**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| GALDERMA LABORATORIES INC., GALDERMA LABORATORIES, L.P., and SUPERNUS PHARMACEUTICALS, INC., | : | |
| Plaintiffs, | : | |
| v. | : | C.A. No. 11-1106-LPS |
| AMNEAL PHARMACEUTICALS, LLC and AMNEAL PHARMACEUTICALS CO. (I) PVT. LTD., | : | |
| Defendants. | : | |

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**MEMORANDUM OPINION**

July 30, 2013
Wilmington, Delaware

**STARK, U.S. District Judge**:

## I. INTRODUCTION

Plaintiffs Galderma Laboratories, Inc., Galderma Laboratories, L.P., and Supernus Pharmaceuticals, Inc. (collectively, "Plaintiffs" or "Galderma") filed suit against defendants Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals Co. (I) PVT. LTD. (collectively, "Defendants" or "Amneal"), alleging infringement of United States Patent Nos. 7,749,532 ("the '532 patent") and 8,206,740 ("the '740 patent") (collectively, the "patents-in-suit" or "Chang patents").[1] (*See* Docket Item ("D.I.") 1, 128) The patents-in-suit are each entitled "Once Daily Formulations of Tetracyclines" and relate to the Oracea® drug product, a delayed-release doxycycline capsule approved for the treatment of rosacea.

The Court held a Markman hearing on November 30, 2012. (*See* Transcript of November 30, 2012 Markman hearing (D.I. 158) (hereinafter "Tr."))[2]

## 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.

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[1]The '532 patent may be found at D.I. 115, J.A. C Ex. 1; the '740 patent may be found at *id.* Ex. 2. Dr. Richard Chang is the lead inventor of the patents-in-suit. (*See* D.I. 143 at 10; '532 patent; '740 patent)

[2]The parties have reached agreement as to the proper construction of two terms – "steady state blood levels of doxycycline of a minimum of 0.1 μg/ml and a maximum of 1.0 μg/ml" and "steady state blood levels of the doxycycline of between 0.3 μg/ml to 0.8 μg/ml" (D.I. 114 at 1-2) – and the Court will adopt their agreed-upon constructions.

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).

"Differences 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 may also 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. 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).

## III. CONSTRUCTION OF DISPUTED TERMS

### A. "pellets" ('532 patent claims 1-3, 15, 17 and 20; '740 patent claims 7 and 10)

1. Plaintiffs' Proposed Construction: "one or more of a small solid dosage form of reasonable size and robustness suitable for incorporation into, e.g., a capsule or tablet"

2. Defendants' Proposed Construction: "a plurality of beads or beadlets, but excluding granules, a tablet, a powder, a sachet, a capsule, a gel, a dispersion or a suspension"

3. Court's Construction: "one or more of a small solid dosage form of reasonable size and robustness suitable for incorporation into, e.g., a capsule or tablet"

The parties agree that the patents use "pellets" interchangeably with "beads" or "beadlets." (*See, e.g.*, Tr. at 5-8, 12, 16, 35, 46, 81) Accordingly, the parties' constructions both include "beads" and "beadlets." The dispute is whether other solid dosage forms – including tablets, capsules, and granules – are included within a proper construction of "pellets," as

Plaintiffs contend, or should be expressly excluded from the construction, as Defendants contend. (*See, e.g.*, D.I. 131 at 10-11; D.I. 133 at 10-16; D.I. 143 at 3-6, 8; D.I. 144 at 4; Tr. at 7-12, 76)

The Court agrees with Plaintiffs that "pellets," as used in the Chang patents, is a broader, more inclusive term than Defendants' construction allows. (*See, e.g.*, '532 patent, col. 6 lines 20-21, 35-49, 53-62; *id.* col. 8 lines 15-17, 27-29; D.I. 134, Rudnic Decl., ¶¶ 23, 29, 38, 40-41) Defendants have failed to persuade the Court that the various terms in dispute – for instance, granules, tablets, powder, sachets, capsules, gels – are entirely mutually exclusive; rather, it appears there is overlap among these types of dosage forms. (*See, e.g.*, '532 patent, col. 6 lines 35-38, 43-49; Tr. at 5-6, 12-14)

Defendants rely largely on what they contend is a prosecution history disclaimer. (*See, e.g.*, Tr. at 57) Specifically, "the applicants initially sought broad claims without limit to any particular dosage form and sought narrower dependent claims drawn to a variety of embodiments, including granules, pellets, and tablet dosage forms." (D.I. 144 at 5; *see also* D.I. 131 at 5) For example, application claim 12 required a composition "in the form of a granule, tablet, pellet, powder, sachet, capsule, gel, dispersion or suspension." (D.I. 115, J.A. C Ex. 3 at GLD0001081 (as-filed Claim 12 of the original (U.S. Patent Application Serial No. 10/819,620))) The Examiner suggested, instead, that the applicants add a structural limitation. (*See* D.I. 115, J.A. C Ex. 3 at GLD0001301 ("The claims were discussed with respect to the structure of the instantly claimed compositions and the scope of the functional limitations. The examiner suggested claim amendments to advance the prosecution of the claims. Applicants will respond with a supplemental amendment.")) Thereafter, the applicants rewrote independent

claim 1 to refer only to pellets. (*See id.* at GLD0001297 ("As noted in the Interview Summary of same date, interpretation of the 'functional' language in the claims and corresponding 'structural' limitations were discussed. Applicants have amended the claims in accordance with the Examiner's suggestion . . . ."); *id.* at GLD0001292 ("49. (Currently amended) An oral pharmaceutical composition comprising a pharmaceutically effective amount of doxycycline, which at a once-daily dosage will give steady state blood levels of doxycycline of a minimum of about 0.1 μg/ml and a maximum of about 1.0 μg/ml, the composition comprising an immediate release (IR) portion comprising about 30 mg doxycycline and a delayed release (DR) portion comprising about 10 mg doxycyline, in which the DR portion is in the form of pellets coated with at least one enteric polymer.")) Defendants assert that "[t]hrough a series of amendments . . . the applicants deliberately focused the claims of the '532 patent on one dosage form – one having a DR portion 'in the form of pellets,'" thereby "narrow[ing] the scope of the issued claims." (D.I. 144 at 5-6) (internal quotation marks omitted)

The Court does not agree, for two reasons. First, the burden of demonstrating a prosecution history disclaimer is a heavy one and the evidence on which Defendants rely does not establish a "clear and unmistakable" disavowal. The Court is unaware of any express statement in the prosecution history indicating why the patentee made the amendments. The uncertainty and ambiguity in the prosecution history weighs against finding a disavowal. *See 01 Communique Lab., Inc. v. LogMeIn, Inc.*, 687 F.3d 1292, 1297 (Fed. Cir. 2012) ("There is no 'clear and unmistakable' disclaimer if a prosecution argument is subject to more than one reasonable interpretation, one of which is consistent with a proffered meaning of the disputed term.") (internal quotation marks omitted). Second, Defendants' contention relies largely on

their insistence that "pellets" is a narrow term, distinct from other dosage forms such as tablets, capsules, and granules. As already noted, the Court is not persuaded that this is correct. It follows, then, that when the applicants replaced their lengthy list of dosage forms with the word "pellets," the applicants were not narrowing claim scope.

Defendants further contend that Plaintiffs' construction imports ambiguity, as it is unclear what is a "reasonable size and robustness" and what is "suitable for incorporation." (D.I. 144 at 6-7) The Court does not agree. These terms are taken directly from the specification. (*See, e.g.,* '532 patent, col. 6 lines 8-49, 53-62; *id.* col. 8 lines 15-17, 27-29; '740 patent, col. 6 lines 7-48, 52-61; *id.* col. 8 lines 15-17, 27-29; *see also* D.I. 134, Rudnic Decl., ¶¶ 34-41) There is no basis on the record now before the Court to conclude that a person having ordinary skill in the art would fail to understand what is claimed by the Chang patents.

**B. "pellet" ('740 patent claim 6)**

1. Plaintiffs' Proposed Construction: "one or more of a small solid dosage form of reasonable size and robustness suitable for incorporation into, e.g., a capsule or tablet"

2. Defendants' Proposed Construction: "bead or beadlet, but excluding a granule, tablet, powder, sachet, capsule, gel, dispersion or suspension"

3. Court's Construction: "one or more of a small solid dosage form of reasonable size and robustness suitable for incorporation into, e.g., a capsule or tablet"

The Court agrees with Plaintiffs that, in the context of the Chang patents, a person having ordinary skill in the art would view "pellet" and "pellets" as being used interchangeably. (*See, e.g.,* D.I. 133 at 15-16; D.I. 134, Rudnic Decl., ¶ 44; Tr. at 19; *see also generally Versa Corp. v. Ag-Bag Int'l Ltd.*, 392 F.3d 1325, 1330 (Fed. Cir. 2004) ("[T]he plural can describe a universe

ranging from one to some higher number, rather than requiring more than one item."); *Flash Seats, LLC v. Paciolan, Inc.*, 2010 WL 184080, at *9 (D. Del. Jan. 19, 2010) (construing claim term "asks" to "encompass the singular as well as the plural," given finding that "nothing . . . strictly precludes use of the invention in connection with . . . a single 'ask'"). The specification provides further support for such a construction. (*See, e.g.*, '532 patent, col. 6 lines 35-52; '740 patent, col. 6 lines 34-51)

**C. "coated with at least one enteric polymer" ('532 patent claims 1, 15 and 20)**

1. Plaintiffs' Proposed Construction: No construction necessary[3]

2. Defendants' Proposed Construction: "each having an enteric polymer coating applied to its surface"

3. Court's Construction: No construction necessary.

The parties' dispute is whether the DR portion of the claimed pharmaceutical composition must consist of pellets that are each coated in an enteric polymer, as Defendants propose, or whether it is sufficient that the DR portion be contained within material such that the outermost surface of it is coated with an enteric polymer, as Plaintiffs' proposal implies. (*See, e.g.*, D.I. 131 at 17-20; D.I. 133 at 17-18; D.I. 143 at 12-14; D.I. 144 at 16-20; Tr. at 28, 38, 42-43) The Court agrees with Plaintiffs.

Plaintiffs' construction – which is no construction – would allow what might be thought of as "indirect" coating. (*See* D.I. 134, Rudnic Decl. ¶ 48 (opining that "a person of skill in the art could achieve the enteric coating of pellets (and thus obtain the desired DR profile) by coating

[3]Strictly speaking, Plaintiffs propose to construe "coated with at least one enteric polymer" as "coated with at least one enteric polymer." This is another way of saying that Plaintiffs' position is that no construction is necessary.

each pellet individually, or the pellets can be combined and then be enterically coated as a collective unit"); *see also id.* ¶¶ 46-50) Nothing in the claims or specification excludes an "indirect" coating. Hence, the Court does not agree with Defendants that theirs is "[t]he natural reading of this claim language." (D.I. 131 at 18) To the contrary, it appears that adoption of Defendants' construction would improperly limit the scope of the claims to a preferred embodiment. (*See, e.g.*, D.I. 131 at 19; Tr. at 32-33; '532 patent, col. 8 lines 53-59)

Having agreed with Plaintiffs on the substance of the parties' dispute, the Court concludes that no construction is necessary. *See generally Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365-66 (Fed. Cir. 2012) ("The words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history.").

## IV. CONCLUSION

For the reasons given above, the Court will construe the terms of the patents-in-suit consistent with this Memorandum Opinion. An appropriate Order will be entered.

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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|---|---|---|
| GALDERMA LABORATORIES INC., GALDERMA LABORATORIES, L.P., and SUPERNUS PHARMACEUTICALS, INC., | : | |
| Plaintiffs, | : | |
| v. | : | C.A. No. 11-1106-LPS |
| AMNEAL PHARMACEUTICALS, LLC and AMNEAL PHARMACEUTICALS CO. (I) PVT. LTD., | : | |
| Defendants. | : | |

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**ORDER**

At Wilmington this 30th day of July 2013:

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

IT IS HEREBY ORDERED that the following claim terms as used in U.S. Patent Nos. 7,749,532 ("the '532 patent") and/or 8,206,740 ("the '740 patent") are construed as follows:

1. The term "**steady state blood levels of doxycycline of a minimum of 0.1 µg/ml and a maximum of 1.0 µg/ml**," as it appears in claims 1, 15 and 20 of the '532 patent, and in claims 1, 19 and 22 of the '740 patent, is construed to mean "steady state plasma concentrations of doxycycline of a minimum of 0.1 µg/ml and a maximum of 1.0 µg/ml," as agreed upon by the parties.

2. The term "**steady state blood levels of the doxycycline of between 0.3 µg/ml to 0.8 µg/ml**," as it appears in claims 4 and 18 of the '532 patent, and in claims 2 and 21 of the '740 patent, is construed to mean "steady state plasma concentrations of the doxycycline of between 0.3 µg/ml and 0.8 µg/ml," as agreed upon by the

parties.

3. The term "**pellets**," appearing in claims 1-3, 15, 17 and 20 of the '532 patent, and in claims 7 and 10 of the '740 patent, is construed to mean "one or more of a small solid dosage form of reasonable size and robustness suitable for incorporation into, e.g., a capsule or tablet."

4. The term "**pellet**," appearing in claim 6 of the '740 patent, is construed to mean "one or more of a small solid dosage form of reasonable size and robustness suitable for incorporation into, e.g., a capsule or tablet."

5. The term "**coated with at least one enteric polymer**," appearing in claims 1, 15 and 20 of the '532 patent, does not require construction.

UNITED STATES DISTRICT JUDGE