

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVEN PHARMACEUTICALS, INC.,	:	
	:	
Plaintiff,	:	
v.	:	C.A. No. 18-699-LPS
	:	
AMNEAL PHARMACEUTICALS LLC,	:	
	:	
Defendant.	:	

NOVEN PHARMACEUTICALS, INC.,	:	
	:	
Plaintiff,	:	
v.	:	C.A. No. 18-758-LPS
	:	
ACTAVIS LABORATORIES UT, INC.,	:	
	:	
Defendant.	:	

John G. Day and Andrew C. Mayo, ASHBY & GEDDES, Wilmington, DE
Liane M. Peterson and Jayita Guhaniyogi, FOLEY & LARDNER, LLP, Washington, D.C.
Attorneys for Plaintiff/Counterclaim Defendant Noven Pharmaceuticals, Inc.

Anne Shea Gaza and Samantha G. Wilson, YOUNG CONAWAY STARGATT & TAYLOR,
LLP, Wilmington, DE
Steven Maddox and Jeremy Edwards, MADDOX EDWARDS, PLLC, Washington, D.C.
Attorneys for Defendant/Counterclaim Plaintiff Amneal Pharmaceuticals LLC

Steven J. Fineman and Katharine Lester Mowery, RICHARDS, LAYTON & FINGER P.A.,
Wilmington, DE
James K. Stronski, CROWELL & MORING, LLP, New York, NY
Attorneys for Defendant/Counterclaim Plaintiff Actavis Laboratories UT, Inc.

MEMORANDUM OPINION

March 8, 2019
Wilmington, Delaware



STARK, U.S. District Judge:

Plaintiff Noven Pharmaceuticals Inc. (“Noven” or “Plaintiff”) filed complaints against Defendants Amneal Pharmaceuticals LLC (“Amneal”) and Actavis Laboratories UT, Inc. (“Actavis”) (collectively, “Defendants”), alleging infringement of U.S. Patent Nos. 9,730,900 (the “’900 Patent”), 9,724,310 (the “’310 Patent”), and 9,833,419 (the “’419 Patent”) (collectively, “patents-in-suit” or “asserted patents”). (D.I. 83 at 3) The patents-in-suit relate “to transdermal drug delivery systems, and more particularly, to transdermal drug delivery systems for the delivery of estrogen.” (’900 patent at 1:17-20)

Presently before the Court is the issue of claim construction. The parties completed consolidated briefing on December 17, 2018. (*See* C.A. No. 18-699 D.I. 83) (“CC”) The Court held a claim construction hearing on January 14, 2018. (*See* D.I. 101) (“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. Conceptoronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While “the claims themselves provide substantial guidance as to the meaning of particular claim terms,” the context of the surrounding words of the claim also must be considered. *Phillips*, 415 F.3d at 1314. Furthermore, “[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent.” *Id.* (internal citation omitted).

It is likewise true that “[d]ifferences among claims can also be a useful guide For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.” *Id.* at 1314-15 (internal citation omitted). This “presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim.” *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that “the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316. It bears emphasis that “[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.” *Hill-Rom Servs., Inc. v. Stryker*

Corp., 755 F.3d 1367, 1372 (Fed. Cir. 2014) (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)).

I. CONSTRUCTION OF DISPUTED TERMS¹

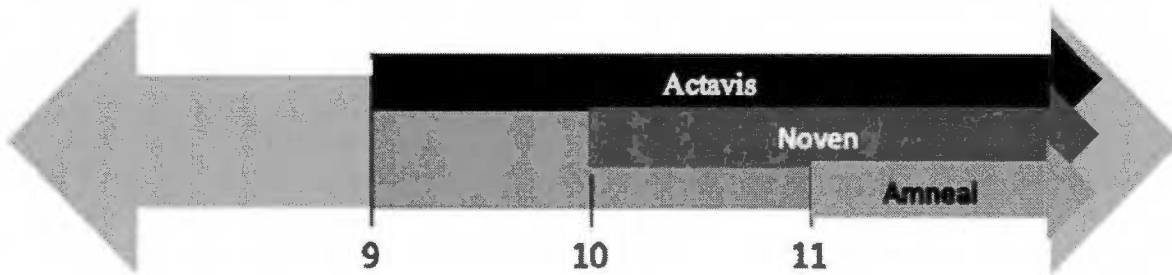
A. “has a coat weight of greater than about 10 mg/cm²”²

Noven’s Proposed Construction	Actavis’ Proposed Construction	Amneal’s Proposed Construction	Court’s Construction
greater than approximately 10 mg/cm ² , but not less than 10 mg/cm ²	has a coat weight greater than 9 mg/cm ²	having a coat which weighs more than 110% of 10 mg/cm ²	having a coat which weighs more than 110% of 10 mg/cm ²

The parties dispute the meaning of “greater than about 10 mg/cm²” in the ’900 and ’310 patents. The parties’ competing constructions can be depicted graphically:

¹ The Court will also adopt the parties’ agreed-upon constructions.

² ’900 patent, claims 1 and 16; ’310 patent, claim 1.



All of the parties have had to contend with the patent’s statement regarding “about:”

The term “about” and the use of ranges in general, whether or not qualified by the term about, means that the number comprehended is not limited to the exact number set forth herein, and is intended to refer to ranges substantially within the quoted range while not departing from the scope of the invention. As used herein, “about” will be understood by persons of ordinary skill in the art and will vary to some extent on the context in which it is used. If there are uses of the term which are not clear to persons of ordinary skill in the art given the context in which it is used, “about” will mean up to plus or minus 10% of the particular term.

(’310 patent at 4:42-52; ’900 patent at 4:42-52)

Amneal argues that its construction accounts for the patent’s definition of “about” as “plus or minus 10%.” (CC at 20) Amneal interprets “about 10 mg/cm²” to mean 9-11 mg/cm², and thus contends that “greater than about 10 mg/cm²” means greater than 9-11 mg/cm², and therefore greater than 11 mg/cm². (*Id.* at 21-22; Tr. at 39-41) Amneal further contends that its construction is consistent with the purpose of the patent because it “distinguish[es] its claimed systems from Vivelle-Dot® on the basis of the numerical coat weight value.” (CC at 24-26) (citing ’310 patent at 13:52-58, 3:46-67; ’310 file history)

Noven asks the Court to replace “about with approximately.” (CC at 17; Tr. at 13-16) Noven notes that “an important aspect of the invention of the asserted patents is the unexpected increase in flux realized by increasing the coat weight above that of Noven’s Vivelle-Dot® product,” and thus argues that the disputed limitation “should not be construed to extend to a

coat weight *less* than the target Vivelle-Dot[®] coat weight of 10 mg/cm².” (CC at 17-18) Noven contends that this construction is supported by the patentee’s lexicography, because “about” is defined as “*up to plus or minus 10%*,” and thus “about” definitionally can mean *minus 0%* and *plus between 0% and 10%: i.e., 10-11 mg/cm²*. (Tr. at 16-17)

Actavis contends that the patentee’s definition of “about” is intended to expand the term or range in question by 10% of the value associated with “about.” (CC at 32) Thus, Actavis asks that the Court lower the bottom end of the claimed range by 10%. (Tr. at 31-32) Actavis opposes both Amneal’s and Noven’s constructions and argues that the patent does not unambiguously require limiting the claimed value based on the coat weight of Vivelle-Dot[®]. (CC at 54-57; Tr. at 36-37)

The Court confronts an “awkward situation” (Tr. at 41) in that it has before it three plausible constructions of a disputed term. Having carefully considered the competing positions, and of course the evidence (intrinsic and extrinsic), the Court is most persuaded by Amneal. Amneal’s construction most accurately captures the patentee’s lexicography and intent to avoid the coat weight of Vivelle Dot[®].

More specifically, the Court is persuaded – by, among other things, the existence of the parties’ multiple not-unreasonable proposals, and the Court’s own struggles to resolve their dispute – that a POSA would turn to the third sentence of the patent’s definition of “about”³ and resort to the “plus or minus 10%” formula, as it would not otherwise be “clear . . . given the context in which [this term] is used” that “about” has some other meaning. The Court further agrees with Amneal that there is no basis in the patent to read “plus or minus 10%” as “plus or

³ “If there are uses of the term which are not clear to persons of ordinary skill in the art given the context in which it is used, ‘about’ will mean up to plus or minus 10% of the particular term.”

minus” some number *less than* 10% (i.e., plus or minus 5%); nor is there any reason to believe a POSA would read “plus or minus 10%” as meaning a different percentage above than the percentage below (e.g., plus 10% and minus 5%). (See Tr. at 16-17) Instead, a POSA would read “plus or minus 10%” in the pertinent context to mean “10% above 10 mg/cm² and 10% below 10 mg/cm²,” which equates to a range of 9 to 11 mg/cm². Therefore, “greater than about 10 mg/cm²” means “greater than 9 to 11 mg/cm²” and, more simply, “greater than 11 mg/cm².” Accordingly, the Court will adopt Amneal’s proposed construction.

B. “coat weight of greater than 10 mg/cm²”⁴

Noven’s Proposed Construction	Actavis’ Proposed Construction	Amneal’s Proposed Construction	Court’s Construction
No construction Required	Coat weight of greater than or equal to 9.5 mg/cm ²	No construction required	No construction required

The Court agrees with Noven and Amneal that “[t]he language of the term is unambiguous” and, thus, no construction is necessary. (CC at 34) The absence of “about” gives this term sufficient precision require no additional construction. (See CC at 57-58)

For its position, Actavis relies on the Court’s ruling in *Noven Pharmaceuticals, Inc. v. Actavis Laboratories UT, Inc.*, No. 15-249-LPS (D. Del. July 5, 2016) (D.I. 98) (“Prior Actavis Case”), in which the Court found that the term “15 mg/cm²” would be understood to be a measurement with (at most) two significant figures, meaning it would be read as 15 plus or minus .5.” (CC at 35-36) (quoting Prior Actavis Case at 8) Based on this use of significant figures, Actavis asks the Court to expand “greater than 10 mg/cm²” to “greater than 9.5 mg/cm².” Here, however, the Court agrees with Noven “there is no similar need to invoke a significant

⁴ ’419 patent, claim 1.

digits analysis because the claims do not recite specific coat weight values but instead a range, bounded by an unambiguous lower end.” (*Id.* at 35)

III. CONCLUSION

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