

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

HOSPIRA, INC.

Plaintiff,

v.

FRESENIUS KABI USA, LLC,

Defendants.

C.A. No. 1:16-cv-00651

C.A. No. 1:17-cv-07903

Hon. Rebecca R. Pallmeyer

**FRESENIUS KABI'S OPPOSITION TO HOSPIRA'S MOTION TO EXCLUDE
DR. ERIC SHEININ'S DEPOSITION TESTIMONY AT TRIAL**

Defendant Fresenius Kabi USA, LLC files this reply in opposition to Hospira's tardy motion in limine to exclude deposition testimony of Hospira's own expert, Dr. Eric Sheinin. Hospira retained Dr. Sheinin as an FDA expert, to address the FDA's view on the ready-for-patenting test, but now hopes to avoid his deposition testimony on the issue and instead rely on other non-FDA experts at trial.

Fresenius Kabi made clear—in the witness lists exchanged before the pretrial order—that it would call Dr. Sheinin by deposition if he was not called live. (D.I. 53-7, 17-cv-07903.) Hospira did not file a motion in limine. Fresenius Kabi again raised the issue with the Court during the July 6, 2018 pretrial conference. (Transcript of Proceedings Before the Honorable Rebecca R. Pallmeyer, 42:19-44:22). Again, Hospira did not file any motion. Indeed, the Court indicated that it could “take this up at trial” without further motion practice. (*Id.* at 44:22). Nonetheless, Hospira waited until July 15, the day before trial, to file a motion, and that too a 15-page motion.

I. The Designated Testimony is Within the Scope of Dr. Sheinin's Expert Report

The questions and answers designated by Fresenius Kabi are well within the scope of Dr. Sheinin's expert report.

a) Questions Related To The Sufficiency of Stability Data In The Asserted Patents

Dr. Sheinin's expert report opines that the IND did not disclose an invention that was ready for patenting. Sheinin Rep. ¶ 22.¹ To do so, Dr. Sheinin specifically addressed stability data. In paragraph 30 of his report he states that in order to be ready for patenting the invention needs to be described in sufficient detail to allow a person of ordinary skill in the art (POSA) to practice the invention. *Id.* at ¶ 30. On page 26 of his report, Dr. Sheinin supports his position by arguing that the "stability data in IND 32, 934 does not indicate long-term stability." He then dedicates six paragraphs to explain that the stability data in the IND is not sufficient detail for the invention therein to be ready for patenting. *Id.* at ¶¶ 91-96.

Given Dr. Sheinin's opinion focused on stability data, Fresenius Kabi asked about related stability data and the amount of stability data sufficient for an invention to be ready for patenting. That was the scope of his expert opinion that Hospira offered, and now has chosen to withdraw. But Dr. Sheinin's previous opinion as to whether the stability data in the asserted patents is sufficient to support the claimed inventions opened the door to assessing the basis of his opinion, the stability data in the IND, and the methodology applied in coming to that opinion. Indeed, the very purpose of an expert deposition is to test the bounds of an expert's opinions through questions, and to explore conflict with other experts that the same party is offering.

¹The Rebuttal Report of Dr. Eric Sheinin, dated May 21, 2018 is attached as Exhibit A to Hospira's Motion in Limine. (D.I. 60, 17-cv-07903)

At deposition, Dr. Sheinin answered questions applying his own analysis about ready-for-patenting to the stability data in the IND to show that a POSA would find the data sufficient to demonstrate stability. Sheinin Tr. at 82:17-83:9.² Dr. Sheinin further testified that he believed he was a POSA and further testified that he reviewed the '106 patent and had relied on it in coming to his opinion. Thus, the now objected-to questions were appropriate and within the scope of the expert report.

b) Questions Related to Disclosures In The IND

The basis for Dr. Sheinin's opinion that the invention in the IND was not ready for patenting is based on an evaluation of the disclosures set forth in that document. As already discussed above, Dr. Sheinin opined that there is not enough information generally and stability data specifically for the invention in the IND to be ready for patenting. The questions that Hospira is now trying to exclude relate exactly to the very contents of that same IND. Sheinin Tr. at 107:22-109:6. For example, the objected-to questions asked about linearity data in the IND. *Id.* Per Dr. Sheinin's testimony that data provides information regarding the stability of the dexmedetomidine drug – undermining Dr. Sheinin's original view of how much data was enough to reach conclusions. Thus, there is no argument that the objected-to questions were appropriate and within the scope of the expert report.

c) Questions Related to The Review of Stability Data By Statisticians At the FDA

Dr. Sheinin's expert report provides extensive opinions regarding the review process that an IND may undergo at the FDA. In paragraph 72 of his report he provides a list of individuals at the FDA who may review an IND submission. In that list he specifically identified

² The Deposition Transcript of Eric Sheinin, dated June 15, 2018 is attached as Exhibit B to Hospira's Motion in Limine. (D.I. 61, 17-cv-07903)

“Statistician.” He also provided information regarding the role of a Statistician in the IND review process including stating that they “[m]ay also evaluate stability data provided in the submission.” The objected-to questions merely inquires further into the role of a statistician, including the type of data that a statistician would review. Sheinin Tr. at 73:22-75:12. Such questions are entirely appropriate. Just because those opinions contradict opinions of Hospira’s other trial witnesses is not a basis to exclude.

II. The Law permits Fresenius Kabi to Use Dr. Sheinin’s Deposition At Trial

Dr. Sheinin’s deposition testimony is admissible both because (a) it is a deposition of an unavailable witness and (b) the testimony is a party admission.

a) Fresenius Kabi Is Entitled To Use Dr. Sheinin’s Deposition Pursuant to the Federal Rules of Evidence

Pursuant to FRCP 32(4) “A party may use for any purpose the deposition of a witness, whether or not a party, if the court finds ... (c) that the witness cannot attend or testify because of age, illness, infirmity or imprisonment.” Such is the case here. Since the pretrial conference, the parties have learned that Dr. Sheinin is unavailable, and is no longer able to testify at trial even if Hospira intended to call him live. Therefore, Fresenius Kabi has the right to use Dr. Sheinin’s deposition testimony as part of its case in chief.

Further, the Northern District of Illinois has held that the deposition testimony of an opposing expert sought to be introduced at trial is considered a party admission, and therefore would not constitute hearsay. *Bone Care Int’l, LLC v. Pentech Pharms., Inc.*, Case No. 08-cv-1083, 2010 U.S. Dist. LEXIS 10489 at *34-*35 (N.D. Ill. 2010); *see also Glendale Fed. Bank, FSB v. U.S.*, 39 Fed. Cl. 422, 425 (1997) (holding that prior deposition testimony of an expert witness put forward as a testifying expert at trial is an admission against the party that retained the expert.)

b) The Seventh Circuit Law Permits the Use of An Opposing Expert's Deposition Testimony At Trial

In *S.E.C. v. Koenig*, the defendant argued that the district court committed error when it allowed the S.E.C. to use defendant's expert video deposition as part of its case in chief even though the expert was not listed in the S.E.C.'s list of potential witnesses. 557 F.3d 736, 743 (7th Cir. 2009). The 7th Circuit determined that no error was made and held "[a] witness identified as a testimonial expert is available to either side; such a person can't be transformed after the report has been disclosed, and a deposition conducted, to the status of a trial-preparation expert whose identity and views may be concealed." *Id.* at 744. In this case, not only has Dr. Sheinin been proffered as an expert witness on behalf of Hospira, submitted an expert report and been deposed, but he was also listed on Fresenius Kabi's pretrial witness list. There is simply no basis to exclude his deposition testimony.

The Northern District has similarly determined that a party cannot exclude prior expert testimony that it has proffered but later determined "was more harmful than helpful" because expert's prior testimony "was an admission of a party opponent under Federal Rule of Evidence 801(d)(2)(c)." *Pentech*, 2010 U.S. Dist. LEXIS 10489 at *35, citing *In re Hanford Nuclear Reservation Litig.*, 534 F.3d 986, 1016 (9th Cir. 2008). That is the situation here: Hospira cannot withdraw Dr. Sheinin's opinions simply because it no longer likes them.

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