IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

HOSPIRA, INC., Plaintiff, v. FRESENIUS KABI USA, LLC, Defendant.	Civil Action Nos. 1:16-cv-00651 1:17-cv-07903 Hon. Judge Rebecca R. Pallmeyer

MOTION TO EXCLUDE DR. ERIC SHEININ'S TESTIMONY

INTRODUCTION AND BACKGROUND

Plaintiff Hospira, Inc. ("Hospira") files this motion in limine to exclude certain designated deposition testimony of an expert witness, Dr. Eric Sheinin.

Defendant Fresenius Kabi ("Fresenius") listed Dr. Sheinin on their may-call witness list, and designated testimony from his deposition transcript last week. Fresenius has not disclosed Dr. Sheinin as a witness pursuant to the parties' advance-disclosure exchanges, so this motion may not be ripe. However, Hospira is filing this motion in the event that Fresenius attempt to play Dr. Shenin's deposition during trial.

Hospira designated Dr. Sheinin as a rebuttal expert and served an expert report. Dr. Sheinin is an expert on the regulatory process at the FDA. As such, he offered opinions on a single, narrow topic: Whether documents submitted to the FDA in connection with an Investigational New Drug ("IND") application established whether that drug was "ready for patenting" and not for "experimental use," for purposes of the so-called "on-sale bar" to patentability. At his deposition, Hospira's counsel stipulated on the record that he was not offering opinions on other topics, including enablement and obviousness.

Yet, despite those stipulations, counsel for Fresenius posed questions on enablement, obviousness based on inherency, and other issues beyond the scope of the witnesses' expertise. Hospira's counsel noted her objections on the record and allowed Dr. Sheinin to respond, as required by the Federal Rules. Dr. Sheinin attempted to provide answers to Fresenius' questions, despite the fact that they addressed matters wholly outside the scope of the opinions he was designated to provide. Hospira did not conduct a re-direct examination at the deposition; Hospira assumed that he could testify at trial and that Fresenius' cross-examination would be limited to matters addressed in his direct testimony.

After Dr. Sheinin's deposition, he experienced an unexpected medical issue that renders him unable to testify at trial. Fresenius now seeks to take advantage of Dr. Sheinin's unexpected unavailability by introducing into evidence Dr. Sheinin's testimony on issues outside the scope of his report as affirmative evidence in support of its case-in-chief.

The Court should exclude this testimony. Not only is this testimony unhelpful to the Court, but admitting it would violate the Federal Rules of Civil Procedure, which do not permit a party to obtain expert testimony by ambushing an opposing expert with questions on topics outside the scope of his report. Additionally, given that Dr. Sheinin gave extemporaneous answers on issues he had never studied, the testimony lacks basic indicia of reliability and is inadmissible under *Daubert*. The Court should also exercise its discretion to exclude the testimony under Rule 403, because it is not probative and would waste the Court's time—particularly given courts' consistent reluctance to admit un-cross-examined expert deposition testimony. The Court should instead decide the issues via the live testimony of experts who were and are designated to testify on topics in their expertise.

ARGUMENT

At Dr. Sheinin's deposition, Fresenius posed questions on enablement and obviousness—despite the express stipulations of Hospira's counsel that he was not offering opinions on those matters. The Court should exclude Dr. Sheinin's testimony on those topics.

I. Fresenius posed questions beyond the scope of Dr. Sheinin's expert report.

Hospira designated Dr. Sheinin as a rebuttal expert to provide opinions related to a single discrete issue: whether the patent is invalid because it is subject to the "on-sale bar" under 35 U.S.C. § 102. Fresenius takes the position that the patent-in-suit is invalid because it was "on sale" based on a license and supply agreement between Orion (which developed the dexmedetomidine compound at issue) and Abbott Laboratories in 1994. It argues that Orion's Investigational New Drug ("IND") application submitted to the FDA in 1989 confirms that the criteria for the on-sale bar are satisfied—that is, that the invention was "ready for patenting," and the use of the invention was not "experimental." *See Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 996-97 (Fed. Cir. 2007). Dr. Sheinin's opinions pertained solely to whether, from a regulatory perspective, the IND application established that the criteria for the on-sale bar are satisfied. He opined that the documents submitted to the FDA were "experimental in nature, and do not disclose a ready to use dexmedetomidine formulation that was ready for patenting." Ex. A, Sheinin Rep. ¶ 22.

Dr. Sheinin's opinions were tailored to his expertise. Dr. Sheinin's report explains that he is a "regulatory specialist and organic chemist with substantial experience in the regulatory process at the [FDA]." Ex. A, Sheinin Rep. ¶ 1. At his deposition, he testified he was offered as an expert on "certain aspects of regulatory issues." Ex. B, Sheinin Tr. 19:10-11. He elaborated that he would opine on "what an IND is, what the various phases of an IND are, what types of information are in an IND, who at FDA would be involved in reviewing an IND, what kind of

information they would be reviewing, similar expertise in as it would relate to a New Drug Application, how it's filed, what type of information, and so on, as well as just general FDA procedures for the review and approval of applications and the allowing, how FDA determines whether or not to allow an IND protocol to go forward and have a drug introduced into humans." *Id.* 19:13-23.

Consistent with this testimony, Hospira's counsel expressly stipulated on the record that Dr. Sheinin was *not* offering any opinions on obviousness or enablement:

> 5 MS. HORTON: I can stipulate that Dr. Sheinin does
> 6 not have an obviousness opinion, if that helps.
> …
>
> 12 MR. RIAZ: ... And with respect to
> 13 enablement, can you also stipulate that he doesn't have
> 14 any opinion?
>
> 15 MS. HORTON: He does not have any 112 opinions.

Ex. B, Tr. 26:5-15.

Yet, after receiving that stipulation, Fresenius' counsel then proceeded to pose questions on those very topics, over Hospira's objection. Fresenius has now designated Dr. Sheinin's deposition testimony on those topics.

Specifically, Fresenius has designated the following testimony:

> 17 Q. Sure. So a POSA looking at the data in the
> 18 '049 patent would understand that you could obtain no
> 19 more than 2 percent loss after five months if
> 20 dexmedetomidine is stored in what type of container
> 21 closure system?
>
> 22 MS. HORTON: Object to form. Beyond the scope.
>
> 23 A. I don't see that there is any data here that
> 24 would allow one to say it would be stable for five
> 1 months at 25 degrees, because there is no data for five
> 2 months.

3 Q. Is there data enough in the patent to come to
4 the conclusion that dexmedetomidine would not lose more
5 than 2 percent concentration after, at least, five
6 months?

7 MS. HORTON: Object to form. Asked and answered.
8 Beyond the scope of his opinions in this case.

9 A. I don't see data that would support that.

Ex. B, Tr. 82:17-83:9.[1] This testimony relates to Fresenius' enablement defense under 35 U.S.C. § 112. Fresenius contends that the claim limitation that dexmedetomidine would not lose more than 2 percent concentration after five months is not enabled based on the patentee's data. Dr. Sheinin, however, offered no opinions on enablement.

Fresenius has also designated the following testimony:

24 Q. -- that's the actual charting of the linearity
1 data, correct?

2 A. Correct.
…
10 Q. Okay. And here they actually test it as low
11 as 5 mcg/mL; do you see that? It's going to be
12 difficult.

13 A. I believe it was 5. They talk about it.
14 Actually, they said that concentrations were between
15 zero and 30 mcg/mL. So they do have a test point at
16 zero.

17 Q. Okay. And so this shows that, as low as 5
18 mcg/mL, that dexmedetomidine is stable for the duration

[1] By expressly objecting to these questions on the ground that they were beyond the scope, Hospira's counsel preserved Hospira's objection, even though the witness answered the question to the best of his ability. Fed. R. Civ. P. 30(c)(3) ("An objection at the time of the examination … must be noted on the record, but the examination still proceeds; the testimony is taken subject to any objection."). Indeed, it would have been for improper Hospira's counsel to instruct the witness not to answer the question. *See id.* (instruction not to answer permissible only "when necessary to preserve a privilege, to enforce a limitation ordered by the court, or to present a motion under Rule 30(d)(3)," none of which apply here).

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