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

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| GALDERMA LABORATORIES, L.P.; NESTLÉ SKIN HEALTH S.A.; and TCD ROYALTY SUB, LLC, | : | |
| Plaintiffs, | : | |
| v. | : | C.A. No. 16-1003-LPS |
| SUN PHARMACEUTICAL INDUSTRIES LIMITED and SUN PHARMACEUTICAL INDUSTRIES, INC., | : | |
| Defendants. | : | |

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**MEMORANDUM OPINION**

November 21, 2017
Wilmington, Delaware

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

Plaintiffs Galderma Laboratories, L.P., Nestlé Skin Health S.A., and TCD Royalty Sub, LLC (collectively, "Galderma" or "Plaintiffs") filed suit against Defendants Sun Pharmaceutical Industries Limited and Sun Pharmaceutical Industries, Inc. (collectively, "Sun" or "Defendants") on October 27, 2016, alleging infringement of two families of patents: the Ashley patents, U.S. Patent Nos. 7,211,267 (the "'267 patent"); 7,232,572 (the "'572 patent"); 8,603,506 (the "'506 patent"); and 9,241,946 (the "'946 patent") (collectively, the "Ashley patents"), and the Chang patents, U.S. Patent Nos. 7,749,532 (the "'532 patent"); 8,206,740 (the "'740 patent"); 8,394,405 (the "'405 patent"); 8,394,406 (the "'406 patent"); 8,470,364 (the "'364 patent"); and 8,709,478 (the "'478 patent") (collectively, the "Chang patents"). (*See* D.I. 1 ¶ 6) The patents-in-suit are generally directed to doxycycline formulations used to treat papules and pustules of acne and rosacea.

Presently before the Court is the issue of claim construction. The Court previously construed various terms of the patents-in-suit in the context of other cases. *See Galderma Labs., L.P. v. Amneal Pharm. LLC*, 2017 WL 1882499, at *5 (D. Del. May 9, 2017) ("*Amneal II*"); *Mylan Pharm. Inc. v. Galderma Labs., Inc.*, 2011 WL 1113383 (D. Del. Mar. 24, 2011) ("*Mylan DJ*"). The Patent Trial and Appeal Board ("PTAB") also construed one set of terms in *inter partes* proceedings. (*See* JA Exs. 31-33) ("*Amneal* IPRs") On July 31, 2017, the parties stipulated to the use of this Court's *Amneal II* claim constructions for four terms from the Ashley patents for the purpose of this litigation.[1] (*See* D.I. 60) The parties completed briefing on

[1]The terms are: (1) "amount that . . . results in no reduction of skin microflora during a six-month treatment," which appears in claims 28-30 of the '267 patent, claims 1 and 20 of the '572 patent, claims 1 and 8 of the '506 patent, and claims 1 and 7 of the '946 patent; (2) "wherein the amount results in no reduction of skin microflora during a six-month treatment," which appears in claim 15 of the '506 patent and claim 13 of the '946 patent; (3) "sub-

September 8, 2017. (*See* D.I. 61, 62, 64, 65) The Court held a claim construction hearing on October 2, 2017. ("Tr.")

## I. LEGAL STANDARDS

The ultimate question of the proper construction of a patent is a question 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." *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).

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antibacterial amount," which appears in claims 1 and 28-30 of the '267 patent; and (4) "an amount that is effective to treat the papules and pustules of rosacea, but has substantially no antibiotic activity," which appears in claims 1 and 20 of the '572 patent. (*See* D.I. 54, 60) The Court will adopt the parties' agreed-upon constructions for these terms.

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) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)) (alteration in original) (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) (citing *Vitronics*, 90 F.3d at 1583).

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) (quoting *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1550 (Fed. Cir. 1996)).

## II. CONSTRUCTION OF DISPUTED TERMS

### A. "delayed release"[2] / "DR"[3]

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| **Plaintiffs**<br>release of a drug at a time other than immediately following oral administration |
| **Defendants**<br>release of a drug at a time other than immediately following oral administration, excluding formats that result in release of drug starting promptly after oral administration |
| **Court**<br>release of a drug at a time other than immediately following oral administration |

[2]This term appears in claims 1, 15, and 20 of the '532 patent; claims 1, 19, 22, 23, and 26-28 of the '740 patent; claims 1, 17, and 20 of the '405 patent; claims 1, 17, and 21 of the '406 patent; claims 1, 2, 16, and 17 of the '364 patent; and claims 1 and 20 of the '478 patent.

[3]This term appears in claims 1, 15, and 20 of the '532 patent; claims 1, 10, 11, 19, 22, 23, 26, and 28 of the '740 patent; claims 1, 3, 8, 9, 17, and 20 of the '405 patent; claims 1, 3, 7, 8, 17, and 21 of the '406 patent; claims 1, 2, 7, 8, 16, and 17 of the '364 patent; and claims 1, 5, 19, 20, 24, and 37 of the '478 patent.

The parties agree that "delayed release" and its shorthand, "DR" (the "delayed release terms"), have a consistent meaning across the patents-in-suit. (*See* D.I. 54 at 4) The Court previously construed the delayed release terms according to their plain and ordinary meaning as "release of a drug at a time other than immediately following oral administration." *See Amneal II*, 2017 WL 1882499, at *5. The PTAB provided the same construction in its Final Written Decisions in the *Amneal* IPRs. (*See* JA Ex. 31 at 8; JA Ex. 32 at 13; JA Ex. 33 at 13) Sun seeks to supplement this construction to specify that the delayed release terms exclude formats that result in release of drug promptly after oral administration, based on what it contends was a disclaimer during the *Amneal* IPRs. (*See* D.I. 61 at 5) Galderma contends that Sun's construction "adds an extraneous negative limitation" lacking a valid basis. (Tr. at 7)

Disclaimer of claim scope must be "clear and unmistakable." *Avid Tech., Inc. v. Harmonic, Inc.*, 812 F.3d 1040, 1045 (Fed. Cir. 2016) (internal quotation marks omitted). The record here does not support a finding of disclaimer.

During the *Amneal* IPRs, the patent owner distinguished prior art, U.S. Patent No. 5,348,748 ("Sheth '748"), by arguing that the polymer disclosed in Sheth '748 provided a "modified sustained release," rather than a "delayed release," because in Sheth '748 release "beg[an] slowly but promptly in the stomach, followed by rapid release in the intestine." (JA Ex. 31 at 12) The patent owner's expert, Dr. Rudnic, offered supporting testimony. (*See* JA Ex. 31 at 12-13; JA Ex. 88 at 103-05) Both the patent owner and Dr. Rudnic used "promptly" and "immediately" interchangeably to describe the release in Sheth '748. (*See, e.g.*, JA Ex. 42 at 50:17-20; JA Ex. 67 at 18-20; JA Ex. 70 at 25)

These statements do not meet the "high" and "demanding" standard for disclaimer. *See*

*Avid Tech.*, 812 F.3d at 1045. Having heard the statements on which Sun now relies, the PTAB adopted the same construction proposed here by Galderma, and noted, "we discern nothing in the use of the term 'delayed release' in the '740 patent specification that is inconsistent with those [plain and ordinary meaning] definitions or more limiting than them." (JA Ex. 31 at 8) While the patent owner consistently distinguished Sheth '748 based on the timing of release, and the overall release profile of Sheth '748 is not a delayed release format – and, therefore, is not within the claim scope (*see* Tr. at 10, 21-22) – at no point did the patent owner clearly and unambiguously disclaim all embodiments that release drug at a time other than immediately after oral administration solely because they also release some amount of drug "starting promptly after oral administration."

**B. "Comprising" terms**

**1. "comprising 30 mg doxycycline"[4]**

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| **Plaintiffs**<br>Plain and ordinary meaning |
| **Defendants**<br>with 30 mg doxycycline |
| **Court**<br>Plain and ordinary meaning |

**2. "comprising 10 mg doxycycline"[5]**

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|---|
| **Plaintiffs**<br>Plain and ordinary meaning |

[4]This term appears in claims 1, 19, 22, 23, and 28 of the '740 patent.

[5]This term appears in claims 1, 19, 22, 23, and 28 of the '740 patent.

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|---|
| **Defendants**<br>with 10 mg doxycycline |
| **Court**<br>Plain and ordinary meaning |

"Comprising" is a term of art with a well-established meaning. *See Glaxo Grp. Ltd. v. Teva Pharm. USA Inc.*, 2009 WL 1220544, at *2 (D. Del. Apr. 30, 2009). Comprising "'means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.'" *Id.* (quoting *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501 (Fed. Cir. 1997)). Sun essentially asks the Court to construe "comprising" as "with." (*See* D.I. 61 at 14)

The Court agrees with Galderma that Sun is asking the Court to depart from the plain and ordinary meaning. The Court further agrees with Galderma that there is no persuasive reason to adopt Sun's proposed construction. (*See* D.I. 62 at 15; D.I. 65 at 13)

The term "with" – as well as "no more, no less," a phrase Sun also suggests for "comprising" in the context of the disputed claim terms (D.I. 61 at 14) – does not appear in connection with any milligram amount of doxycycline anywhere in the '740 patent. Rather, the claims consistently use "comprising," and no intrinsic evidence suggests that the patentee intended to depart from the customary meaning of "comprising." (*See, e.g.*, JA Ex. 6 at col. 11:56-64; col. 13:12-17; col. 14:19-22)

During the IPR, the patent owner stated to the PTAB, "I don't think [the comprising language] opens up the term 30 milligrams to something different." (JA Ex. 42 at 37) But this is not a clear and unmistakable disclaimer. The patentee was not unambiguously stating that, for example, "comprising 30 mg doxycycline" means that any formulation containing any amount

other than precisely 30 mg doxycycline is outside the scope of the claims. *See Glaxo Grp.*, 2009 WL 1220544, at *2 (refusing to adopt "specialized definition" of "comprising" absent intrinsic evidence requiring court to do so). "Comprising" is a term of art to patent claim drafters and permits some flexibility (here, for instance, in terms of the amount of doxycycline in a claimed formulation) and no persuasive basis has been given to adopt Sun's more restrictive construction.

### C. "About" terms

#### 1. "about 30 mg doxycycline"[6]

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| **Plaintiffs**<br>30 mg doxycycline, within the pharmaceutically acceptable limits found in the United States Pharmacopeia (USP-NF 21), 2003 Annual Edition, pp. 666-71 |
| **Defendants**<br>30 mg doxycycline, within the pharmaceutically acceptable limits found in the United States Pharmacopeia (USP-NF 21), 2003 Annual Edition, which excludes amounts less than 27 mg and more than 33 mg of doxycycline |
| **Court**<br>30 mg doxycycline, within the pharmaceutically acceptable limits found in the United States Pharmacopeia (USP-NF 21), 2003 Annual Edition |

#### 2. "about 10 mg doxycycline"[7]

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|---|
| **Plaintiffs**<br>10 mg doxycycline, within the pharmaceutically acceptable limits found in the United States Pharmacopeia (USP-NF 21), 2003 Annual Edition, pp. 666-71 |
| **Defendants**<br>10 mg doxycycline, within the pharmaceutically acceptable limits found in the United States Pharmacopeia (USP-NF 21), 2003 Annual Edition, which excludes amounts less than 9 mg and more than 11 mg of doxycycline |

[6]This term appears in claims 1, 15, and 20 of the '532 patent; claims 1, 2, 16, and 17 of the '364 patent; and claims 1 and 20 of the '478 patent.

[7]This term appears in claims 1, 15, and 20 of the '532 patent; claims 1, 2, 16, and 17 of the '364 patent; and claims 1 and 20 of the '478 patent.

| **Court**<br>10 mg doxycycline, within the pharmaceutically acceptable limits found in the United States Pharmacopeia (USP-NF 21), 2003 Annual Edition |
|---|

The Chang patent specifications expressly define "about" to mean "within the pharmaceutically acceptable limits found in the United States Pharmacop[e]ia (USP-NF-21), 2003 Annual Edition [("USP 2003")] . . . for amount of active pharmaceutical ingredients." (JA Ex. 5 at col. 3:66-4:2; JA Ex. 9 at col. 4:8-11; JA Ex. 10 at col. 3:66-4:2) The parties dispute which portion of the USP 2003 is relevant to discerning the "pharmaceutically acceptable limits" of doxycycline. Galderma's proposed construction incorporates the pages of the USP 2003's official monograph for doxycycline, which describe various oral dosage forms containing doxycyline as an active ingredient. (*See* D.I. 62 at 13; *see also* JA Ex. 46 at 666-71) Sun's proposed construction relies on the "General Notices and Requirements" section of the USP 2003, which defines "about" in the context of "the appropriate quantities to be taken for assays and tests." (D.I. 61 at 10-11; *see also* JA Ex. 46 at 7)

The Court is not persuaded by either parties' proposal to limit the portion of the USP 2003 to be considered to only a few pages. Rather, the Court views the entire USP 2003 to be relevant to determining the meaning of "about." The Court's construction is consistent with the express definition provided by the patentee, which does not limit the reference to the USP 2003 to certain sections or pages. *See Sinorgchem Co., Shandong v. Int'l Trade Comm'n*, 511 F.3d 1132, 1138 (Fed. Cir. 2007) ("When the specification explains and defines a term . . ., without ambiguity or incompleteness, there is no need to search further for the meaning of the term.") (internal quotation marks omitted). Hence, the Court will not place a limitation on the portion of the USP 2003 that may be relevant to understanding the scope of the claims.

## D. "Blood level" terms[8]

### 1. "steady state blood levels of doxycycline of a minimum of 0.1 μg/ml and a maximum of 1.0 μg/ml"[9]

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| **Plaintiffs**<br>steady state plasma concentrations of doxycycline of a minimum of 0.1 μg/ml and a maximum of 1.0 μg/ml |
| **Defendants**<br>steady state plasma concentrations of doxycycline of a minimum of 0.1 μg/ml and a maximum of 1.0 μg/ml maintained over a 24-hour period |
| **Court**<br>steady state plasma concentrations of doxycycline of a minimum of 0.1 μg/ml and a maximum of 1.0 μg/ml |

### 2. "steady state blood levels of the doxycycline of between 0.3 μg/ml to 0.8 μg/ml"[10]

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|---|
| **Plaintiffs**<br>steady state plasma concentrations of the doxycycline of between 0.3 μg/ml to 0.8 μg/ml |
| **Defendants**<br>steady state plasma concentrations of the doxycycline of between 0.3 μg/ml to 0.8 μg/ml maintained over a 24-hour period |
| **Court**<br>steady state plasma concentrations of the doxycycline of between 0.3 μg/ml to 0.8 μg/ml |

The Court has previously construed the "blood levels" terms. *See Mylan DJ*, 2011 WL 1113383. The parties agree that "blood levels" should be construed consistent with this Court's

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[8]The parties agree that the two disputed terms listed and discussed here are representative of their disputes with respect to the blood level terms.

[9]This term appears in claims 1, 15, and 20 of the '532 patent; claims 1, 19, 23, and 28 of the '740 patent; and claims 1 and 17 of the '405 patent.

[10]This term appears in claims 4 and 18 of the '532 patent; claims 2, 21, and 25 of the '740 patent; claims 2 and 19 of the '405 patent; and claims 2 and 19 of the '406 patent.

previous construction to mean "plasma concentrations." (D.I. 54 at 5-6) Sun asks the Court to clarify that the specified concentrations must be "maintained over a 24-hour period." (*See* D.I. 61 at 17) Galderma contends that Sun's construction "add[s] unnecessary extraneous language." (*See* D.I. 62 at 3)

The Court is not persuaded that imposing the additional limitation Sun seeks is warranted. The claim language provides that the dosage must be "once-daily," and the specification consistently refers to "once daily" or "once-a-day" dosages. (*See, e.g.*, JA Ex. 5 at col. 1:6-7, 2:26-27, 3:48-49, 11:65, 12:11-12) The claim language, which is directed to the frequency of administration, does not require that the blood levels be maintained over "24-hours;" nor do the specification nor the patent owner's statements during the *Amneal* IPRs support such a reading. (*See* JA Ex. 5 at col. 3:55-57 ("Preferably, the blood levels stay within the preferred blood level, with daily dosing, for the entire course of treatment."); *id.* at col. 8:63-64 (discussing formulations "to achieve the desired levels of the drug . . . over the course of ***about*** 24 hours at steady state") (emphasis added); JA Ex. 70 at 4 ("Goal was to achieve a ***once-daily*** doxycyline formulation.")) While it is preferable that a particular blood level be maintained over approximately 24 hours, based on daily dosing, Sun's construction appears to more narrowly constrain the claim scope, which is not supported.

## III. CONCLUSION

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