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SECTION VI-B-1



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

HOSPIRA, INC.,

v.

Plaintiff,

Civil Action Nos. 1:16-cv-00651

1:17-cv-07903

FRESENIUS KABI USA, LLC, Hon. Judge Rebecca R. Pallmeyer

Defendant.

HOSPIRA'S RESPONSE TO FRESENIUS KABI'S MOTIONS IN LIMINE



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I. INTRODUCTION

The Court should deny Fresenius Kabi's motions *in limine* for many reasons, not the least of which is that Fresenius Kabi fails to spell out the specific relief that it seeks as to any of the four categories of evidence that it challenges. Just as importantly, Fresenius Kabi is wrong about the import of the evidence that Hospira proposes to offer at trial and is equally mistaken about the proper legal standard against which Hospira's evidence should be measured in this bench trial, where the Court is free to rely on expert testimony and other evidence as it chooses within the exercise of its sound discretion.

In the following pages, Hospira shows:

- The proposed testimony of James White, an admitted expert on the Uniform Commercial Code, will not usurp the Court's role in interpreting law, but rather constitutes appropriate (indeed routine) rebuttal of Fresenius Kabi's own expert witness, Peter Lankau, who fails to account for the requirements of the UCC in his own opinion testimony. Moreover, Fresenius Kabi can show no prejudice that could result from Professor White's testimony in this bench trial.
- The proposed testimony of Dr. Stephan Ogenstad, who Fresenius Kabi concedes is a qualified biostatistician, is directed to measuring the variability of stability data relied on by James Kipp, Fresenius Kabi's expert, where it is also conceded that the data is variable and the issue is whether it is so variable that it cannot be relied upon to prove that the 2% stability limitation is inherent to dexmedetomidine formulations. Dr. Ogenstad's testimony is highly probative on this disputed question, will result in no unfair prejudice to Fresenius Kabi, and should be received by the Court.
- The evidence relating to FDA approval is misconceived by Fresenius Kabi. It is germane to the question of whether the invention was on sale, a question that the Court will be called on to resolve as part of the trial. Relatedly, experimental use is a well-established exception to the on-sale bar and there is no basis in patent or trial law for excluding evidence relevant to that issue, particularly, where Fresenius Kabi again has not shown there will be prejudice in this bench trial.
- Finally, the question of "long felt need" is most because Hospira has no plan to offer evidence of "long felt need" in its case-in-chief.



II. LEGAL STANDARD

"[W]here the factfinder and the gatekeeper are the same, the court does not err in admitting the evidence subject to the ability later to exclude it or disregard it if it turns out not to meet the standard of reliability established by Rule 702." *In re Salem*, 465 F.3d 767, 777 (7th Cir. 2006). Exclusion is appropriate where the proffered evidence is "clearly inadmissible on all potential grounds." *Hawthorne Partners v. AT&T Techs.*, 831 F. Supp. 1398, 1400 (N.D. Ill. 1993). Expert testimony may be excluded if it is unreliable or will not assist the trier of fact. *Se-Kure Controls, Inc. v. Vanguard Prods. Grp.*, 2008 WL 169054, at *3 (N.D. Ill. Jan. 17, 2008). When admissibility is unclear, evidentiary rulings should be "deferred until trial so questions of foundation, relevancy, and prejudice can be resolved in their proper context." *Marlow v. Winston & Strawn*, No. 90 C 5715, 1994 WL 424124, at *3 (N.D. Ill. Aug. 11, 1994).

III. ARGUMENT

A. The Court Should Not Exclude Professor White's Testimony

Fresenius Kabi does not dispute that Professor James White is an expert in the Uniform Commercial Code ("UCC"). Yet Fresenius Kabi argues that Professor White's testimony should be excluded, citing cases that merely state the general proposition that an expert must be qualified in the field in which he is providing expert opinions are sought. Unlike in those cases, Professor White will opine on subject matter squarely within his expertise: application of the UCC to Fresenius Kabi's on-sale bar theories. ¹

¹ There is no *per se* rule against allowing expert testimony on the law. Courts in this district regularly allow legal expert testimony. *See e.g.*, *The Medicines Co. v. Mylan Inc.*, No. 11-CV-1285, 2014 WL 1758135, at *3 (N.D. Ill. May 2, 2014) ("Dr. Linck is qualified by her experience and expertise to testify as a patent law expert regarding the application and issuance of the '727 patent relating to Mylan's inequitable conduct claims"); *Se-Kure Controls, Inc. v. Vanguard Prod. Grp., Inc.*, No. 02 C 3767, 2008 WL 169054, at *3 (N.D. Ill. Jan. 17, 2008) ("Mr. Gerstman is permitted to testify about general procedures involved in the patent application process and the operations and functions of the PTO. This type of testimony can be



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