmaceuticals Inc. ("Mylan") filed the instant lawsuit on October 18, 2010 against Defendants Galderma Laboratories, Inc., Galderma Laboratories, L.P., and Supernus Pharmaceuticals, Inc. (collectively, "Galderma"). (D.I. 1)[1] In this lawsuit, Mylan seeks a declaratory judgment that its generic version of the drug Oracea® does not infringe any valid claim of U.S. Patent No. 7,749,532 (the "'532 patent")[2] owned by Defendant Supernus. (D.I. 1) Presently pending before the Court is claim construction. Briefing was completed on March 13, 2011, and the Court held a *Markman* hearing on March 21, 2011. (D.I. 113) ("Tr.") This is the Court's opinion on the proper construction of the disputed terms.

I. BACKGROUND

A. Overview

The '532 patent, entitled "Once Daily Formulations of Tetracyclines," lists Rong-Kun Chang et al. as named inventors. (D.I. 94 Ex 1)[3] Generally, the '532 patent relates to the use of antibiotics, such as doxycycline, to treat inflammatory skin conditions, including rosacea. (D.I. 93 at 1; *see also* '532 patent, col. 1 lines 65-67) In the usual course, antibiotics are used to treat bacterial infections. ('532 patent, col. 1 lines 20-22) Using normal doses of antibiotics over a longer period of time, however, can lead to undesirable side effects, including allowing bacteria

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[1]The parties are involved in another patent infringement lawsuit in this District concerning the same drug, Oracea®. *See Research Found. of State Univ. of N.Y. v. Mylan Pharms., Inc.*, 723 F. Supp. 2d 638 (D. Del. 2010) (Civ. No. 09-184-LPS) (hereinafter "*Mylan Op.*").

[2]The '532 patent is found at D.I. 94 Ex. 1.

[3]The '532 patent is also referred to as the "Chang patent." (*See* D.I. 1 at 5)

to become resistant to antibiotics. (*Id.* col. 2 lines 8-10)

Doxycycline and related tetracyclines, however, have therapeutic uses that do not rely on their antibiotic capabilities, particularly when the dosage level is lower. These additional uses include treating inflammatory skin conditions, such as rosacea or periodontal disease. (*Id.* col. 1 lines 30-39) While the dosage must be low enough to avoid an "antibacterial effect," the dosage must also be sufficiently high to be effective to target and treat a condition.

The prior art discloses using lower dosages of antibiotics to treat inflammatory conditions. (*Id.* col. 1 lines 64-66) Periostat®, for example, is an oral medication of 20 mg of doxycycline that is administered twice daily. According to the '532 patent's specification, because of the twice-daily formulation, "Periostat® . . . raises concerns about patient compliance. Thus, it would be highly beneficial to develop a once-a-day formulation for doxycycline." (*Id.* col. 2 lines 3-5) The '532 patent, thus, is directed at a once-daily formulation that provides doxycycline at levels that are "high enough to be effective to have a beneficial effect . . . but not as high as to exert an antibacterial effect." (*Id.* col. 2 lines 23-25)

According to Galderma, its drug Oracea® is the commercial embodiment of the '532 patent. (D.I. 95 at 4) Oracea® is a "40 mg once-daily orally administered pharmaceutical dosage form containing 30 mg immediate release beads and 10 mg delayed release beads." (*Id.*) Galderma owns New Drug Application ("NDA") 50-805, relating to Oracea®.[4] Oracea® is a

[4]Galderma's patents are: U.S. Patent No. 7,211,267 and No. 7,232,572 (the "Ashley patents"), as well as No. 5,789,395 and No. 5,919,775 (the "Amin patents"). (D.I. 93 at 1) The Ashley and Amin patents are directed to methods of using tetracycline compounds to help treat rosacea and other inflammatory skin conditions. *See Mylan Op.*, 723 F. Supp. 2d at 644.

drug that is used to treat rosacea.[5] In October 2008, Mylan filed Abbreviated New Drug Application ("ANDA") 90-855 with the U.S. Food and Drug Administration ("FDA"), pursuant to § 505(j) of the Federal Food, Drug, and Cosmetic Act.[6] In its ANDA application, Mylan sought approval of a generic form of Oracea®.[7] (D.I. 1 at 3) Galderma sued Mylan in this Court in March 2009, alleging that Mylan's generic version of Oracea® infringes Galderma's patent rights. Galderma successfully petitioned the Court for a preliminary injunction preventing Mylan from launching its generic. *See Mylan Op.*, 723 F. Supp. 2d at 644.

The Chang patent issued on July 6, 2010, during the pendency of the previous litigation between the parties. (D.I. 94 Ex. 1) After the Chang patent issued, Galderma added the '532 patent to the FDA's Orange Book. (D.I. 1 at 6) In October 2010, Mylan initiated the current lawsuit based on the'532 patent. (D.I. 1) In its complaint, Mylan sought a declaratory judgment that its generic drug would not violate any valid claims of the Chang patent.

The two cases have been consolidated for purposes of trial, which is scheduled to begin July 5, 2011. (D.I. 32) All of the patents – the Ashley patents, the Amin patents, and the Chang

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[5]Rosacea is a chronic inflammatory skin condition characterized by lesions and permanent dilation of blood vessels. (D.I. 95 at 2) While there is no known cure for rosacea, Oracea® is the first and so far only oral treatment for rosacea approved by the FDA. *Mylan Op.*, 723 F. Supp. 2d at 644. Like Periostat®, Oracea® operates by using low doses of doxycycline. (D.I. 95 at 3)

[6]21 U.S.C. §355(j) provides, in relevant part, "(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug." The statute goes on to explain that, in order to obtain approval, the person filing the ANDA application must certify that the use of the drug for which approval is sought does not infringe a valid patent, or, if it does infringe a patent, that the patent's information has not been filed, the patent has expired, or that the patent is invalid. 21 U.S.C. § 355(j)(2)(A)(7)(I-IV).

[7]On July 2, 2010, the FDA approved Mylan's ANDA application. (D.I. 1 at 5)

patent – are directed toward using antibiotics for purposes other than treating bacterial infection. (D.I. 95 at 3) The patents-in-suit, therefore, teach doxycycline dosages that are below a certain level, in order to prevent antibiotic resistance that accompanies the use of antibiotics at higher dosages for longer timeframes. (*Id.*)

B. Terms in Dispute

The '532 patent claims that are presently at issue are independent claims 1, 15, and 20 along with dependent claims 4 and 18. (D.I. 93 at 50) Specifically, the parties dispute the meaning of the "steady state" terms. Claims 1 and 4 are representative of the disputes. They are reproduced below, with the disputed language highlighted.

> 1. An oral pharmaceutical composition of doxycycline, which at a once-daily dosage will give ***steady state blood levels of doxycycline of a minimum of 0.1 μg/ml and a maximum of 1.0 μg/ml***, the composition consisting of (i) an immediate release (IR) portion comprising a drug, wherein the drug consists of about 30 mg doxycycline; (ii) a delayed release (DR) portion comprising a drug, wherein the drug consists of about 10 mg doxycycline, in which the DR portion is in the form of pellets coated with at least one enteric polymer; and (iii) one or more pharmaceutically acceptable excipients.
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> 4. The composition of claim **1**, which at a once-daily dosage will give ***steady state blood levels of the doxycycline of between 0.3 μg/ml to 0.8 μg/ml.***

II. 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).

III. CONSTRUCTION OF DISPUTED TERMS

The parties identify two terms in the '532 patent that require construction.[8] (D.I. 93 at 5) Both of the terms relate to the amount of doxycycline found in the blood of an individual taking the drug in the manner taught by the patent. (*Id*) As Mylan puts it, the fundamental dispute is whether the plasma concentrations resulting from administration of the claimed formulation may be "below (not less than) the 'minimum' . . . or above (not more than) the 'maximum.'" (*Id.*)

A. "steady state blood levels of doxycycline of a minimum of 0.1 μg/ml and a maximum of 1.0 μg/ml"

Claims 1, 15, and 20 are each independent claims that recite "steady state blood levels of doxycycline of a minimum of 0.1 μg/ml and a maximum of 1.0 μg/ml." ('532 patent, col. 11 lines 65-67; *id.* col. 12 line 67 to col. 13 line 2; *id.* col. 14 lines 4-6) Mylan proposes that this term means:

> plasma concentrations of doxycycline at steady state of not less than 0.1 μg/ml and not more than 1.0 μg/ml.

(D.I. 93 at 5) Galderma, on the other hand, proposes that the term be construed as:

> steady state plasma concentration of doxycycline of a minimum of 0.1 μg/ml and a maximum of 1.0 μg/ml.

(*Id.*)

The parties' differences effectively present two distinct disputes. First, the parties'

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[8]Mylan also contends that claims 4 and 18 are invalid under 35 U.S.C. 112 ¶ 1. (D.I. 93 at 6; *id.* at 3 n.4) The Federal Circuit distinguishes between claim construction issues and issues of invalidity. *See Markman,* 52 F.3d at 986 ("Ambiguity, undue breadth, vagueness, and triviality are matters that go to claim validity for failure to comply with 35 U.S.C. § 112-¶ 2, not to interpretation or construction.") (internal citations omitted). Accordingly, the Court will generally not address invalidity contentions in the context of claim construction.

competing constructions differ on the use of the singular or plural form for the language "plasma concentration(s)." Second, the parties dispute whether "minimum and maximum" should be interpreted to impose a "not less than" or "not more than" limitation. The Court will discuss each dispute separately.

1. "blood levels"

The parties agree that "blood levels" in the claim language should be construed to mean "plasma concentration" or "plasma concentrations." (D.I. 93 at 5) Mylan argues that Galderma's proposed construction improperly uses the singular "plasma concentration" instead of the plural "plasma ***concentrations***," the latter being (in Mylan's view) more consistent with the claim language, which is plural ("blood ***levels***"). (D.I. 93 at 6) In the briefing, Galderma suggested the singular versus plural issue was "of no moment." (D.I. 105 at 6 n.5) At the hearing, Galderma confirmed that it is not insisting on a singular form. (Tr. at 35)

Because the claim language recites "blood levels" in the plural, and because Galderma no longer appears to be advocating "plasma concentration" in the singular, the Court will use the plural "plasma concentrations" in its construction.

2. "a minimum of 0.1 μg/ml and a maximum of 1.0 μg/ml"

The heart of the dispute involves the minimum and maximum limitations. Galderma contends that the claim term is clear on its face and does not require construction by the Court. (D.I. 95 at 6) The operative terms here that create the tension – minimum and maximum – are well known to one of skill in the art. In Galderma's view, Mylan seeks to change the language of the claims, and thereby "narrow the scope," to be more precise than the claim language requires. (D.I. 105 at 2) In Galderma's view, Mylan also confuses claim construction with an

infringement analysis, because whether a person of ordinary skill in the art would consider blood levels at a steady state that are very close to the numerical thresholds – say, 0.09 as compared to 0.1 – to be within the scope of the claim is a question of infringement, not one of claim construction. (D.I. 105 at 3 n.2)

Mylan, on the other hand, insists that when the claims recite a blood concentration range, any blood concentration level that is outside that range does not meet the claims. In Mylan's view, the entire teaching of the '532 patent is that the blood levels will "stay within" the preferred levels recited in the claims, such that the claim language "***precludes*** plasma concentrations outside the specified ranges." (D.I. 93 at 7; D.I. 104 at 5) The '532 patent specification also emphasizes that the invention has ***both*** a maximum and minimum concentration level. Thus, according to Mylan, claims 1, 15, and 20 require plasma concentrations of "not less than" 0.1 μg/ml and "not more than" 1.0 μg/ml.

The patent clearly contemplates that the blood levels will remain within a certain concentration range. ('532 patent, col. 9 lines 9-13; *id.* col. 10 line 60 to col. 11 line 4) Using antibiotic drugs at lower doses for non-infection related purposes is founded on the premise that the blood concentration will not surpass a certain threshold and result in an antibacterial effect. Even Galderma recognizes this fact, writing: the "Oracea® drug product is specially formulated to maintain, with once daily dosing, a drug level that is subantibiotic, yet above the therapeutic level." (D.I. 95 at 4)

Claims 1, 15, and 20 contain the limitation "a minimum of 0.1 μg/ml and a maximum of 1.0 μg/ml." ('532 patent, col. 11, line 64 to col. 12 line 6; *id.* col. 12 line 64 to col. 13 line 8; *id.* col. 14 lines 3-12) The Court perceives no justification to rewrite this limitation to read, as

Mylan requests, "not less than 0.1 μg/ml and not more than 1.0 μg/ml." The phrases "not less than" and "not more than" appear nowhere in the '532 patent. Instead, in addition to the claim language itself, the specification also consistently recites the minimum and maximum language with respect to the 0.1 to 1.0 range. ('532 patent, col. 2 lines 40-41; *id.* col. 9 lines 11-12; *id.* col. 11 lines 1-3; *see also* Tr. at 8-9) Moreover, the terms maximum and minimum would be readily understandable to a lay judge and jury. *See generally U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997) (emphasizing that claim construction process should not devolve into an "exercise of redundancy"). While the Court is not persuaded by Galderma's fear that adoption of Mylan's proposed construction would improperly add greater precision to the claims, the Court also sees no reason to depart from the claim language used.

3. Conclusion

Therefore, the Court construes "steady state blood levels of doxycycline of a minimum of 0.1 μg/ml and a maximum of 1.0 μg/ml" to mean "steady state plasma concentrations of doxycycline of a minimum of 0.1 μg/ml and a maximum of 1.0 μg/ml."

B. Claims 4 and 18: "steady state blood levels of the doxycycline of between 0.3 μg/ml to 0.8 μg/ml"

Claims 4 and 18 depend from claims 1 and 15 respectively. ('532 patent, col. 12 lines 11-13; *id.* col 13 lines 13-15) Like claims 1, 15, and 20, claims 4 and 18 also recite a range of steady state blood levels, this time "between 0.3 μg/ml to 0.8 μg/ml." (*Id.*) Unlike the previous claims, however, claims 4 and 18 do not explicitly recite the "minimum" and "maximum" limitation. Instead, claims 4 and 18 provide, "steady state blood levels of the doxycycline of ***between*** 0.3 μg/ml ***to*** 0.8 μg/ml." (*Id.* (emphasis added))

Mylan proposes that the Court construe this term to mean:

> plasma concentrations of doxycycline at steady state of not less than 0.3 μg/ml and not more than 0.8 μg/ml.

(D.I. 93 at 5) Galderma, on the other hand, would have the Court construe the term (if at all) to mean:

> steady state plasma concentration of the doxycycline of between 0.3 μg/ml to 0.8 μg/ml.

(*Id.*)[9]

Galderma takes issue with Mylan's proposal, pointing out that claims 1, 15, and 20 use "minimum" and "maximum" with respect to the plasma concentrations range, whereas claims 4 and 18 do not. As Galderma sees it, Mylan is attempting to make different claim language have the same meaning, in violation of the doctrine of claim differentiation. (D.I. 105 at 1)

Mylan rejects Galderma's claim differentiation argument, observing that claim differentiation is not a "rigid rule" to be applied inflexibly, but rather is "one of several claim construction tools." *See ICU Med. Inc. v. Alaris Med. Sys.*, 558 F.3d 1368, 1376 (Fed. Cir. 2009). Two claims with different terminology can cover the same subject matter when the written description and prosecution history indicate that such a reading is proper. (D.I. 104 at 3) In fact, according to Mylan, the intrinsic evidence compels the conclusion that the two steady state ranges should be construed "symmetrically." (D.I. 104 at 4) In Mylan's opinion, claims 4 and 18 merely narrow the target concentration levels. (D.I. 93 at 4) Mylan also advances an

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[9]The same dispute relating to whether plasma concentrations should be in the singular or in the plural exists for this term as well. For the reasons the Court articulated earlier in this Opinion, the Court will again use the plural form in its construction.

argument that the patentee, during prosecution, narrowed the scope of the claims by removing the word "about" as related to the steady state blood levels. (D.I. 93 at 5; D.I. 94 Ex. 11 at 2)

As the Court has noted, claims 4 and 18 use the word "between" as opposed to reciting a "minimum" and "maximum," as claims 1, 15, and 20 do. This different claim language is presumed to have different meaning. *See Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 448 F.3d 1324, 1333 n.3 (Fed. Cir. 2006) ("[T]he use of two terms in a claim requires that they connote different meanings . . . ."). That presumption is not overcome here. This is particularly so because the specification consistently uses "preferably between" or "between" when the referring to the 0.3 to 0.8 range. ('532 patent, col. 3 lines 57-58; *see also* Tr. at 9-10) On the other hand, the specification uses "minimum" and "maximum" when referring to the 0.1 to 1.0 range.

Mylan cites to a single passage in the '532 patent to argue that the concentration levels recited in dependent claims 4 and 18 "are ***expressly*** described . . . as 'minimum' and 'maximum' values – just like the levels recited in claims 1, 15, and 20." (D.I. 104 at 5 (emphasis added)) The exact language of the specification, however, is not as "express" as Mylan portrays. The portion upon which Mylan relies states: "a minimum of about 0.1 μg/ml, ***preferably about 0.3 μg/ml***, and a maximum of about 1.0 μg/ml, ***more preferably about 0.8 μg/ml***." ('532 patent, col. 9 lines 9-13; *id.* col. 10 line 60 to col. 11 line 4 (emphasis added)) Here, again, the specification is specifically linking the words minimum and maximum with the 0.1 to 1.0 concentration range. Contrary to Mylan's reading, in this sentence minimum does not necessarily also modify 0.3 and maximum does not necessarily also modify 0.8.

The Court is also unpersuaded by Mylan's prosecution disclaimer argument. Such a

disclaimer is present only if, during prosecution, the patentee distinguished the patent from prior art in the manner suggested through a "clear and unmistakable surrender" of claim scope. *See Elbex Video, Ltd. v. Sensormatic Electronics Corp.*, 508 F.3d 1366, 1371-72 (Fed. Cir. 2007). Here, Mylan argues that the patentee removed the word "about" from the claims to distinguish the invention from prior art. While true, it is also true that the reason the PTO examiner had rejected the claims was due to the dosage levels of the drug, and not the blood concentration levels. (D.I. 94 Ex. 11 at 5) The patentee explained that the PTO examiner determined that "it was reasonable, absent a definition to the contrary in the specification, to interpret the term 'about' such that 23.3 mg is encompassed by 'about 30 mg' and 16.3 mg is encompassed by 'about 10 mg.'" (*Id.*) The patentee responded, "in the interest of speeding prosecution, Applicants have canceled the term 'about' from claims 49 and 52." (*Id.*)

Thus, the Court will construe "steady state blood levels of the doxycycline of between 0.3 μg/ml to 0.8 μg/ml" to mean "steady state plasma concentrations of the doxycycline of between 0.3 μg/ml and 0.8 μg/ml."

IV. CONCLUSION

An Order, consistent with this Memorandum Opinion resolving the parties' claim construction disputes, will be entered.