# SECTION VI-A-1

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

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| HOSPIRA, INC.<br><br>Plaintiff,<br><br>v.<br><br>FRESENIUS KABI USA, LLC,<br><br>Defendant. | C.A. No. 1:16-cv-00651<br>C.A. No. 1:17-cv-07903<br>(Consolidated)<br><br>Hon. Rebecca R. Pallmeyer<br><br>CONTAINS CONFIDENTIAL INFORMATION |

**FRESENIUS KABI'S MEMORANDUM IN SUPPORT OF ITS**
**MOTIONS *IN LIMINE***

Fresenius Kabi USA, LLC moves *in limine* to exclude or limit the following expert testimony and evidence by Hospira, Inc.:

(A) Hospira's expert, law professor James White, who intends to provide his legal interpretation of contract provisions under the U.C.C.—a legal issue for the Court not suitable for witness testimony (page 3);

(B) Hospira's expert Dr. Stephan Ogenstad, a statistician, who is not a person of ordinary skill in the art that makes formulations, and instead relies on unreliable and unverified statistics (page 7);

(C) evidence erroneously applying the higher threshold for FDA approval to show whether prior art was "on sale," and applying a nonexistent experimental use exception to show whether prior art was "ready for patenting" (page 10); and

(D) testimony regarding the secondary consideration of "long-felt need," as the evidence proffered by Hospira contradicts this Court's claim construction and was not provided in Hospira's discovery responses (page 12).

These issues are inadmissible under Rules 402, 403, 702, and *Daubert*. Resolving these issues will help to streamline the trial by removing irrelevant and time-wasting evidence and testimony.

## I. Background

This section lists background pertinent to the four issues raised in this motion.

One issue at trial will be whether the subject of the patents in this case was already part of a prior commercial sale, which would invalidate the invention. Hospira's patents-in-suit[1] generally relate to putting the drug dexmedetomidine in glass. But while Hospira did not file for its patents until 2012, others had already used the same drug and put it in the same container in 1989. Back then, Farmos Group Ltd. filed Investigational New Drug Application No. 32,934 ("the Dexmedetomidine IND"). (*See* Ex. A, HOSPIRA_00308480–00308778.) That Dexmedetomidine IND was sold to Abbott Laboratories in 1994. (Ex. B, HOSPIRA_02501571–

[1] U.S. Patent Nos. 8,648,106 ("the '106 patent"); 8,455,527 ("the '527 patent"); 9,320,712 ("the '712 patent"); and 9,616,049 ("the '049 patent") (collectively, "the Patents-in-Suit").

02501705.) Abbott sold that same IND in 2004 to Hospira. (Ex. C, HOSPIRA_02501093–02501570.) As discussed further below, Hospira disputes whether these two transactions count as "prior sales" and, as part of that challenge, offers the testimony of a law professor—James White—to give his interpretation of the Uniform Commercial Code ("U.C.C."). (*See* Ex. D, White ¶¶ 13-15.)

Hospira also provides testimony from other experts, including Dr. Eric Sheinin, that an invention is "ready for patenting" as part of the on-sale bar only when the FDA standard for approval to commercialize a drug product is met. As discussed below, it is legally erroneous to confuse FDA standards with prior art requirements.

For the '106 patent, the claims require a certain stability result ("no more than about 2% decrease" at five months). The evidence at trial will show that this result is an inherent property, because all tests of dexmedetomidine in glass—the claimed invention—showed less than about 2% decrease at five months. This was shown by analyzing and graphing the raw data, and by drawing a "regression" line or "best fit line" for the raw data points. Yet in response, Hospira's expert Dr. Stephan Ogenstad will apparently argue that he created "simulated" data and new "confidence interval" analyses—not actual data—that he will use to say the 2% claim limitation is not met. (*See* Ex. E, Ogenstad ¶¶ 39, 54-55, 58-59, 64, 73-75, 79-83.) Both sides' experts ***agree*** that no person of ordinary skill in the art would use these techniques, so the evidence should be excluded. In any event, there is no precedent for the methodology, which uses a random number generator, and it should not be allowed in this case.

In response to Fresenius Kabi's evidence of obviousness, Hospira asserts that there was a long-felt but unmet need in the industry for a product described by the Patents-in-Suit. Long-felt need is a secondary consideration, but Hospira's only purported evidence for it involves

pharmaceutical compounding facilities and how they could have made dexmedetomidine formulations. This is an argument offered by Hospira's economics expert, Mr. Andrew Carter, and its medical expert, Dr. Michael Ramsay. But Hospira's own technical experts concede that compounding facilities could not make "ready-to-use" dexmedetomidine formulations as that term has been construed by the Court. As a result, the compounding facility argument is irrelevant. Moreover, Hospira failed to identify the compounding facility argument in response to discovery requests, so should not be allowed to present it now at trial.

## II. Legal Standard

"Motions in limine are well-established devices that streamline trials and settle evidentiary disputes in advance, so that trials are not interrupted mid-course for the consideration of lengthy and complex evidentiary issues." *U.S. v. Tokash*, 282 F.3d 962, 968 (7th Cir. 2002). District court judges have "broad discretion" in ruling on motions *in limine*. *Jenkins v. Chrysler Motors Corp.*, 316 F.3d 663, 664 (7th Cir. 2002). Ruling on motions *in limine* to "ensure the trial proceeds efficiently and economically without unnecessarily consuming judicial resources or the resources of the parties" is a "proper use of a motion *in limine* even in a bench trial." *Sellers Capital, LLC v. Wight*, No. 15-C-7644, 2017 WL 3037802, *1 n.1 (N.D. Ill. July 18, 2017).

## III. Argument

### A. The Court Should Exclude Professor White's Testimony.

The Court should exclude Hospira's law professor James White because he opines only about purely legal issues (contract interpretation), and does so without any industry knowledge to lend to his interpretation. That is irrelevant and unhelpful to the Court. Professor White teaches contracts at the University of Michigan Law School, but he admitted that he does not have any personal experience or expertise relating to the pharmaceutical industry or the types of

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