IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVEN PHARMACEUTICALS, INC.,	:	
Plaintiff/Counterclaim-Defendant,	:	
v.	:	C.A. No. 15-249-LPS
ACTAVIS LABORATORIES UT, INC.,	:	
Defendant/Counterclaimant.	:	
ACTAVIS LABORATORIES UT, INC.,	:	
Third-Party Plaintiff,	:	
v.	:	
HISAMITSU PHARMACEUTICAL CO., INC.,	:	
Third-Party Defendant.	:	

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MEMORANDUM OPINION

July 5, 2016
Wilmington, Delaware

STARK, U.S. District Judge:

On March 20, 2015, Plaintiff Noven Pharmaceuticals, Inc. ("Noven" or "Plaintiff") filed suit against Defendant Actavis Laboratories UT, Inc. ("Actavis" or "Defendants") alleging infringement of U.S. Patent No. 8,231,906 (the "'906 patent"), which is directed to a transdermal product for the delivery of the hormone estradiol. On May 12, 2015, Actavis filed a third-party complaint against Noven's parent company, Hisamitsu ("Hitsamitsu" or "Third-Party Plaintiff"), and a counterclaim against Noven.

The parties submitted claim construction briefs. (*See* D.I. 48, 49, 56, 57) The Court held a claim construction hearing on May 3, 2016. (*See* D.I. 68 ("Tr.")) At the hearing, in addition to presenting argument, Defendants presented the testimony of an expert, whom Plaintiff cross-examined.

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) (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).

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)) (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 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.*

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 TERM

"coat weight selected from the group consisting of 12.5 mg/cm^2 and 15 mg/cm^2"[1]

Noven Plain and ordinary meaning; no construction required
Actavis coat weight selected of precisely 12.5 mg/cm^2 or precisely 15.0 mg/cm^2
Court Plain and ordinary meaning; i.e., "15 mg/cm^2" means 15 plus or minus at least .5, yielding a claimed range of greater than or equal to 14.5 mg/cm^2 and less than 15.5 mg/cm^2.

The parties disagree about whether the upper bound of the coat weight range claimed by the patent, 15 mg/cm^2, is defined by three significant figures, or whether it may have some other number of significant figures, such as just two significant figures.[2] As is explained in the treatise Actavis's expert cited as authoritative (*see* Tr. at 50-51), significant figures are used to describe the precision of a measurement, given sources of error including the instruments used to take measurements (Tr. at 93-94; *see also* D.I. 50-1 at 100 (excerpt from treatise)).

Actavis argues that the numbers in the claims have three significant figures. Accordingly, Actavis urges the Court to construe "15 mg/cm^2" as having three significant figures, that is as "15.0 mg/cm^2." Construing the claim term in this manner would mean that the literal scope of the upper bound of the coat weight would be 14.95 mg/cm^2 up to (but less than) 15.05 mg/cm^2. Noven counters that no construction is required. Alternatively, Noven contends that the plain

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[1] This term appears in claims 1, 10, 11, and 14 of the '906 patent.

[2] Actavis also proposed that the coat weight must be "precisely" the recited amount, but at the hearing Actavis's counsel stated that "precisely" is unnecessary, and the substantive dispute is about the number of significant figures associated with the recited coat weights. (Tr. at 109-110)

and ordinary meaning of 15 mg/cm^2 would be understood as being no more precise than two significant figures, i.e., 14.5 mg/cm^2 up to (but less than) 15.5 mg/cm^2.

To support its position, Actavis presented the testimony of an expert, Dr. Bozena Michniak-Kohn, a Professor of Pharmaceutics at Rutgers University, who specializes in topical, transdermal, and buccal drug delivery. (Tr. at 40-41) The Court finds Dr. Michniak-Kohn is qualified to testify and that her testimony is sufficiently reliable to be helpful to the Court. Even though Dr. Michniak-Kohn has no industry experience, no knowledge of how to measure coat weight, and no direct experience with measurements of Vivelle-Dot® (*see* Tr. at 73-76), she has conducted pertinent research and teaches in the relevant area (*see id.* at 41-43). Accordingly, Noven's objections are OVERRULED.

The Court found Dr. Michniak-Kohn's testimony credible. Ultimately, however, the Court is not persuaded by her opinion, in light of the intrinsic evidence.

Dr. Michniak-Kohn's opinion that a person of ordinary skill in the art ("POSA") would understand "15" to mean "15.0" proceeds in several steps. First, she opined that the claimed coat weights are the arithmetical product of the coat weight of a prior art transdermal drug delivery product – Vivelle-Dot® – and a scale-up factor. Second, she stated that the coat weight of Vivelle-Dot® is 10.0 mg/cm^2 – and, thus, has three significant figures. Third, she testified that the scale-up factors listed in the patent each have three significant figures. Finally, she relied on a POSA's knowledge that multiplying two numbers that each consist of three significant figures results in a product that is measured in three significant figures. While the Court has doubts about each step of the expert's analysis, it focuses its attention on only some of them.

Assuming, arguendo, that the claimed coat weight of 15 is the arithmetical product of the

coat weight of Vivelle-Dot® and a scale-up factor,[3] and further assuming that the coat weight of Vivelle-Dot® is precisely 10.0 mg/cm^2 (i.e., three significant figures),[4] the Court is not persuaded that the scale-up factors of the patent are limited to three significant figures. To the extent the concept of significant figures even has application to scale-up factors,[5] Dr. Michniak-Kohn's testimony that a POSA would read all the scale-up factors in the '906 patent to include three significant figures is unpersuasive.

For her opinion, Dr. Michniak-Kohn relies on the following portion of the specification:

> [I]n some embodiments, the systems have a coat weight such that the amount of estradiol per unit area of the active surface area is greater than . . . Vivelle-Dot® products, such as a coat weight that is about 1.25, 1.33, 1.5, 1.67, 1.75, 2 or 3 times the coat weight of the Vivelle-Dot® products, or greater. In specific embodiments, the systems have a coat weight that is about 1.25 times the coat weight of the Vivelle-Dot® products, e.g. a coat weight of about 12.5 mg/cm^2. In other specific embodiments, the systems have a coat weight that is about 1.5 times the coat weight of the Vivelle-Dot® products, e.g. a coat weight of about 15 mg/cm^2.

'906 pat. col. 13:18-31. Dr. Michniak-Kohn testified that a POSA would read this string of

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[3]While the specification supports Actavis's position that the described embodiments can generally be thought of as heavier-coat-weight versions of Vivelle-Dot®, the claims do not reference Vivelle-Dot®. Noven disagrees with Actavis's view that a person of ordinary skill in the art would understand the claimed coat weights to be limited to the precision of the arithmetic product of the Vivelle-Dot coat weight and a scale-up factor. (Tr. 16-17)

[4]The patent does not state the coat weight of Vivelle-Dot®. It contains only references to the surface area of Vivelle-Dot®, some of which have three significant figures (*see, e.g.*, col. 2:40, 53, 65; col. 3:29; col. 13:40-41 (referring to a surface area of "10.0 cm^2")), and some of which have two significant figures (*see, e.g.*, col. 12:6; col. 13:45 (referring to a surface area of "10 cm^2")).

[5]Dr. Michniak-Kohn appeared to agree with Noven that a scale-up factor does not have units, as it is not a measured quantity. (*See* Tr. at 65-66) From this it would seem to follow that the scale-up factors would not be understood by a POSA as being limited to any precise number of significant figures. (*See* Tr. at 93-94; *see also* D.I. 50-1 at 100 (excerpt from treatise))

scale-up factors – 1.25, 1.33, 1.5, 1.67, 1.75, 2, and 3 – as all being carried out to three significant figures, that is: 1.25, 1.33, 1.50, 1.67, 1.75, 2.00, and 3.00. (Tr. at 49-50, 53-54) But the Court is not persuaded. As Plaintiff observes, the actual number of significant figures given in this list of scale-up factors is sometimes one ("2 or 3"), sometimes two ("1.5"), and only sometimes three ("1.25, 1.33, . . . 1.67, 1.75"). As the expert's opinion is contradicted by the intrinsic evidence, the Court rejects it.

Another problem with Actavis's proposed construction is that it requires the Court to believe the patentee gave careful thought to how it used significant figures in some portions of the specification (e.g., when drafting the description of the 12.5 mg/cm^2 embodiment) but not in other closely-related portions (e.g., 15 mg/cm^2), and further that the patentee was relying on an unstated certainty that a POSA would understand the patentee always and obviously meant all coat weights (at least) should be understood as including three significant figures. The Court does not read the intrinsic evidence to support these conclusions.[6]

In sum, Actavis has provided the Court no persuasive basis to limit the scope of the claims in the manner proposed by Actavis. Accordingly, the Court will construe the disputed term to have its plain and ordinary meaning to a POSA in the context of the patent-in-suit. To such a person, the "15 mg/cm^2" would be understood to be a measurement with (at most) two significant figures, meaning it would be read as 15 plus or minus .5, resulting in a range of literal claim scope of greater than or equal to 14.5 mg/cm^2 and less than 15.5 mg/cm^2.

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[6]Similarly, claim 1 contains four different numbers – 12.5, 15, 0.156, and 0.01 – which do not have the same number of significant figures. In the context of the patent-in-suit, this suggests that patentee did not intend to limit the claims to measurements based solely three significant figures, as Actavis proposes.

III. CONCLUSION

The Court construes the disputed term as explained above. An appropriate Order follows.

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NOVEN PHARMACEUTICALS, INC.,	:	
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v.	:	C.A. No. 15-249-LPS
ACTAVIS LABORATORIES UT, INC.,	:	
Defendant/Counterclaimant.	:	
ACTAVIS LABORATORIES UT, INC.,	:	
Third-Party Plaintiff,	:	
v.	:	
HISAMITSU PHARMACEUTICAL CO., INC.,	:	
Third-Party Defendant.	:	

ORDER

At Wilmington this **5th** day of **July, 2016**:

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

IT IS HEREBY ORDERED that the disputed claim term of U.S. Patent No. 8,231,906 (the '906 patent) is construed as follows:

Claim Term	Court's Construction
coat weight selected from the group consisting of 12.5 mg/cm^2 and 15 mg/cm^2 ['906 patent, claims 1, 10, 11, and 14]	Plain and ordinary meaning; i.e., "15 mg/cm^2" means 15 plus or minus at least .5, yielding a claimed range of greater than or equal to 14.5 mg/cm^2 and less than 15.5 mg/cm^2.

HON. LEONARD P. STARK
UNITED STATES DISTRICT JUDGE