IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OREXIGEN THERAPEUTICS, INC., Plaintiff; v. ACTAVIS LABORATORIES FL, INC., Defendant.	Civil Action No. 1:15-cv-451-RGA

MEMORANDUM ORDER

The parties have submitted letter briefing related to two disputes that arose at the pretrial conference. (D.I. 123, 124, 125, 126).

The parties dispute whether Defendant may offer obviousness combinations at trial that Plaintiff alleges were disclosed for the first time in the Pretrial Order. (D.I. 117-1 at 389). Defendant states that it will rely only on the Jain-O'Malley obviousness combination and purports to identify the paragraphs in Dr. Ahima's expert report in which the Jain-O'Malley combination was disclosed. (D.I. 123). Plaintiff argues this combination was never expressly disclosed. (D.I. 125). I agree that this specific combination of references was not expressly disclosed in Dr. Ahima's report. It strains credulity for Defendant to suggest, for example, that discussing Jain as one of three references disclosing bupropion, followed by a list of five naltrexone references, followed by O'Malley as one of three references disclosing the combination of the two drugs, constitutes a disclosure of the Jain-O'Malley combination. (D.I. 125 at 3; D.I. 125-1 at 55, ¶118). There are dozens of possible ways of combining the eleven

references from this one paragraph and I do not think Plaintiff was fairly put on notice of any of them.

Despite this failure to disclose, however, Plaintiff has not demonstrated the kind of prejudice that would warrant excluding this theory at trial. In fact, Plaintiff notes that these two references were before the PTO during prosecution of both of the patents in suit. Plaintiff also provides specific reasons why these references do not render the asserted claims obvious. Therefore, I will allow Defendant to present this obviousness combination at trial. Defendant's expert's testimony is limited to what is fairly disclosed in his report. At Plaintiff's option, its expert may submit a report of no more than fifteen pages in length addressing this combination no later than Tuesday, May 30, 2017. Defendant will not be permitted to depose Plaintiff's expert or submit a reply report.

Defendant objects to Plaintiff's inclusion of "certain highly prejudicial new paragraphs of Contested Facts" in the pre-trial order. (D.I. 124 at 1). Plaintiff contends that the paragraphs were added in response to Defendant's allegations of insufficiency of proof of infringement of certain claim limitations, which, according to Plaintiff, were made for the first time in the pre-trial order. (D.I. 126 at 2).

As an initial matter, I note that the "exclusion of critical evidence is an 'extreme' sanction not normally to be imposed absent a showing of willful deception or 'flagrant disregard' of a court order by the proponent of the evidence." *Meyers v. Pennypack Woods Home Ownership Assn.*, 559 F.2d 894, 905 (3d Cir. 1977) (internal citation omitted). Factors to consider when determining whether to exclude evidence include:

> (1) the prejudice or surprise in fact of the party against whom the excluded witnesses would have testified, (2) the ability of that party to cure the prejudice, (3) the extent to which [allowing late-offered contested facts] would disrupt the

> orderly and efficient trial of the case or of other cases in the court, and (4) bad faith or willfulness in failing to comply with the court's order.

Id. at 904–05. I am hard pressed to see any prejudice to Defendant from including these paragraphs. Defendant argues "extreme prejudice" would result from allowing Plaintiff to use these facts at trial "under the guise of alleged 'background' and invalidity rebuttal evidence of 'secondary considerations.'" (D.I. 124 at 1). The relief Defendant seeks appears to be to require that Plaintiff's presentation of evidence be "[c]onsistent with the Court's rulings and [Plaintiff's] representations." (*Id.* at 2). Assuming Plaintiff does in fact present its case consistent with my rulings, I fail to see any prejudice to Defendant. I also fail to see any bad faith on Plaintiff's part, as the allegedly "new" facts were submitted in response to Defendant's new non-infringement theories. I decline to strike these paragraphs from the pre-trial order.

It seems clear from the record that Defendant has, in fact, raised new infringement defenses on the eve of trial. For example, Interrogatory No. 6 states, "Describe in detail the factual and legal bases for Actavis's contentions, if any, that Actavis's ANDA Product would not infringe . . . any asserted claim of the patents-in-suit." (D.I. 126-1 at 3). The Interrogatory also specifically requested "a claim chart showing the presence or absence in Actavis's ANDA Product of each claim element of each asserted claim" along with citations to evidence that would support Defendant's non-infringement position. (*Id.*). In response, Defendant failed to submit a claim chart and also failed to address each limitation of the asserted claims. As to the '111 patent, Defendant stated that it did not infringe because the '111 patent is invalid. (*Id.* at 4). Defendant described no other bases for non-infringement of the '111 patent. As to the '626 patent, in addition to invalidity, Defendant stated it did not infringe because it "will not administer any compounds" as required by the asserted claims and because a single entity would not perform all steps of the claimed method. (*Id.* at 5-6). Defendant further asserted that it

would not induce infringement because its product's proposed label "does not include instructions to co-administer naltrexone and bupropion . . . 'to increase satiety in the individual' or 'to suppress the appetite of the individual,'" as required by the asserted claims. (*Id.* at 6). As to the '195 patent, in addition to invalidity, not administering any compounds, and no single entity performing all steps, Defendant stated it did not infringe because its product "does not meet the recited dissolution profile using the recited dissolution test parameters in claim 11." (*Id.* at 8).

In its Preliminary Infringement Contentions, Plaintiff stated that Defendant had not contested infringement in its Paragraph IV certification. (D.I. 119 at 350-55). Plaintiff included with its Infringement Contentions a detailed claim chart specifying its contentions for how Defendant's product met each limitation of the asserted claims. (*Id.* at 357-90). Plaintiff's Interrogatory No. 7 asked Defendant to provide its bases for any disagreement with Plaintiff's infringement contentions. (D.I. 126-1 at 11). Defendant's response was to incorporate its response to Interrogatory No. 6. (*Id.* at 12).

Defendant never alleged, prior to submitting the pre-trial order, that its ANDA product did not meet the following claim limitations of the '626 and '111 patents: (1) "bupropion . . . effective to induce weight loss"; and (2) "naltrexone . . . effective to enhance the weight loss effect of the bupropion." Nor did Defendant make any allegations of non-infringement of the additional "sustained release" limitation of the '111 and '195 patents. Nor did Defendant make any allegations, prior to submitting the pre-trial order, of any failure of proof of infringement in response to Plaintiff's detailed claim chart and infringement contentions. It would be extremely prejudicial to allow Defendant to proceed at trial with arguments of failure of proof and non-infringement that were presented for the first time in the pre-trial order. *See Intellectual*

Ventures I LLC v. Symantec Corp., 2015 WL 294240, at *1 (D. Del. Jan. 21, 2015) (excluding marking defense to which defendant failed to respond in interrogatories or provide expert discovery); *Vehicle IP, LLC v. Werner Enters., Inc.*, No. 10-503-SLR, D.I. 209 (D. Del. Sept. 20, 2013) (excluding non-infringement arguments first raised in expert's rebuttal report).

For these reasons, Defendant has waived the right to contest the following limitations of the asserted claims: (1) "bupropion . . . effective to induce weight loss" ('626 and '111 patents); (2) "naltrexone . . . effective to enhance the weight loss effect of the bupropion" ('626 and '111 patents); and (3) "sustained release" ('111 and '195 patents).

Entered this 19 day of May, 2017.

Richard G. Andrews
United States District Judge