

**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.	:	

MEMORANDUM ORDER

At Wilmington this **24th** day of **October, 2019**:

Having reviewed the proposed final pretrial order (“PTO”) (D.I. 169-71) submitted by Plaintiff Noven Pharmaceuticals, Inc. (“Noven” or “Plaintiff”) and Defendant Amneal Pharmaceuticals L.L.C. (“Amneal” or “Defendant”), IT IS HEREBY ORDERED that:

1. Plaintiff’s motion in limine (“MIL”) number 1, to preclude Dr. Alekha K. Dash from testifying regarding noninfringement of U.S. Patent No. 9,833,419 (“the ’419 patent”), is DENIED. It does not appear to the Court that Dr. Dash intends to improperly compare the Amneal ANDA Product to prior art Vivelle-Dot®. Nor is there anything improper about one basis of Dr. Dash’s opinion being confidential documents to which a POSA would not have access; non-public information may appropriately be the basis for an illustration that provides additional support for an opinion grounded in public information. Noven’s arguments are best understood as being directed to the weight to be accorded to Dr. Dash’s testimony, not its admissibility. Finally, the Court is not (yet) persuaded that Amneal’s non-infringement position depends on an untimely request for claim construction. The testimony of Dr. Dash may be helpful to the Court, as finder of fact, in understanding and applying the plain and ordinary

meaning of the coat weight term, or alternatively may provide the basis for what the Court might ultimately determine is an obligation to further construe disputed claim terms. *See generally Pressure Prods. Med. Supplies, Inc. v. Greatbatch Ltd.*, 599 F.3d 1308, 1315-16 (Fed. Cir. 2010) (recognizing that Court “may engage in a rolling claim construction, in which [it] revisits and alters its interpretation of the claim terms as its understanding of the technology evolves”).

2. Plaintiff’s MIL number 2, to preclude Dr. M. Laurentius Marais from offering his statistical probability analysis in support of Defendant’s anticipation theory, is DENIED. Dr. Marais’s statistical analysis is sufficiently reliable to be helpful to the Court as a trier of fact in determining whether Defendant has met its burden in proving that Vivelle-Dot®, sold pre-critical date, met all disputed claim limitations. *See* 35 U.S.C. § 102(b). The Court agrees with Amneal that “Noven’s motion merely describes fact issues to be resolved at trial through weighing of evidence and credibility determinations.” (PTO Ex. 12 Ans. Br. at 3)

3. Plaintiff’s MIL number 3, to preclude portions of Dr. M. Laurentius Marais’s anticipated testimony relating to non-prior art products, is DENIED. The Court agrees with Amneal: “fluxes achieved by post-critical date Vivelle-Dot® (or flux achieved by samples taken from Vivelle-Dot® lots that were not sold) can be representative of fluxes achieved by Vivelle-Dot® sold before the critical date.” (PTO Ex. 13 Ans. Br. at 1) The Court further agrees with Amneal that Noven’s motion presents issues that “go[] to weight, not admissibility.” (*Id.*) There appears to be a genuine dispute of material fact on the representativeness issue and both parties will have the opportunity to present their competing evidence on this dispute at trial.

4. Defendant’s MIL number 1, to exclude Plaintiff’s “claim of infringement under the doctrine of equivalents [“DOE”] due to prosecution history estoppel [“PHE”],” is DENIED. Amneal’s motion appears to be an unauthorized motion for summary judgment. Regardless of

how the motion is characterized, the Court will benefit from hearing the parties' evidence on DOE so that it can make any necessary factfinding in the event the Court concludes PHE does not apply or the Court decides to reach the DOE issue in the alternative (even if PHE does apply). (See PTO Ex. 14 Ans. Br. at 1) ("The parties should brief the issue of PHE post-trial, and the Court should hear the DOE analysis so that if it determines PHE does not apply, it can decide infringement under the DOE.") The parties are both permitted to argue and brief their positions on the applicability (or not) of PHE. See also *Noven Pharmaceuticals, Inc. v. Actavis Lab. UT, Inc.*, C.A. No. 15-249-LPS D.I. 252 at 35-45 (D. Del. Dec. 28, 2017) (deciding PHE applied to bar DOE theory of infringement in connection with related patent *after trial*).

5. Defendant's MIL number 2, to exclude Noven's expert witness Dr. Richard Guy from testifying about a publication by van der Bijl (1998) that was not cited in his expert reports, is DENIED. Application of the *Pennypack* factors supports this conclusion. Although Plaintiff produced the publication after Dr. Guy's expert reports were served, there is no indication that Plaintiff acted willfully or flagrantly disregarded any Court Order. Instead, Dr. Guy identified and reviewed the 1998 publication during preparation for his September 11, 2019 deposition, and provided testimony about it during redirect examination in that deposition, providing Defendant with notice of his opinion on the import of the publication. While there is some prejudice to Defendant, it is not substantial, for reasons including: (i) van der Bijl 1998 is only five pages long and was cited in another reference that was disclosed in Dr. Guy's expert reports; (ii) Amneal's expert had more than a week to consider the new reference and the opportunity to provide his opinion on it at his deposition (had he wished to do so); and (iii) van der Bijl 1998 is not the basis for any new opinion but rather is cited by Dr. Guy only in the nature of reasonable elaboration of previously-disclosed opinion, consistent with proper rebuttal. Although the new

reference does not appear to be crucially-important evidence, the Court's admission of it does not threaten to disrupt the trial and is warranted under the totality of circumstances.

6. Plaintiff's Motion for Clarification (D.I. 147) of the Court's July 25, 2019 discovery order (D.I. 144) is GRANTED. Noven is not required to stipulate with respect to Novartis's belatedly produced third-party documents. The parties shall execute a stipulation consistent with this clarification and the July 25 order no later than the first day of trial.

7. With respect to other issues raised in the PTO:

a. The parties are permitted and encouraged to make opening statements and closing arguments, although they are not required to do either, and they will not be permitted to make a closing argument if they have already used all of their allocated trial time. (*See* PTO at p. 10)

b. The parties need not list exhibits they may offer at trial to be used solely for impeachment or cross-examination. (*See* PTO ¶¶ 43, 44, 46, 48)

c. The parties need not serve one another with non-demonstrative exhibits, nor make available for inspection any physical exhibits, when such exhibits are to be used solely for impeachment or cross-examination. (*See* PTO ¶¶ 49, 57)

d. The parties are directed to raise the issue of post-trial briefing with the Court at the conclusion of trial. (*See* PTO at p. 22)

8. At the pretrial conference ("PTC") tomorrow, the parties shall be prepared to address:

a. The procedure for requesting that the courtroom be closed and the burden on the party making such a request;


b. The procedure for motions for judgment as a matter of law;

c. Any disputes in connection with accommodating witnesses' schedules;
and

d. The trial length and schedule, as further referenced below.

9. The parties have failed to request a specific number of hours for their trial presentations, although they request five trial days. (*See* PTO at pp. 22-23) Having reviewed the PTO, and considering how the Court counts time, the Court finds that a reasonable and appropriate amount of time to enable each side to fully and fairly present its case on all disputed issues is between 8 and 10 hours per side. The Court will discuss with the parties at the PTC tomorrow the specific number of hours each side will be given.

10. Finally, the parties are advised that, due to other trials and other commitments, the Court no longer anticipates being available to preside at this trial as currently scheduled, on November 4-8. At the PTC tomorrow, the parties shall be prepared to discuss at least the following scheduling options: (i) holding trial during parts of days (e.g., 4:00 pm to 7:00 pm) when the Court expects to be in another trial: i.e., November 4, 5, 13, 18, 19, 21, 22, 25, and/or 26; (ii) holding trial on Saturday, November 9; (iii) holding trial on Monday, November 11 (Veterans Day); and (iv) moving trial to the first available 5-day open date, which is currently May 4-8, 2020.


HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE