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

HOSPIRA, INC.,	)	
	)	
Plaintiff,	)	Docket Nos. 16 C 651
	)	17 C 7903
vs.	)	
	)	
FRESENIUS KABI USA, LLC,	)	Chicago, Illinois
	)	July 18, 2018
Defendant.	)	10:10 a.m.

VOLUME 3A
TRANSCRIPT OF PROCEEDINGS - Bench Trial
BEFORE THE HONORABLE REBECCA R. PALLMEYER

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THE COURT: All right. We are prepared, I think, to hear continued cross-examination.

MS. HORTON: Yes, your Honor.

THE COURT: I want to remind you, sir, that you are under oath.

You may proceed, counsel.

JAMES KIPP, DEFENDANT'S WITNESS, PREVIOUSLY SWORN

CROSS-EXAMINATION - Resumed

BY MS. HORTON:

Q. Good morning, Dr. Kipp.

A. Good morning.

Q. I just have a few more things to ask you about.

You mentioned *Remington's* in your testimony yesterday; is that right?

A. Yes.

Q. What is *Remington's*?

A. It's a general guidance book that formulators would consult, basically a bible that any formulator would consult.

Q. Okay. Let's look at JTX20.1, please.

This is *Remington's*?

It's also in the binder in front of you, if you would like to look at the --

A. I can see it on the screen.

Q. Okay. So yes, this is *Remington's*?

A. Yes.

Q. Okay. If we could look at Page JTX20.5, please, there is a heading entitled "Product Stability."

Do you see that?

A. Yes.

Q. And that says, "Many factors affect the stability of a pharmaceutical product and include the stability of the active ingredients; the potential interaction between active and inactive ingredients; the manufacturing process; the dosage form; the container, liner, closure system; and the environmental conditions encountered during shipment, storage, and handling; and the length of time between manufacture and usage."

Is that right?

A. Yes.

Q. Do you agree with that as a general statement?

A. Yes, I do.

Q. Okay. Let's talk a little bit more about this, as it says, container system.

We talked yesterday about sealed glass vials.

A. Yes.

Q. And those have to have stoppers to make sure it's closed?

A. Yes.

Q. Okay. And the drug could have some interaction or some sorption issues with a stopper, right?

A. It could, yes.
Q. Okay. And one of the ways to deal with that would be to use a coated stopper?
A. Yes.
Q. And there are many coated stoppers that you could use on the market?
A. It's not unlimited. There are a few select stoppers that could be used, yes. They have to be approved and, obviously, acceptable in pharmaceutical products, especially in injectables.
Q. Are there more than ten on the market?
A. I don't know the exact number.
Q. Okay. So there is something -- because of this potential sorption issue, that's why the FDA requires testing in both the upright and inverted configuration; is that right?
A. Yes.
Q. And what's the reason for the inverted testing, I guess?
A. Well, you want to look at the worst case. The FDA always wants you to look at the worst possible case. So the stopper material would be in constant contact with the fluid inside the bottle.
Q. Okay. And that could be something that happens, for example, in shipping or handling or something?
A. Yes.

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