

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VIFOR FRESENIUS MEDICAL CARE)	
RENAL PHARMA LTD. and VIFOR)	
FRESENIUS MEDICAL CARE RENAL)	
PHARMA FRANCE S.A.S.,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 18-390 (MN)
)	
LUPIN ATLANTIS HOLDINGS SA,)	
LUPIN PHARMACEUTICALS, INC., and)	
TEVA PHARMACEUTICALS USA, INC.,)	
)	
Defendants.)	

MEMORANDUM ORDER

At Wilmington this 13th day of August 2020:

This is a patent case brought by Plaintiffs Vifor Fresenius Medical Care Renal Pharma Ltd. and Vifor Fresenius Medical Care Renal Pharma France S.A.S. (collectively, “Plaintiffs”) against Defendants Lupin Atlantis Holdings SA, Lupin Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc. (collectively, “Defendants”). The Court has scheduled a bench trial to begin on January 19, 2020. Pending before the Court are four motions seeking to limit testimony at trial: (1) Defendants’ Joint Motion to Exclude Certain Expert Testimony Concerning Infringement of Dr. Anjay Rastogi, Dr. Wesley Harris, Dr. Adam Myers and Dr. Robert O. Williams III under Federal Rule of Evidence 702 (D.I. 211);¹ (2) Plaintiffs’ Motion to Strike the Reply Expert Report of Robert Linhardt, Ph.D., or in the alternative, to preclude Dr. Linhardt from testifying in Defendants’ case-in-chief (D.I. 213); (3) Plaintiffs’ Motion to Preclude Portions of the Expert

¹ Defendants’ motion addressed claims 29, 30, 31 and 51 of U.S. Patent No. 9,561,251 (“the ‘251 patent”). In connection with narrowing the issues for trial, Plaintiffs dropped claims 31 and 51. Therefore, Defendants’ motion is denied as moot with respect to those claims.

Testimony of Walter G. Chambliss, Ph.D. (D.I. 215); and (4) Defendants' Joint Motion to Exclude Certain Expert Testimony of Dr. Anjay Rastogi, Dr. Robert O. Williams, III and Carla Mulhern Relating to Secondary Considerations (D.I. 217). The Court will address each motion in turn.

I. DISCUSSION

A. D.I. 211

1. Claim 29

Defendants seek to limit the infringement opinions of Drs. Rastogi and Harris under *Daubert*, asserting that they are unreliable and fail to “fit” the issues in the case. As to Dr. Rastogi, Defendants argue that his opinions “are not based on any testing or analysis of Defendants’ ANDA Products or data concerning absorption of ‘iron oxy-hydroxide’ as claimed (as opposed to ‘iron’ uptake).” (D.I. 212 at 2). Plaintiffs respond that Dr. Rastogi relied on a clinical study of Plaintiffs’ Velphoro® product that is cited in Defendants’ proposed labels (D.I. 229 at 1-2) and that Dr. Rastogi relied on the data in the studies to offer opinions as to the iron hydroxide uptake, not just iron (*id.* at 6). Plaintiffs point out that Defendants relied on the same studies to conclude that iron oxy-hydroxide is “practically insoluble and therefore not absorbed and not metabolized.” (*Id.* at 6). The dispute here appears to be whether Dr. Rastogi could make the conclusions he did based on the information he relied on. That, however, goes to the sufficiency of Dr. Rastogi’s opinions and not their admissibility. Thus the Court will deny Defendants’ motion as to Dr. Rastogi. And in light of the fact that Defendants’ motion as to Dr. Harris is based on Dr. Harris’s reliance on the opinions of Dr. Rastogi, that motion will also be denied.

2. Claim 30

Defendants assert that the Court adopted Plaintiffs' proposed construction of "iron release rate below 2.5%" to mean:

The iron release measured in water at a pH of 3 according to European Pharmacopeia chapter 2.9.3 using standard dissolution equipment and parameters as described in the monograph, where iron content is analyzed by titration after 2 hours, wherein the quantity of iron dissolved after 2 hours is less than 2.5%.

Defendants then argue that Plaintiffs' expert, Dr. Myers, did not test the accused products starting at a pH of 3 and thus his opinions should be excluded. (D.I. 212 at 7). Plaintiffs argue that the claim as construed does not require the starting pH to be 3, but rather that the "resultant" pH (*i.e.*, the pH after the tablet is added) should be 3. (D.I. 229 at 7-8). Plaintiffs cite to portions of expert testimony to support their argument. After reviewing the submissions, it is apparent that the Court would benefit from hearing full expert testimony (and cross examination) on this issue. Thus, Defendants' motion as to claim 30 will be denied.²

B. D.I. 213

Plaintiffs assert that Defendants improperly submitted a reply report from Dr. Linhardt that includes opinions about inherency that should have been included in an opening report. (D.I. 214). Defendants dispute that the opinions are new and assert that Dr. Linhardt's reply report "is a direct rebuttal" of Plaintiffs' expert's report on inherency. (D.I. 227 at 1). The Court cannot, on the record before it, determine whether the opinions in Dr. Linhardt's reports are new or a fair rebuttal to Plaintiffs' expert. It is clear, however, that the opinions were not included in the opening report,

² Teva similarly asserts that Dr. Myers's opinions as to its product should also be excluded because Dr. Myers adjusted the starting pH of the medium down to a pH of 2.31 and he did not test the Teva tablets at a resultant pH of 3 (the resultant pH average was 3.25). (D.I. 212 at 8-9). Plaintiffs assert that anything from pH 2.5 through 3.4 would round to 3 and thus fit within the pH of 3 in the Court's construction. (D.I. 229 at 10-11). This again is a dispute that expert testimony and cross examination would help the Court to understand more thoroughly.

and were offered as a response to Plaintiffs' expert's criticism of Dr. Chambliss. The opinions should therefore not be part of Defendants' case-in-chief. Thus, Plaintiffs' motion to strike will be denied, but Plaintiffs' motion to preclude Dr. Linhardt (and Dr. Chambliss) from offering the challenged opinions in Defendants' case-in-chief will be granted.³

C. D.I. 215

Plaintiffs seek to exclude from trial Dr. Chambliss's opinions regarding reverse doctrine of equivalents and incorporation by reference, asserting that he applied the wrong legal standards. (D.I. 216 at 3-8). Plaintiffs point to certain portions of Dr. Chambliss' report and Defendants point to others in support of their arguments. The Court finds that the issues raised – including whether opinions were fairly disclosed in expert reports – will be better addressed in context at trial. Thus, Plaintiffs' motion regarding Dr. Chambliss's application of legal standards will be denied.

Plaintiffs also seek to exclude Dr. Chambliss's opinions on Dr. Philipp's state of mind, including what he knew and was aware of when he submitted a declaration to the Patent Office in 2015. (D.I. 216 at 8-10). Defendants assert that "Dr. Chambliss did not give such an opinion . . . and *will not testify at trial* as to Dr. Philipp's state of mind or intent at the time he signed and submitted his sworn declarations" to the Patent Office. (D.I. 225 at 5 (emphasis in original)). Defendants assert that many of the examples given by Plaintiffs were opinions Dr. Chambliss offered in response to Plaintiffs' questions – and not opinions elicited by Defendants. (*Id.* at 5-6).

³ The Court notes that Defendants do not really oppose Plaintiffs' motion to the extent it seeks to preclude the testimony in Defendants' case-in-chief. Defendants simply argue that decisions about the order of testimony are premature.

Thus, the parties and the Court agree that such testimony would be inappropriate. Plaintiffs' motion will be granted.⁴


D. D.I. 217

Defendants seek to exclude testimony from three of Plaintiffs' experts on various aspects of secondary considerations of non-obviousness. (*See generally* D.I. 218). As Plaintiffs point out, however, the Court is conducting a bench trial in this case. "And although Rule 702 applies, it is plain the Court can address with minimal prejudice any assertion that a particular piece of testimony is outside an expert's area of expertise, assess whether it supports the assertion that it supports a finding that objective indicia undermine Plaintiffs' obviousness contention, and Defendants can cross examine Plaintiffs' experts to elicit evidence that they believe supports their views." (D.I. 228 at 1). Indeed, the Court believes that addressing each of the above (or similar) assertions is something more easily done in the context of specific questions and answers at trial. Thus, Defendants' motion to exclude testimony on secondary considerations will be denied.

II. CONCLUSION

THEREFORE, for the reasons stated above, IT IS HEREBY ORDERED that:

1. Defendants' motions (D.I. 211 & 217) are DENIED; and
2. Plaintiffs' motions (D.I. 213 & 215) are GRANTED-IN-PART and DENIED-IN-PART.


The Honorable Maryellen Noreika
United States District Judge

⁴ In granting the motion, the Court is not ruling on each of the examples (or other uncited examples) of purported opinions on Dr. Phillip's state of mind in Plaintiffs' papers. To the extent Defendants elicit opinions of Dr. Chambliss at trial that Plaintiffs believe call for state of mind testimony, the Court expects Plaintiffs to object at trial. To the extent that Plaintiffs ask such questions of Dr. Chambliss, they do so at their own peril.