

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS AG, NOVARTIS
PHARMACEUTICALS CORPORATION,
MITSUBISHI TANABE PHARMA
CORPORATION, and MITSUI SUGAR CO.,
LTD.,

Plaintiffs,

C.A. No. 14-1487-LPS

v.

ACTAVIS ELIZABETH LLC,

Defendant.

NOVARTIS AG, NOVARTIS
PHARMACEUTICALS CORPORATION,
MITSUBISHI TANABE PHARMA
CORPORATION, and MITSUI SUGAR CO.,
LTD.,

Plaintiffs,

C.A. No. 15-150-LPS

v.

EZRA VENTURES, LLC,

Defendant.

NOVARTIS AG, NOVARTIS
PHARMACEUTICALS CORPORATION,
MITSUBISHI TANABE PHARMA
CORPORATION, and MITSUI SUGAR CO.,
LTD.,

Plaintiffs,

C.A. No. 15-151-LPS

v.

HEC PHARM CO., LTD., HEC PHARM
GROUP, and HEC PHARM USA INC.,

Defendants.

NOVARTIS AG, NOVARTIS
PHARMACEUTICALS CORPORATION,
MITSUBISHI TANABE PHARMA
CORPORATION, and MITSUI SUGAR CO.,
LTD.,

Plaintiffs,

C.A. No. 15-975-LPS

v.

APOTEX INC. and APOTEX CORP.,

Defendants.

MEMORANDUM ORDER

At Wilmington this **17th** day of **April, 2017**, having reviewed the parties' proposed pretrial order (C.A. No. 14-1487¹ D.I. 275), including briefing on various motions *in limine*, and the parties' *Daubert* motions and motion for summary judgment (D.I. 208, 209),

IT IS HEREBY ORDERED that:

¹All references to the docket index ("D.I.") are to C.A. No. 14-1487, unless otherwise noted.

1. The following motions are **DENIED** as moot in light of their withdrawal (*see* D.I. 281, 282):

- A. Plaintiffs' motion to preclude Defendants' experts' testimony at trial (D.I. 208) with respect to witnesses Drs. Robert S. Coleman and Chander Raman.
- B. Plaintiffs' motion for summary judgment (D.I. 209).
- C. Defendants' motion to preclude testimony of patent law expert (D.I. 216).

2. In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993), the Supreme Court explained that Federal Rule of Evidence 702 creates "a gatekeeping role for the [trial] judge" in order to "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." Rule 702(a) requires that expert testimony "help the trier of fact to understand the evidence or to determine a fact in issue." Expert testimony is admissible only if "the testimony is based on sufficient facts or data," "the testimony is the product of reliable principles and methods," and "the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(b)-(d). There are three distinct requirements for proper expert testimony: (1) the expert must be qualified; (2) the opinion must be reliable; and (3) the expert's opinion must relate to the facts. *See Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000).

3. Plaintiffs' motion to exclude testimony of Dr. John Kornak (D.I. 208) is **DENIED**. Plaintiffs contend that Dr. Kornak is not a person of skill in the art and, therefore, is not qualified to offer an opinion about the experimental examples of the '229 patent. Dr. Kornak is a biostatistician who is regularly consulted by members of research teams evaluating drug-treatment efficacy. (*See* D.I. 228 Ex. 1 at ¶¶ 1-6; Ex. 2) Dr. Kornak has relevant technical

expertise and is qualified to offer opinions about the statistical significance of the experiments reported in the patent. *See SEB S.A. v. Montgomery Ward & Co.*, 594 F.3d 1360, 1373 (Fed. Cir. 2010). That Dr. Kornak does not meet either parties' proposed definition of a person of ordinary skill in the art does not mean that he lacks relevant expertise. Rather, Dr. Kornak's knowledge, skill, experience, training, and education are likely to assist the trier of fact.

4. Plaintiffs' motion to exclude the testimony of Drs. Anthony DeFranco and Steven Tanis (D.I. 208) is **DENIED**. Plaintiffs do not question these experts' qualifications or contend that their opinions are based on insufficient facts or data, unreliable scientific principles or methods, or unreliable application of scientific principles and methods to the facts of this case. Plaintiffs contend, instead, that the opinions expressed by these witnesses are based on erroneous instruction on applicable law, making them unreliable. Specifically, Plaintiffs assert that these opinions apply an incorrect commercial-use standard for enablement and fail to analyze each asserted claim separately. But Plaintiffs do not take issue with the recitations of law included in the expert reports, which do not purport to apply a commercial-use standard. (*See* D.I. 241 Ex. 2 at ¶¶ 97-102; Ex. 4 at ¶¶ 51-57) Further, the expert reports show that Drs. DeFranco and Tanis did sufficiently consider each asserted claim separately. (*See* D.I. 241 Ex. 2 at ¶¶ 81-91, 268-71; Ex. 4 at ¶¶ 64, 67-84, 236-51) Nor is the Court persuaded that Dr. Tanis' written-description opinion is unreliable or insufficient. Additionally, all of Plaintiffs' concerns may be adequately addressed at trial through cross-examination.

5. Plaintiffs' motion *in limine* No. 1, to preclude Defendants from introducing argument and evidence regarding the breadth of unasserted claims, is **DENIED** without prejudice to renew in post-trial briefing. Defendants contend that discussion of unasserted claims is

required, because each of the asserted claims is a dependent claim that necessarily depends from unasserted, independent claims. The Court agrees. Further, the Court disagrees with Plaintiffs that Defendants' evidence and arguments "are calculated to confuse the issues, waste time, and cause unfair prejudice." (PTO Ex. 13 A at Pls. 3) Invalidity is evaluated on a claim-by-claim basis, *see Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1379 (Fed. Cir. 2009); *Capon v. Eshhar*, 418 F.3d 1349, 1360 (Fed. Cir. 2005), and this uncontested statement of law may have implications for what legal arguments will ultimately be persuasive. Still, it will be most helpful to the Court for Plaintiffs to address in their post-trial briefing any concerns that Defendants are making improper arguments about the breadth of the unasserted claims, rather than ask the Court – before or during trial – to make a broad finding as to what arguments Defendants may properly make based on certain evidence that will be admitted.

6. Plaintiffs' motion *in limine* No. 2, to preclude Defendants from using the inventors' journey to discovery to support invalidity defenses, is **DENIED**. Evidence on the quantity of experimentation by the inventors may be relevant to the enablement inquiry. *See Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1372-73 (Fed. Cir. 1999). Therefore, the disputed evidence is not irrelevant, and the Court is not persuaded that the evidence is unfairly prejudicial or will confuse the issues.²

7. Plaintiffs' motion *in limine* No. 3, to preclude Defendant Ezra from offering at trial its double-patenting defense, is **DENIED**. Plaintiffs contend that Ezra has submitted no evidence, including no expert testimony, on this defense and, therefore, cannot meet its burden to

²Given Defendants' withdrawal of the obviousness defense (*see* D.I. 281), this motion is moot with respect to Dr. Coleman's testimony.

show invalidity due to double patenting by clear and convincing evidence. A motion *in limine* is a vehicle to exclude inadmissible or prejudicial evidence before it is offered at trial. *See Luce v. United States*, 469 U.S. 38, 40 n.2 (1984). But Plaintiffs do not identify any specific evidence they seek to exclude here. Moreover, the Court disagrees with Plaintiffs' suggestion that "the Court has already rejected" the entirety of Defendants' double patenting defense(s). (PTO Ex. 13 C at Pls. 1) While Defendants confront a heavy burden, the Court cannot reject at this point their contention that sufficient facts are and will be in evidence – even in the absence of expert testimony – to persuade the Court to invalidate asserted claims based on double patenting. (PTO Ex. 13 C at Defs. 1)

8. Defendants' motion *in limine*, to strike entries 1, 3, 4, 5, 8 and 9 of the deposition errata of Peter Waibel, is **DENIED**. Defendants contend that Mr. Waibel's errata materially changed his answers to several questions. To the extent that Mr. Waibel's testimony remains relevant despite the Court's ruling on standing (*see* D.I. 230), it is within the discretion of the Court to allow substantive changes to deposition testimony. *See EBC, Inc. v. Clark Bldg. Sys., Inc.*, 618 F.3d 253, 268 (3d Cir. 2010). Any prejudice to Defendants stemming from Mr. Waibel's changed testimony has already been addressed by Mr. Waibel's second deposition, in which Defendants had the opportunity to question him about his changes (*see* D.I. 275 Ex. 14 at 17-19, 23), and may further be alleviated by cross-examining him at trial. Moreover, Mr. Waibel's "earlier testimony is not expunged from the record, thus subjecting [him] to cross-examination and impeachment at trial with respect to the contradictory testimony." *EBC*, 618 F.3d at 267.

9. The parties' disputes regarding the Court's standing decision, the order of

presentation at trial, and identifying which witnesses will be called to testify at trial (PTO at 9-16, 33-34) will be discussed at the pretrial conference tomorrow.

10. Plaintiffs' proposal regarding witness sequestration (PTO at 13) is **ADOPTED**.

11. Defendants' proposal regarding impeachment with prior inconsistent testimony (PTO at 20-21) is **ADOPTED**.

12. Defendants' request that the Court strike portions of Plaintiffs' Statement of Uncontested Facts and Statement of Law (D.I. 276; *see also* PTO at 34-36) is **DENIED**. The Court is not persuaded that Plaintiffs' revisions introduced any new or surprising legal or factual disputes into this case. Nor does the Court view Plaintiffs' conduct, in the totality of circumstances, to be unfairly prejudicial to Defendants, who may (if they wish) supplement their statement of facts prior to trial,³ will have a full and fair opportunity to present evidence at trial, and will be permitted to submit proposed findings of fact as well as legal argument in post-trial briefs.

13. Given the remaining issues to be tried, the Court allocates to each side a maximum of eleven (11) hours 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, particularly given the extensive post-trial briefing which the parties have proposed (PTO at 32) and which the Court will allow.

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

a. Tuesday, April 25: 1:00 p.m. - 6:00 p.m.

³Defendants shall propose a deadline for doing so, should they wish.

- b. Wednesday, April 26: 10:00 a.m. - 6:00 p.m.
- c. Thursday, April 27: 8:30 a.m. - 6:00 p.m.
- d. Friday, April 28: 8:30 a.m. - 1:00 p.m.



HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE