IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVEN PHARMACEUTICALS, INC. Plaintiff/Counterclaim-Defendant, v. ACTAVIS LABORATORIES UT, INC., Defendant/Counterclaimant.	:	C.A. No. 15-249-LPS **REDACTED - PUBLIC VERSION**
ACTAVIS LABORATORIES UT, INC. Third-Party Plaintiff, v. HISAMITSU PHARMACEUTICAL CO., INC., Third-Party Defendant.	:	Original Filing Date: January 19, 2017

At Wilmington this **19th** day of **January, 2017**:

Having reviewed the proposed pretrial order and associated materials (*see* D.I. 149, 150, 151) ("PTO"), submitted by Noven Pharmaceuticals, Inc. ("Noven" or "Plaintiff") and Actavis Laboratories, Inc. ("Actavis" or "Defendant"),

IT IS HEREBY ORDERED that::

1. Noven's motion *in limine* ("MIL") No. 1, to preclude Actavis' expert, Dr. Michniak-Kohn from testifying "on purportedly obvious design approaches for modifying . . . Vivelle-Dot" to arrive at the claimed invention (D.I. 150 Ex. 13 Tab 1 at 1), is DENIED.

Noven's criticisms go to the weight and not admissibility of the proposed testimony. Despite not having actually undertaken the type of design modifications she proposes, and not having advised any entity to undertake such modifications, Dr. Michniak-Kohn is qualified to express the opinions at issue, for reasons including that she meets both parties' definition of a person of ordinary skill in the art. Just because the expert cannot identify anyone who has made the type of design modification she proposes does not mean her opinion as to what could be done is inadmissible. That Dr. Michniak-Kohn has not "identified any scientific literature that accepts her proposed methodology as reliable" (*id.* at 3) does not render it *per se* unreliable, as her methodology may still be found to be "based on valid reasoning and reliable methodology" even if it is not generally accepted. *In re TMI Litig.*, 193 F.3d 613, 665 (3d Cir. 1999) (internal quotation marks omitted). At the forthcoming bench trial, the Court expects to find the disputed testimony to be helpful and will give it whatever weight it deserves.

2. Actavis' MIL No. 1, to preclude Noven's expert, Dr. Guy, from offering certain statistical analyses (D.I. 150 Ex. 14 Tab A at 1), is DENIED. Actavis essentially faults the statistical tests Dr. Guy chose to run, a matter on which reasonable experts may disagree and on which the Court may receive competing evidence. Dr. Guy is sufficiently qualified to perform the type of statistical tests he performed here (tests whose general acceptability do not appear to be disputed), regardless of whether he is also qualified to perform more complex statistical analysis.

Actavis has requested (in the alternative) to present testimony from its statistical expert, Dr. Scharfstein, purportedly identifying errors in Dr. Guy's analysis. (*See id.* at 2-3) The Court will discuss this request with the parties at the pretrial conference later today.

3. Actavis' MIL No. 2, to preclude Dr. Guy from offering validity opinions based on his analysis of Figure 1 of the patent-in-suit and unexpected results (D.I. 151 Ex. 15 Tab A at 1), is DENIED. Actavis has not provided a persuasive argument that Dr. Guy's analysis is so lacking in reliability that it should be stricken, particularly given that he had earlier disclosed all of the materials on which his opinion is based, he has been deposed on this topic, and Actavis' expert (Dr. Michniak-Kohn) did not address [redacted] until her reply report. Actavis' alternative requested relief, which seems to be to narrowly circumscribe Dr. Guy's testimony to specifically what he disclosed in his expert report, is also denied, as Dr. Guy will be permitted to provide "reasonable . . . elaboration" on the opinions he adequately disclosed as well as appropriate rebuttal testimony. *See nCube Corp. v. SeaChange Int'l, Inc.*, 809 F. Supp. 2d 337, 347 (D. Del. 2011) ("[C]ourts do not require verbatim consistency with the report but . . . allow [] testimony which is consistent with the report and is a reasonable synthesis . . . of the opinions contained in the expert's report.") (internal quotation marks omitted).[1]

4. Actavis' MIL No. 3, to exclude evidence of testing and opinions about batches of Defendant's proposed generic product [redacted] (D.I. 151 Ex. 16 Tab A at 1), is DENIED. The parties raised disputes over the course of this litigation about [redacted]. (*See* D.I. 137 at 5-6) The Court will benefit from hearing whatever evidence either side wishes to present regarding [redacted]. Under the circumstances, which include the fact that this is a bench trial and the Court has presided over

[1]Nonetheless, Actavis (like Noven) is free at trial to object to any expert testimony it believes, in good faith, goes beyond what was previously and adequately disclosed.

disputes [redacted], the concerns of Federal Rule of Evidence 403 (e.g., risk of unfair prejudice, confusion, waste of time) do not substantially outweigh the potential probative value of the evidence at issue. The Court further rejects Actavis' contention that Dr. Guy's proposed opinions as to [redacted] are so speculative as to be inadmissible and Actavis' suggestion that the Court lacks subject matter jurisdiction.

5. With respect to the parties' dispute as to the order of presentation at trial (PTO p. 9), Noven's proposal is ADOPTED, with the modification that both sides may have a rebuttal closing argument. The parties are encouraged to use some portion (whatever amount they believe will be most effective) of their trial time for opening statements; closing arguments are permitted but not required, although in past cases of this nature the Court has found them to be helpful.

6. The parties' dispute relating to designating deposition testimony and identifying and resolving objections to such designations (PTO pp. 10-12) will be discussed at the pretrial conference.

7. Noven's proposal with respect to demonstrative exhibits for opening statements (PTO p. 17) is ADOPTED.

8. The parties' dispute with respect to demonstrative exhibits to be used during direct examination will be discussed at the pretrial conference.

9. The parties' dispute with respect to whether Noven will be permitted to include a technology tutorial as part of its direct examination of its expert (PTO p. 22) will be discussed at the pretrial conference.

10. Given the issues to be tried – which include infringement and invalidity, in a case

involving one patent-in-suit – the Court allocates to each side a maximum of eleven (11) hours per side for its trial presentation. This amount of time will be sufficient for both sides to make fair and reasonable presentations of all the evidence and argument the Court will need in order to resolve the disputed issues.

11. The Court will hold trial, subject to the parties' time allocation noted above, at some or all of the following times:

a. Monday, January 30: 8:30 a.m. - 6:00 p.m.

b. Tuesday, January 31: 8:30 a.m. - 5:00 p.m.

c. Wednesday, February 1: 8:30 a.m. - 2:30 p.m.

d. Thursday, February 2: 10 a.m. - 6:00 p.m.

12. Because this Memorandum Order has been filed under seal, the parties shall meet and confer and shall, no later than January 20, 2017, submit a proposed redacted version of it. Thereafter, the Court will issue a public version.

HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT COURT