EXHIBIT 4

RAO TATA-VENKATA

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

HOSPIRA, INC.,

Plaintiff,

vs.

FRESENIUS KABI USA, LLC.,

Defendant.

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

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HOSPIRA, INC.,

Plaintiff/Counterclaim Defendant.

vs.

AMNEAL PHARMACEUTICALS, LLC

Defendant/Counterclaim Plaintiff.

C.A. No. 15-cv-697-RGA

VIDEOTAPED DEPOSITION OF RAO TATA-VENKATA
Wednesday, November 9, 2016
Chicago, Illinois

Reported By:
TRICIA J. FLASKA, CSR, RPR
JOB NO. 115353

48 hours, correct?
A Yes.
Q Okay. So it's not 24 hours?
A Yes.
Q Okay. And there's -- and it refers to data on file.
Do you see that?
A Yes.
Q And so that's referring to an internal Hospira study?
A Yes.
Q Okay. And that's a study that would have been performed within the R&D group?
A Yes.
Q Okay. And so it's actually 48 hours that this is available -- that this is stable, correct?
A That is correct.
Q Okay. Now, you also said that it would -- would have been unexpected for a formulation of dexmedetomidine to be stable in a glass container at a -- what you called a low concentration, correct?
A Yes.
Q Okay. Now, the range in the Wu Declaration and in the patent we saw was up to 50 micrograms per

milliliter.
Do you remember that?
A Yes. Yes.
Q Okay. So would you consider anything less than 50 micrograms per milliliter a low concentration?
A The term "low concentration" is very broad unless it's actually defined. What do you mean by that? Tell me.
Q Well, you said there was an expectation of -- of -- that it wouldn't be stable in a glass container at a low concentration.
A Right.
Q And the claims of the patent go up to 50 micrograms per milliliter.
So my question is: Is that 50 micrograms per milliliter included in your expectation for a lack of stability?
A The data was generated across a range from one microgram per mil to 50 microgram per mil. So --
Q Right.
A -- if -- if your question is what expectations did we have -- did we have about the

outcome?
Q Yeah.
A That was the purpose of the experiment.
Q You didn't have an expectation --
A Yes.
Q -- ahead of time?
A Yes.
Q Okay. But you previously said that you would have expected that, for a low concentration product in a glass vial, it would not show stability because of the low concentration, correct?
MR. RAY: Objection. Mischaracterizes testimony.
BY MR. WALLACE:
Q Is that not your testimony?
A No.
Q Maybe I got it wrong.
A No, the 100 microgram per mil is a concentration that we -- we had whatever data we had as far as stability is concerned.
Q Okay.
A When we go to low concentrations, things -- phenomena can occur at low concentrations that will not -- can occur at low concentrations that do not

occur at high concentrations.
Q Okay.
A And that would have to be only determined and confirmed with studies.
Q Okay. And were you aware of any studies involving concentrations of dexmedetomidine at a concentration of less than 100 micrograms per milliliter in a glass container before you began your work -- or before Hospira began its work --
A No.
Q -- on dexmedetomidine?
A No.
Q Okay. Okay. I'll give you the next document.
(Exhibit 17 marked for identification.)
BY MR. WALLACE:
Q I'm giving you what's been marked as Defendant's Exhibit -- or Exhibit 17 --
A Okay.
Q -- documents bearing the Bates number Hospira00308480 through 308778.
A Yes.
Q And I can tell you this is only the first 300 pages of this document because it actually is a

2,000-page document, but I --
A Okay.
Q -- we chopped it down for -- for ease of carrying it around.
Have you ever seen this document before?
A Yes. I -- as you said, it's a very large document. I scrolled through it very quickly.
Q Okay. And this is the Investigational New Drug Application for Dexmedetomidine, correct?
A Yes.
Q And the name of the drug is identified in box 5 on the front page, correct?
A Yes.
Q Okay. And so an investigational new drug application is the application even before any clinical studies can be run, correct?
A Yes. Yes.
Q Okay. And this is -- this was data that was available to -- to -- that was used by Abbott in order -- in order to develop its clinical program, correct?
A Yes.
Q Okay. And this is data that would have -- that was in -- that was available to Hospira's

regulatory group in order to maintain the new drug application and the regulatory file for dexmedetomidine, correct?
A That would be available with the Regulatory Affairs, yes.
Q Okay. Available with the Regulatory Affairs within Hospira, correct?
A Right.
Q Okay. I want to jump ahead -- I'm sorry -- first we'll look at the Table of Contents, and you can see the Table Of Contents extends on for several pages and describes both -- well, protocols, chemistry, manufacturing, pharmacology, toxicology and many other studies.
Do you see that?
A Yes.
Q Okay. And included with -- within those, if you look on page 2 of the Table of Contents, which is -- ends in Bates number 8483 under section 7, you see chemistry, manufacturing and control data?
A Yes.
Q Okay. And you see that the second to last entry here is stability?

A Yes.
Q Okay. So this is stability data that was generated on these products --
A Yes.
Q -- correct? Okay.
So let's turn to that stability data. It's internal page three hundred and about -- well, it's about 278, but I'll tell you the Bates number at the bottom ends in 8761. It's most of the way to the back.
A Yes.
Q You see there's a cover sheet, "Stability data" -- you know what, I'm sorry. I jumped too far ahead.
It's actually, we're going to start on page -- the number ends in 751. And it says, "Stability data from batch NI027L1 is enclosed."
Do you see that?
A Yes.
Q Okay. And so we turn to the next page, page Bates number 8752 of Exhibit 17 --
A Yes.
Q -- and we see an identification of the same batch number, NI027L1.

Do you see that?
A Yes.
Q And the strength is 20 micrograms per milliliter.
Do you see that?
A Yes.
Q This is a product manufactured in September of 1987?
A Yes.
Q Okay. And I want you to look down at the entry three package. It's packaged in a clear, colorless, glass ampoule.
Do you see that?
A Yes.
Q And as you described earlier, an ampoule is a glass container that's sealed on itself, correct?
A Yes.
Q So it's a completely sealed glass container, right?
A Yes.
Q Okay. And we see, in part 2 here, the conditions of storage.
Do you see that?
A Yes.

Q And it was stored for up to 12 months at 25C?
A Yes.
Q And that's considered a room temperature storage condition?
A Yes.
Q And that's the same type of storage conditions that were used in the -- the Wu Declaration, correct?
A Yes.
Q And it's the same storage conditions that were used for the submission of the Precedex premix to the FDA?
A Along with other conditions, but this is one of the conditions.
Q Yes. Okay. And it says, "The results are presented in table 1."
Do you see that?
A Uh-huh.
Q And so if we turn to Bates number 8756, we find table 1.
You see that, Doctor?
A Yes.
Q Okay. And we see that at the initial time

point, the assay here is 98 percent.
Do you see that?
A Yes.
Q And do you understand that the assay refers to the amount of dexmedetomidine as compared to the claimed concentration of 20 micrograms per milliliter?
A Yes.
Q Okay. And then we see that, after two months of being stored at 25C, the result is 97 percent of assay, correct?
A Yes.
Q So it has lost no more than one percent of concentration, correct?
A Yes.
Q Okay. And then the next entry is three months of 25C and the assay is, again, 97 percent, correct?
A Yes.
Q So, again, it has lost no more than one percent from the initial assay, correct?
A Yes.
Q Okay. If we turn to the third entry, we have six months data.

Do you see that?
A Yes.
Q Stored at 25C?
A Yes.
Q And here the assay is 98 percent again, correct?
A Uh-huh.
Q So it's identical to the initial assay of -- for this sample, correct?
A Yes.
Q Okay. And then if we turn -- if we go to the next line, we have nine month data for the same sample, correct?
A Yes.
Q And we see the assay is a hundred percent?
A Yes.
Q So it's still -- it has not lost potency at this point, correct?
A Yes.
Q And then we see 12 month data here.
Do you see that, the line for 12 months?
A Yes.
Q And we're back, again, at 97 percent assay.
You see that?

A Yes.
Q So it has lost no more than one percent from the -- from when it was initially placed on stability, correct?
A Yes.
Q Now, to be clear, a 20 microgram per milliliter concentration of dexmedetomidine falls within the range that is claimed in the patents that we looked at before, correct?
A Yes.
Q So there was data that would provide an expectation for stability of dexmedetomidine in a sealed glass container at a concentration of less than 100 micrograms per milliliter, correct?
A According to this data that's here, yes.
Q Okay. And this is an IND, correct?
A Yes.
Q So an IND is data that is provided to the FDA?
A Yes.
Q So it is accurate data, presumption is that it's accurate data?
A The date is accurate.
Q Okay. If we turn, now, to the page ending

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