

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HORIZON MEDICINES, LLC., :
 :
 Plaintiff, :
 :
 v. : Civil Action No. 18-1014-RGA
 :
 ALKEM LABORATORIES, LTD., :
 :
 Defendant. :

ORDER ON DEFENDANT’S MOTION IN LIMINE #2

Defendant’s second motion in limine was briefed (D.I. 189-27, 189-28, 189-29), the subject of an order (D.I. 190), discussed at the pretrial conference, and the subject of some follow up (D.I. 193).

Let me restate my understanding of the relevant facts. For Defendant’s invalidity case, there are two patents at issue – the ‘451 patent and the ‘033 patent. Defendant wants to use U.S. Patent Application Publication No. 2007/0043096 A1 (the ‘096 publication) as prior art in its obviousness challenges. According to Plaintiff, the ‘451 patent claims, through a provisional application, the priority date of January 24, 2007, and the ‘033 patent claims, also through a provisional application, the priority date of November 30, 2007. The ‘096 publication was published in between, on February 22, 2007. It lists three inventors, Dr. Tidmarsh, Mr. Golombik, and Mr. Tianshuan Lii. (D.I. 189-27, Exh. 1). Defendant challenges the ability of both patents to claim the provisional application dates, although I think the only dispute on that issue that matters is in regard to the ‘451 patent.

Plaintiff wants to argue that the '096 publication is not prior art to the '451 patent because the provisional application means that the '451 patent came first, and, as to both patents, the '096 publication is not prior art because it is “derived from a joint inventor’s own work,”¹ and “the subject matter of the '096 publication and the claimed invention were owned by, or subject to an obligation of assignment to, the same person.” (D.I. 189-28).²

Defendant seeks to prevent Plaintiff from challenging the prior art status of the '096 publication. Defendant’s position is that the first it ever heard of any of these arguments is when the parties were preparing the pretrial order – Plaintiff’s briefing in regard to the motion in limine on July 31, 2020 (*see* D.I. 189-28) – and that Plaintiff’s disclosures come too late.

Defendant says it challenged the priority dates for both patents in its contentions. Defendant says its expert, in an expert report, challenged the priority date for the '451 patent, stating that the provisional application that was the basis for the Jan. 24, 2007 priority claim did not disclose everything that was later claimed. Defendant says Plaintiff provided nothing in opposition to its expert’s opinion, and, indeed, Plaintiff’s experts assumed the correctness of Defendant’s expert’s opinions. Defendant says Plaintiff’s experts offer no relevant opinions on the provisional application issue or the two inventorship issues, and Plaintiff essentially concedes that this is so.

Plaintiff’s response is that Defendant knew that it was not conceding that the '096 publication was prior art, because it denied requests for admission to that effect. Specifically, Plaintiff denied that it was not “challeng[ing]” that the '096 publication was prior art to both

¹ The listed inventors of the '451 patent are Dr. Tidmarsh, Mr. Golombik, and Mr. Puneet Sharma. The listed inventors of the '033 patent are Mr. Jerry Xu and Dr. Tidmarsh. I gather that Plaintiff expects that Dr. Tidmarsh and Mr. Golombik will testify that, as to the '096 publication, Mr. Lii, had no input into the relevant conception. (D.I. 189-2, ¶¶ 684-86).

² The '096 publication states that it is assigned to Horizon Therapeutics, Inc. (D.I. 189-27, Exh. 1). The '033 and '451 patents both say they are assigned to Horizon Pharma USA, Inc.

patents. (D.I. 189-27, Exh. 5 (RFAs 25 and 52) (Jan. 30, 2020)).³ It implies that notice is enough, given that Defendant bears the burden of proving invalidity, which includes proving that art is prior art. Plaintiff will limit itself to cross-examining Defendant's expert (presumably in regard to the provisional application issue), and it will offer non-expert testimony from the two inventors about what they did, presumably to meet the requirements of both of the inventorship arguments. Plaintiff says it will be prejudiced if it cannot present all these arguments at trial.

I do not think there is much of an issue on the '451 provisional application's contents. The issue was not conceded. Defendant has the burden of proof by clear and convincing evidence. The issue is a matter for expert testimony. Plaintiff can cross-examine. Defendant can prepare its expert to withstand cross-examination.

The closer issue is the remaining one of whether I should exclude the fact testimony of Mr. Golombik and Dr. Tidmarsh about inventorship. Defendant had numerous earlier opportunities to disclose the inventorship theory. (*See, e.g.*, D.I. 189-27, Exh. 3 (supplemental response to interrogatory #2)). Thus, I could exclude the testimony as not being properly disclosed. In deciding this issue, which is addressed to my discretion, I take guidance from *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 905 (3d Cir. 1977), which suggests that the basic considerations for me to consider are: "(1) the prejudice or surprise in fact of the party against whom the excluded [evidence is offered], (2) the ability of that party to cure the prejudice, (3) the extent to which waiver of the [appropriate] rule . . . would disrupt the

³ I think Defendant's view is that since Plaintiff also objected to the RFAs as "premature because [they call] for an opinion derived from expert testimony," the failure to offer such expert opinion when expert discovery did take place means the issue is conceded. But the fact that Plaintiff offers no expert testimony does not mean that it cannot cross-examine Defendant's experts. I do not have to accept expert testimony simply because there is no opposing expert testimony.

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 [rule or] the court's order.”

I think consideration of the *Pennypack* factors suggests that I should not exclude the evidence. I have no reason to doubt that the first Defendant heard of the inventorship arguments was on or after July 31, 2020. Nevertheless, I imagine Defendant can prepare effective cross-examinations of Dr. Tidmarsh and Mr. Golombik.⁴ I do not know what happened in Dr. Tidmarsh's deposition, but Mr. Golombik's certainly provides material to work with. I do not see any great prejudice, particularly since the date set for reduction of invalidity defenses is not until tomorrow. Defendant has asserted about two dozen invalidity defenses. (D.I. 190). If this ruling makes it difficult to use the '096 publication in an obviousness combination, Defendant still has lots of invalidity defenses to pick from. I do not think this ruling will disrupt the orderly and efficient trial of the case, which is still two weeks away. I cannot find bad faith or willfulness. I accept that Plaintiff simply realized late in the game that it had some argument against the '096 publication as prior art.

Thus, I DENY Defendant's motion in limine #2.

IT IS SO ORDERED this 1st day of September 2020.

/s/ Richard G. Andrews
United States District Judge

⁴ In my experience, defendants obtain all relevant documentation of the invention as a part of discovery.