Case: 1:16-cv-00651 Document #: 81-4 Filed: 01/16/18 Page 1 of 6 PageID #:2477

EXHIBIT 4

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Case: 1:16-cv-00651 Document #: 81-4 Filed: 01/16/18 Page 2 of 6 PageID #:2478

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	Page 1
1	RAO TATA-VENKATA
2	IN THE UNITED STATES DISTRICT COURT
	FOR THE NORTHERN DISTRICT OF ILLINOIS
3	EASTERN DIVISION
4	HOSPIRA, INC.,)
)
5	Plaintiff,)C.A. No.
6)1:16-cv-00651
6	vs.)
7	
,	FRESENIUS KABI USA, LLC.,)
8	
)
9	Defendant.)
)
10	IN THE UNITED STATES DISTRICT COURT
	FOR THE DISTRICT OF DELAWARE
11	HOSPIRA, INC.,)
12) Plaintiff/Counterclaim)C.A. No.
	Defendant.)15-cv-697-RGA
13	vs.)
)
14	AMNEAL PHARMACEUTICALS, LLC)
)
15	Defendant/Counterclaim)
1.5	Plaintiff.)
16 17)
17 18	
19	VIDEOTAPED DEPOSITION OF RAO TATA-VENKATA
20	Wednesday, November 9, 2016 Chicago, Illinois
21	
22	Reported By:
23	TRICIA J. FLASKA, CSR, RPR
24	JOB NO. 115353
25	

	Page 270		Page 271
1	RAO TATA-VENKATA	1	RAO TATA-VENKATA
2	48 hours, correct?	2	milliliter.
3	A Yes.	3	Do you remember that?
4	Q Okay. So it's not 24 hours?	4	A Yes. Yes.
5	A Yes.	5	Q Okay. So would you consider anything less
6	Q Okay. And there's and it refers to data	6	than 50 micrograms per milliliter a low
7	on file.	7	concentration?
8	Do you see that?	8	A The term "low concentration" is very broad
9	A Yes.	9	unless it's actually defined. What do you mean by
10	Q And so that's referring to an internal	10	that? Tell me.
11	Hospira study?	11	Q Well, you said there was an expectation of
12	A Yes.	12	of that it wouldn't be stable in a glass
13	Q Okay. And that's a study that would have	13	container at a low concentration.
14	been performed within the R&D group?	14	A Right.
15	A Yes.	15	Q And the claims of the patent go up to 50
16	Q Okay. And so it's actually 48 hours that	16	micrograms per milliliter.
17	this is available that this is stable, correct?	17	So my question is: Is that 50 micrograms
18	A That is correct.	18	per milliliter included in your expectation for a
19	Q Okay. Now, you also said that it would	19	lack of stability?
20	would have been unexpected for a formulation of	20	A The data was generated across a range from
21	dexmedetomidine to be stable in a glass container at	21	one microgram per mil to 50 microgram per mil.
22	a what you called a low concentration, correct?	22	So
23	A Yes.	23	Q Right.
24 25	Q Okay. Now, the range in the Wu Declaration	24 25	A if if your question is what
23	and in the patent we saw was up to 50 micrograms per	23	expectations did we have did we have about the
	Page 272		
	rage z/z		Page 273
1		1	
1 2	RAO TATA-VENKATA outcome?	1 2	RAO TATA-VENKATA
	RAO TATA-VENKATA		
2	RAO TATA-VENKATA outcome? Q Yeah. A That was the purpose of the experiment.	2	RAO TATA-VENKATA occur at high concentrations.
2 3	RAO TATA-VENKATA outcome? Q Yeah.	2 3	RAO TATA-VENKATA occur at high concentrations. Q Okay.
2 3 4 5 6	RAO TATA-VENKATA outcome? Q Yeah. A That was the purpose of the experiment. Q You didn't have an expectation A Yes.	2 3 4 5 6	RAO TATA-VENKATA 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
2 3 4 5 6 7	RAO TATA-VENKATA outcome? Q Yeah. A That was the purpose of the experiment. Q You didn't have an expectation A Yes. Q ahead of time?	2 3 4 5 6 7	RAO TATA-VENKATA 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
2 3 4 5 6 7 8	RAO TATA-VENKATA 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.	2 3 4 5 6 7 8	RAO TATA-VENKATA 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
2 3 5 6 7 8 9	RAO TATA-VENKATA 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	2 3 4 5 6 7 8 9	RAO TATA-VENKATA 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
2 3 5 6 7 8 9 10	RAO TATA-VENKATA 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	2 3 4 5 6 7 8 9 10	RAO TATA-VENKATA 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
2 3 4 5 6 7 8 9 10 11	RAO TATA-VENKATA 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	2 3 4 5 6 7 8 9 10 11	RAO TATA-VENKATA 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.
2 3 4 5 6 7 8 9 10 11 12	RAO TATA-VENKATA 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?	2 3 4 5 6 7 8 9 10 11 12	RAO TATA-VENKATA 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?
2 3 4 5 6 7 8 9 10 11 12 13	RAO TATA-VENKATA 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	2 3 4 5 6 7 8 9 10 11 12 12	RAO TATA-VENKATA 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.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	RAO TATA-VENKATA 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.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	RAO TATA-VENKATA 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:
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	RAO TATA-VENKATA 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	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	RAO TATA-VENKATA 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.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	RAO TATA-VENKATA 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.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	RAO TATA-VENKATA 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
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	RAO TATA-VENKATA 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.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 RAO TATA-VENKATA 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.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	RAO TATA-VENKATA 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.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	RAO TATA-VENKATA 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.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	RAO TATA-VENKATA 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	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	 RAO TATA-VENKATA 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.

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Case: 1:16-cv-00651 Document #: 81-4 Filed: 01/16/18 Page 4 of 6 PageID #:2480

	Page 274		Page 275
1	RAO TATA-VENKATA	1	RAO TATA-VENKATA
2	2,000-page document, but I	2	regulatory group in order to maintain the new drug
3	A Okay.	3	application and the regulatory file for
4	Q we chopped it down for for ease of	4	dexmedetomidine, correct?
5	carrying it around.	5	A That would be available with the Regulatory
6	Have you ever seen this document before?	6	Affairs, yes.
7	A Yes. I as you said, it's a very large	7	Q Okay. Available with the Regulatory
8	document. I scrolled through it very quickly.	8	Affairs within Hospira, correct?
9	Q Okay. And this is the Investigational New	9	A Right.
10	Drug Application for Dexmedetomidine, correct?	10	Q Okay. I want to jump ahead I'm sorry
11	A Yes.	11	first we'll look at the Table of Contents, and you
12	Q And the name of the drug is identified in	12	can see the Table Of Contents extends on for several
13	box 5 on the front page, correct?	13	pages and describes both well, protocols,
14	A Yes.	14	chemistry, manufacturing, pharmacology, toxicology
15	Q Okay. And so an investigational new drug	15	and many other studies.
16	application is the application even before any	16	Do you see that?
17	clinical studies can be run, correct?	17	A Yes.
18	A Yes. Yes.	18	Q Okay. And included with within those,
19	Q Okay. And this is this was data that	19	if you look on page 2 of the Table of Contents,
20	was available to to that was used by Abbott in	20	which is ends in Bates number 8483 under section
21	order in order to develop its clinical program,	21	7, you see chemistry, manufacturing and control
22	correct?	22	data?
23	A Yes.	23	A Yes.
24	Q Okay. And this is data that would have	24	Q Okay. And you see that the second to last
25	that was in that was available to Hospira's	25	entry here is stability?
	Page 276		Page 277
1	RAO TATA-VENKATA	1	RAO TATA-VENKATA
2	A Yes.	2	Do you see that?
3 4	Q Okay. So this is stability data that was	3	A Yes.
4 5	generated on these products	5	Q And the strength is 20 micrograms per
6	A Yes.	6	milliliter.
7	Q correct? Okay.	7	Do you see that?
	So let's turn to that stability data. It's		A Yes.
8	internal page three hundred and about well, it's	9	Q This is a product manufactured in September
10	about 278, but I'll tell you the Bates number at the	10	of 1987? A Yes.
10	bottom ends in 8761. It's most of the way to the back.	11	
12	A Yes.	12	Q Okay. And I want you to look down at the entry three package. It's packaged in a clear,
13	Q You see there's a cover sheet, "Stability	13	colorless, glass ampoule.
14	data" you know what, I'm sorry. I jumped too far	14	Do you see that?
15	ahead.	15	A Yes.
16	It's actually, we're going to start on page	16	Q And as you described earlier, an ampoule is
17	the number ends in 751. And it says, "Stability	17	a glass container that's sealed on itself, correct?
18	data from batch NI027L1 is enclosed."	18	A Yes.
19	Do you see that?	19	Q So it's a completely sealed glass
20	A Yes.	20	container, right?
21	Q Okay. And so we turn to the next page,	21	A Yes.
22	page Bates number 8752 of Exhibit 17	22	Q Okay. And we see, in part 2 here, the
23	A Yes.	23	conditions of storage.
24	Q and we see an identification of the same	24	Do you see that?
25	batch number, NI027L1.	25	A Yes.

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Case: 1:16-cv-00651 Document #: 81-4 Filed: 01/16/18 Page 5 of 6 PageID #:2481

	Page 278		Page 27
1	RAO TATA-VENKATA	1	RAO TATA-VENKATA
2	Q And it was stored for up to 12 months at	2	point, the assay here is 98 percent.
3	25C?	3	Do you see that?
4	A Yes.	4	A Yes.
5	Q And that's considered a room temperature	5	Q And do you understand that the assay refers
6	storage condition?	6	to the amount of dexmedetomidine as compared to
7	A Yes.	7	claimed concentration of 20 micrograms per
8	Q And that's the same type of storage	8	milliliter?
9	conditions that were used in the the Wu	9	A Yes.
10	Declaration, correct?	10	Q Okay. And then we see that, after two
11	A Yes.	11	months of being stored at 25C, the result is 97
12	Q And it's the same storage conditions that	12	percent of assay, correct?
13	were used for the submission of the Precedex premix	13	A Yes.
14	to the FDA?	14	Q So it has lost no more than one percent of
15	A Along with other conditions, but this is	15	concentration, correct?
16	one of the conditions.	16	A Yes.
17	Q Yes. Okay. And it says, "The results are	17	Q Okay. And then the next entry is three
18	presented in table 1."	18	months of 25C and the assay is, again, 97 percent,
19	•	19	correct?
20	Do you see that? A Uh-huh.	20	
21		21	A Yes.
22	Q And so if we turn to Bates number 8756, we	22	Q So, again, it has lost no more than one
23	find table 1.	23	percent from the initial assay, correct?
	You see that, Doctor?	23	A Yes.
24 25	A Yes.		Q Okay. If we turn to the third entry, we
23	Q Okay. And we see that at the initial time	25	have six months data.
	Page 280		Page 2
1		1	
1 2	RAO TATA-VENKATA		RAO TATA-VENKATA
2	RAO TATA-VENKATA Do you see that?	2	RAO TATA-VENKATA A Yes.
	RAO TATA-VENKATA Do you see that? A Yes.	2 3	RAO TATA-VENKATA A Yes. Q So it has lost no more than one percent
2 3	RAO TATA-VENKATA Do you see that? A Yes. Q Stored at 25C?	2 3 4	RAO TATA-VENKATA A Yes. Q So it has lost no more than one percent from the from when it was initially placed or
2 3 4	RAO TATA-VENKATA Do you see that? A Yes. Q Stored at 25C? A Yes.	2 3 4 5	RAO TATA-VENKATA A Yes. Q So it has lost no more than one percent from the from when it was initially placed of stability, correct?
2 3 4 5 6	RAO TATA-VENKATA Do you see that? A Yes. Q Stored at 25C? A Yes. Q And here the assay is 98 percent again,	2 3 4	RAO TATA-VENKATA 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.
2 3 4 5 6 7	RAO TATA-VENKATA Do you see that? A Yes. Q Stored at 25C? A Yes. Q And here the assay is 98 percent again, correct?	2 3 4 5 6 7	RAO TATA-VENKATA 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
2 3 4 5 6 7 8	RAO TATA-VENKATA 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.	2 3 4 5 6 7 8	RAO TATA-VENKATA A Yes. Q So it has lost no more than one percent from the from when it was initially placed of stability, correct? A Yes. Q Now, to be clear, a 20 microgram per milliliter concentration of dexmedetomidine fa
2 3 4 5 6 7 8 9	RAO TATA-VENKATA 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	2 3 4 5 6 7 8 9	RAO TATA-VENKATA A Yes. Q So it has lost no more than one percent from the from when it was initially placed of stability, correct? A Yes. Q Now, to be clear, a 20 microgram per milliliter concentration of dexmedetomidine fa within the range that is claimed in the patents t
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