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<p>1 2 3 4 5 6 7 Thursday, August 2, 2018 8 9:00 a.m. 9 10 DEPOSITION of ZHAOHUI SUNNY 11 ZHOU, Ph.D., held at Foley Hoag, LLP, 155 12 Seaport Boulevard, Seaport West, Boston, 13 Massachusetts, pursuant to notice, before 14 Michael D. O'Connor, Registered Merit 15 Reporter, Certified Realtime Reporter, 16 Certified Realtime Captioner, and Notary 17 Public in and for the Commonwealth of 18 Massachusetts. 19 20 21 22 23 24 25</p>	<p>1 A P P E A R A N C E S (Continued): 2 3 ATTORNEYS FOR THE PATENT OWNER: 4 STEPTOE & JOHNSON LLP 5 One Market Street 6 San Francisco, California 94105 7 (415) 365-6711 8 BY: JAMIE L. LUCIA, ESQ. 9 jlucia@steptoe.com 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>
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<p>1 A P P E A R A N C E S: 2 3 ATTORNEYS FOR PETITIONER: 4 FOLEY HOAG LLP 5 155 Seaport Boulevard 6 Boston, Massachusetts 02210 7 (617) 832-3077 8 BY: JEREMY YOUNKIN, ESQ. 9 jyoungkin@foleyhoag.com 10 BRENDAN JONES, Ph.D. 11 bjones@foleyhoag.com 12 13 ATTORNEYS FOR THE PATENT OWNER: 14 STEPTOE & JOHNSON LLP 15 115 South LaSalle Street, Suite 3100 16 Chicago, Illinois 60603 17 (312) 577-1264 18 BY: JOHN L. ABRAMIC, ESQ. 19 jabramic@steptoe.com 20 21 22 23 24 25</p>	<p>1 I N D E X 2 3 Deposition of: Page 4 ZHAOHUI SUNNY ZHOU, Ph.D. 5 By Mr. Younkin 6 6 7 ***** 8 9 E X H I B I T S 10 11 No. Page 12 Exhibit 1023 Document submitted to the 13 FDA, dated 3/8/16, Bates 14 000001 - 000099 76 15 16 Exhibit 1025 Document entitled, 17 "Nicotinic Acid, 18 Nicotinamide, and 19 Nicotinamide Riboside: A 20 Molecular Evaluation of 21 NAD+ Precursor Vitamins in 22 Human Nutrition" 70 23 24 ***** 25</p>

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1 P R O C E E D I N G S
2 ZHAOHUI SUNNY ZHOU, Ph.D.
3 *****
4
5 having been satisfactorily identified by the
6 production of his driver's license, and duly
7 sworn by the Notary Public, was examined and
8 testified as follows:
9
10 EXAMINATION
11 BY MR. YOUNKIN:
12 Q. Can you please state your name for
13 the record.
14 A. Yes. My first name is Zhaohui,
15 Z-h-a-o-h-u-i, middle name Sunny, S-u-n-n-y,
16 last name Zhou, Z-h-o-u.
17 Q. How do you pronounce your last
18 name?
19 A. Pronounced just like J-o-e. Zhou.
20 Q. Dr. Zhou, you're here as an expert
21 on behalf of Dartmouth, correct?
22 A. That's right.
23 Q. And you prepared a declaration in
24 these proceedings?
25 A. Yes, I did.

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1 Q. Okay. I'm going to hand it to you
2 so you have it in front of you. I've handed
3 you what has been marked previously as -- well,
4 I will just call it Exhibit 2002. Do you see
5 that on the bottom right-hand corner?
6 A. Yes, I do.
7 Q. Is this your declaration?
8 A. Yes.
9 Q. Okay. I'm going to hand you
10 another declaration that was previously
11 submitted in this case, the declaration of Joe
12 Bauer. That's Exhibit 1002.
13 Do you have that document in front
14 of you?
15 A. Yes, I do.
16 Q. You read Dr. Bauer's declaration
17 before you drafted yours; is that correct?
18 A. Yes, I did read his declaration
19 before mine.
20 Q. If you could turn to Page 4 of his
21 declaration, please. So that's Exhibit 1002 at
22 Page 4.
23 A. Page 4 of Dr. Bauer's declaration?
24 Q. Right.
25 A. Yes.

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1 Q. Do you see there that there is a
2 bullet point list of articles that are
3 discussed in Dr. Bauer's declaration?
4 A. Yes.
5 Q. Do you see that?
6 A. I see that list.
7 Q. And that list carries on to Page 5
8 and even on to Page 6, correct?
9 A. That's right.
10 Q. Okay. Did you read all of these
11 articles that are cited in Dr. Bauer's
12 declaration?
13 A. I did read all of them, yes.
14 Q. Okay. Had you read any of those
15 articles before you began to work on this case?
16 A. I cannot recall whether I read
17 some articles, because I have interest in NAD+
18 myself. So I know the work of this pathway,
19 but I cannot recall whether I read some of the
20 articles before. I might have, but I cannot
21 recall.
22 Q. Okay. Let me ask you some
23 specific questions. Firstly, when did you
24 begin working on this case, do you recall?
25 A. If I recall, it's early this year.

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1 Q. Early in 2018?
2 A. 2018. March perhaps.
3 Q. Okay. And so before you began
4 working on the case, can you recall reading any
5 of the articles written by Joseph Goldberger?
6 A. No, I cannot recall I read any
7 paper by him.
8 Q. Okay. Can you recall reading any
9 papers by Charles Brenner before you began
10 working on this case?
11 A. That's a paper. His work, I was
12 aware of. So I cannot recall whether I read
13 the exact paper or not.
14 Q. You can't remember whether you
15 actually read the Brenner paper before you
16 began work on the case?
17 A. I can't recall whether I read it
18 or not, but I was aware of his work.
19 Q. Okay. How were you aware of his
20 work?
21 A. Because I told you, I'm interested
22 invite minutes in general, and this new pathway
23 as it relates to NAD+, and I have an interest
24 in NAD+ chemistry, chemistry, biology myself.
25 Q. Have you published any articles on

<p style="text-align: right;">Page 10</p> <p>1 nicotinamide riboside?</p> <p>2 A. No, I have not published any paper</p> <p>3 on NR.</p> <p>4 Q. Have you published any articles on</p> <p>5 NAD biosynthesis?</p> <p>6 A. I studied several enzymes using</p> <p>7 NAD as a co-factor or substrate. I studied</p> <p>8 vitamin metabolism for many years and many of</p> <p>9 the pathways involved in NAD+.</p> <p>10 Q. Okay. But have you published any</p> <p>11 articles on the NAD+ pathway?</p> <p>12 A. Yes. I published the papers that</p> <p>13 involved that enzyme, also the enzyme using</p> <p>14 NAD+.</p> <p>15 Q. Okay.</p> <p>16 A. I did publish papers on that.</p> <p>17 Q. Okay. Have you published any</p> <p>18 articles on any NAD+ precursors?</p> <p>19 A. I cannot recall exactly whether in</p> <p>20 the paper I published mentioned that or not.</p> <p>21 Q. Have you received any grants to</p> <p>22 study NAD biosynthesis?</p> <p>23 A. I have received a grant to study a</p> <p>24 pathway involved in NAD, because metabolic</p> <p>25 cycles involves many enzymes and co-factors,</p>	<p style="text-align: right;">Page 12</p> <p>1 riboside, nicotinic acid included in NR and</p> <p>2 NAD+, NADH and NADP. That's a different form</p> <p>3 of NAD+.</p> <p>4 Q. What was the context of these</p> <p>5 lectures? Were they conferences or classes?</p> <p>6 A. Lectures to my students why as it</p> <p>7 relates to their biosynthesis. The other one</p> <p>8 is their biological function, particularly in</p> <p>9 posttranslational modification of proteins</p> <p>10 involve NAD+.</p> <p>11 Q. You understand that we're here</p> <p>12 today to discuss the '086 patent, correct?</p> <p>13 A. '086 patent, yes.</p> <p>14 Q. Why don't I hand it to you so you</p> <p>15 have it in front of you. This is previously</p> <p>16 marked as Exhibit 1001.</p> <p>17 Were you aware of the '086 patent</p> <p>18 before you began work on this case?</p> <p>19 A. No, I wasn't aware of this</p> <p>20 specific patent.</p> <p>21 Q. Have you attended any talks by</p> <p>22 Charles Brenner before you began to work on</p> <p>23 this case?</p> <p>24 A. Not that I can recall.</p> <p>25 Q. Have you spoken with Dr. Brenner?</p>
<p style="text-align: right;">Page 11</p> <p>1 vitamins. Some of these steps involve NAD+.</p> <p>2 Q. What particular pathway do you</p> <p>3 study?</p> <p>4 A. So the pathway studies are two</p> <p>5 pathways. One is transmethylation pathway, and</p> <p>6 the other one is transsulfuration pathway.</p> <p>7 It's a sulfur amino acid metabolic pathway.</p> <p>8 Many of the steps in these two pathways involve</p> <p>9 NAD.</p> <p>10 Q. Okay. But you haven't received a</p> <p>11 grant to study the synthesis of NAD from an NAD</p> <p>12 precursor, correct?</p> <p>13 A. So to clarify, your question is, I</p> <p>14 studied two pathways, transmethylation and</p> <p>15 transsulfuration pathways. So NAD is part of</p> <p>16 this pathway, yes.</p> <p>17 Q. Have you attended any conferences</p> <p>18 that focus on NAD?</p> <p>19 A. No, I haven't attended any</p> <p>20 conferences that focus on NAD.</p> <p>21 Q. Have you given any lectures on NAD</p> <p>22 precursors?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. Which precursors?</p> <p>25 A. The whole pathway, nicotinamide</p>	<p style="text-align: right;">Page 13</p> <p>1 A. No.</p> <p>2 Q. Do you know that the '086 patent</p> <p>3 has been licensed to a company called</p> <p>4 ChromaDex?</p> <p>5 MR. ABRAMIC: Objection. Scope.</p> <p>6 A. In the context I learned this</p> <p>7 after I was involved in the case.</p> <p>8 Q. After you became involved in the</p> <p>9 case you learned that the '086 patent has been</p> <p>10 licensed to ChromaDex?</p> <p>11 A. I can't remember the name, but</p> <p>12 that sounds right.</p> <p>13 Q. So you learned it had been</p> <p>14 licensed to a company?</p> <p>15 A. Yes.</p> <p>16 Q. Do you have any relationship with</p> <p>17 the company ChromaDex?</p> <p>18 A. Not that I can think about.</p> <p>19 Q. Dr. Zhou, what does the word</p> <p>20 "comprising" mean in patent law?</p> <p>21 A. Comprising?</p> <p>22 Q. Yes. The word "comprising."</p> <p>23 A. In patent law?</p> <p>24 Q. Yes. When the word "comprising"</p> <p>25 is used in a claim, what does that mean?</p>

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1 MR. ABRAMIC: Objection to form.
 2 A. Which specific claim are you
 3 talking about?
 4 Q. Do you understand the word
 5 "comprising" to have a special meaning in
 6 patent law?
 7 A. I understand that the special
 8 meaning goes with the context of the word.
 9 Q. What do you mean you understand
 10 the special meaning goes with the context of
 11 the word?
 12 A. For example, phrases used. This
 13 is a very common word, "comprising."
 14 Q. Okay. So you're not aware that
 15 the word "comprising" is a special term of art
 16 in patent law?
 17 A. I was instructed to study this
 18 patent and the claims in this patent, and
 19 within this context, I focused my understanding
 20 of "comprising" in this patent in the claims.
 21 I haven't studied all the comprising in all the
 22 patents, being all the context.
 23 Q. Were you given any information
 24 about the meaning of the word "comprising"
 25 under U.S. patent law?

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1 A. No, not from this case. I have
 2 myself involved filing patents myself. So
 3 during those process, we talked about the word,
 4 and I was an expert witness in previous case.
 5 So the word "comprising" comes up in those
 6 cases as well.
 7 So within those contexts of those
 8 patents, I was explained the meaning of
 9 "comprising" in those patents and my own patent
 10 filing.
 11 Q. Based on your own prior
 12 experience, then, whether as an inventor on a
 13 patent application or a prior expert witness,
 14 did you come to understand that the word
 15 "comprising" has a special meaning in patent
 16 law?
 17 A. Yes. If you're sitting here or in
 18 general, a patent in a broad sense, it means to
 19 include something, yes.
 20 Q. It means to include something?
 21 A. Yes.
 22 Q. And is that the definition that
 23 you applied when you were reviewing the '086
 24 patent?
 25 A. That's a different issue, because

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1 the patent comprising is part of that claim,
 2 part of that phrase. So I interpret the
 3 meaning of "comprising" in that context, the
 4 claim of the patent.
 5 Q. Okay. So let ask it this way. Am
 6 I correct that you understood when you began on
 7 this case that the word "comprising" in patent
 8 law means including; is that right?
 9 MR. ABRAMIC: Objection to form.
 10 A. In a very broad sense, without any
 11 context, that's my -- that's my interpretation
 12 I can use, yes.
 13 Q. Is the word "comprising" defined
 14 in the '086 patent? Is there a definition
 15 provided of that word?
 16 A. Not that I can recall.
 17 Q. Did you depart from your
 18 understanding that "comprising" means
 19 including, did you depart from that concept
 20 when you were interpreting the '086 patent?
 21 MR. ABRAMIC: Objection to the
 22 characterization.
 23 A. No, not from the general sense.
 24 But because of the claim I look at the context,
 25 that's consistent with my general understanding

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1 of the word "comprising" in patent law.
 2 Q. Assume that a patent claim is a
 3 pharmaceutical composition comprising calcium
 4 sulfate. Okay. What would you understand that
 5 claim to mean?
 6 A. Can you repeat that?
 7 Q. Certainly. So assume that a claim
 8 is directed to a pharmaceutical composition
 9 comprising of calcium sulfate. How would you
 10 interpret that claim?
 11 A. There's no other -- so to answer
 12 your question, there's no other limitation for
 13 that phrase?
 14 Q. That's the entirety of the claim,
 15 those words.
 16 A. Okay.
 17 Q. Pharmaceutical composition
 18 comprising calcium sulfate?
 19 MR. ABRAMIC: And you're just
 20 giving him the claim?
 21 MR. YOUNKIN: I'm giving him the
 22 claim.
 23 A. And there's no other limitation on
 24 that claim?
 25 Q. That's the entirety of the claim,

Page 18

1 yes.

2 MR. ABRAMIC: Objecting to the

3 hypothetical.

4 Q. What does that claim mean?

5 A. So sitting here, you asked me to

6 analyze right away, that means the

7 pharmaceutical composition is a --

8 pharmaceutical means has a therapeutic or

9 preventative effect. Composition means

10 chemical compound that has active ingredient or

11 active agent. In this case it's calcium -- did

12 you say sulfate or chloride?

13 Q. I said calcium sulfate.

14 A. Yes.

15 Q. So you would interpret that claim

16 to mean that it's to require the presence of

17 calcium sulfate as an active ingredient; is

18 that right?

19 A. So repeat. Sorry.

20 Q. I want to make sure that I

21 understand your interpretation of the

22 hypothetical claim that I've given you.

23 Am I correct that you would

24 interpret that claim to mean that -- sorry.

25 Am I correct that you would

Page 19

1 require -- try that again.

2 Am I correct that you would

3 interpret that claim to require that calcium

4 sulfate be an active ingredient?

5 MR. ABRAMIC: Objection to the

6 hypothetical.

7 A. So the claim says is a

8 composition, is a compound or chemical, has

9 therapeutic or preventative effect. That's

10 what pharmaceutical means. And has active

11 ingredient and active ingredient is calcium

12 sulfate.

13 Q. Let me give you a different

14 hypothetical claim. Imagine that the claim

15 says a pharmaceutical composition comprising

16 tryptophan. How would you interpret that

17 claim?

18 MR. ABRAMIC: Again, you're just

19 giving him claim, no patent

20 specification?

21 MR. YOUNKIN: Yeah. I would

22 appreciate it if we could just keep the

23 objections to one word and the grounds

24 for the objection.

25 MR. ABRAMIC: Trying to make the

Page 20

1 question clear.

2 MR. YOUNKIN: I'm comfortable with

3 the clarity of the question.

4 Q. Let's try it again. So here's the

5 hypothetical claim. A pharmaceutical

6 composition comprising tryptophan. How would

7 you interpret that claim?

8 A. Again, without any limitation,

9 just sitting here, that would be the same

10 interpretation as I had with the calcium

11 sulfate.

12 Q. Okay. Meaning the tryptophan is

13 the active ingredient, correct?

14 A. Active ingredient for some

15 preventative and therapeutic effects.

16 Q. Okay. I'm going to give you a

17 third hypothetical.

18 A pharmaceutical composition

19 comprising calcium sulfate and tryptophan. How

20 would you interpret that claim?

21 MR. ABRAMIC: Same objection.

22 A. Without any limitation?

23 Q. Those are all of the words of the

24 claim, a pharmaceutical composition comprising

25 calcium sulfate and tryptophan.

Page 21

1 A. First, I haven't thought about

2 this with two components in the past. Also,

3 all the cases I've been involved is only a

4 single active ingredient. So I'm not sure I

5 can exactly answer your question when I have

6 two components.

7 Q. Okay.

8 A. Without any limitation from the

9 patent.

10 Q. What is an active ingredient?

11 A. Active ingredient is a compound or

12 chemical that conferred the activity observed

13 for the composition of the drug.

14 Q. What do you mean when you say "the

15 activity observed"?

16 A. Observed? Activity, basically

17 means activity. You have to observe activity

18 to see whether it's active or not.

19 Q. What sort of activity does an

20 ingredient have to have in order for it to be

21 considered an active ingredient?

22 MR. ABRAMIC: Objection to form.

23 A. So that -- so again, activity with

24 no context. Are we talking about what kind of

25 activity? In patent law, a vacuum activity or

Page 22

1 are we talking about pharmaceutical activity
 2 here? Sorry, I'm not clear about your
 3 question.
 4 **Q.** Okay. Let's turn to Paragraph 31
 5 of your declaration, which is on Page 10.
 6 **A.** My declaration?
 7 **Q.** Yes.
 8 **A.** Paragraph 31?
 9 **Q.** Yes. So the first sentence of
 10 Paragraph 31 of your declaration says, "A
 11 pharmaceutical composition, at its most basic
 12 level, contains an active ingredient," right?
 13 **A.** In Paragraph 31, first sentence,
 14 yes.
 15 **Q.** Okay. What does the word "active
 16 ingredient" mean as you used it in Paragraph
 17 31?
 18 **MR. ABRAMIC:** Asked and answered.
 19 **A.** "Active ingredient" in the
 20 pharmaceutical composition, using the whole
 21 sentence, means it exhibits or confers certain
 22 therapeutic or preventative effects.
 23 **Q.** Does the '086 patent show that NR
 24 has therapeutic or preventative effects?
 25 **MR. ABRAMIC:** Objection to form.

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1 **A.** In the patent of '086, whether it
 2 shows --
 3 **Q.** Yes. Does the '086 patent show
 4 that NR exhibits or confers certain therapeutic
 5 or preventative effects?
 6 **MR. ABRAMIC:** Objection to form.
 7 Vague.
 8 **A.** As I sit here, I cannot recall
 9 specific whether they mention a specific
 10 therapeutic effect. The patent is to have a
 11 claim of NR used as a pharmaceutical
 12 composition. So I cannot recall whether they
 13 specifically mention any pharmaceutical effect
 14 of NR in the patent.
 15 **Q.** But you interpret the claim to
 16 require a pharmaceutical composition to have a
 17 therapeutic or preventative effect, correct?
 18 **MR. ABRAMIC:** Objection to form.
 19 **A.** Can you repeat the question?
 20 **Q.** Sure. Is it your understanding
 21 that the claims of the '086 patent require the
 22 claimed pharmaceutical composition to have a
 23 therapeutic or preventative effect?
 24 **A.** Sorry. Can you clarify the
 25 question?

Page 24

1 **Q.** Sure. In your declaration you
 2 opine on the meaning of Claim 1, correct?
 3 **A.** Yes, I did opine on Claim 1 in the
 4 patent.
 5 **Q.** Okay. But you opined specifically
 6 on what Claim 1 means, correct?
 7 **A.** Yes. I was asked to do that.
 8 **Q.** How a person of ordinary skill in
 9 the art would understand Claim 1, right?
 10 **A.** Yes, that's correct.
 11 **Q.** Okay. So is it your opinion that
 12 a person of ordinary skill in the art would
 13 understand Claim 1 to require that the
 14 pharmaceutical composition of Claim 1 brings
 15 about a therapeutic or preventative effect?
 16 **MR. ABRAMIC:** Objection to form.
 17 **A.** My understanding of patent law, in
 18 general, is you can claim something may be with
 19 or without its showing the intended use of a
 20 composition.
 21 **Q.** Okay.
 22 **A.** That's where my confusion comes
 23 from when you say "required."
 24 **Q.** Okay. So let's discuss this a
 25 little bit further. So is it your opinion that

Page 25

1 the part of the claim that is -- the
 2 pharmaceutical -- the reason you're saying that
 3 an active ingredient has to have a therapeutic
 4 or preventative effect is because the claim is
 5 directed to a pharmaceutical composition; is
 6 that right?
 7 **MR. ABRAMIC:** Objection to the
 8 characterization and the form of the
 9 question.
 10 **Q.** Is that true?
 11 **A.** Sorry, can you repeat the
 12 question. I was interrupted by counsel.
 13 **Q.** The reason that you believe that
 14 the active ingredient -- sorry, let me rephrase
 15 that.
 16 The reason that you believe that
 17 Claim 1 requires a -- well, let me try that yet
 18 one more time.
 19 You're interpreting the words
 20 "pharmaceutical composition" to connote a
 21 substance that has a therapeutic or
 22 preventative effect, correct?
 23 **MR. ABRAMIC:** Objection to the
 24 characterization.
 25 **A.** So my understanding of patent law

Page 26

1 is you can claim -- so the Claim 1 said
 2 nicotinamide riboside, NR, in Claim 1 is the
 3 active ingredient for that pharmaceutical
 4 composition. That's what Claim 1 says.
 5 **Q.** Okay. So how do you know whether
 6 or not NR is an active ingredient in a
 7 pharmaceutical composition?
 8 **A.** How do I know it's an active
 9 ingredient?
 10 **Q.** Yes.
 11 **A.** So this experimentally someone can
 12 test out, because -- related to this patent,
 13 Claim 1 does not specify any therapeutic area
 14 or indication. But in the patent itself, it
 15 talks about different potential indications,
 16 different disease. So scientists study that
 17 with or without NR, for example, and see
 18 whether the fact, you know, are observed or not
 19 and that the person will establish whether NR
 20 is responsible to the observed activity.
 21 **Q.** So in order to determine whether
 22 or not NR in a pill, for example, is an active
 23 ingredient, you would need to establish that
 24 the NR in the pill does what?
 25 **MR. ABRAMIC:** Objection to the

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1 form and scope.
 2 **Q.** In other words, imagine this.
 3 Imagine I came to you and said, Dr. Zhou, here
 4 is a pill that has NR in it. I would like you
 5 to tell me whether or not the NR is an active
 6 ingredient. How would you answer that
 7 question?
 8 **MR. ABRAMIC:** Same objection.
 9 **A.** So to answer that question, we
 10 need to know what we want to find out, whether
 11 NR is active for what? And the "what" part is
 12 what we have to define first, active for
 13 treating disease, to prevent disease?
 14 So we need to know what the
 15 ultimate outcome of what we want to measure in
 16 terms of activity.
 17 **Q.** And the amount of NR that would be
 18 needed to bring about a therapeutic effect
 19 would vary with whatever it is that you're
 20 treating; is that correct?
 21 **MR. ABRAMIC:** Objection to form
 22 and scope.
 23 **A.** That's not something I was asked
 24 to opine on.
 25 **Q.** Do you believe that to be true?

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1 **MR. ABRAMIC:** Same objection.
 2 **A.** If you ask me to answer that
 3 question, can you repeat it, because I wasn't
 4 asked to opine on that.
 5 **Q.** Okay. Let me ask you a different
 6 question.
 7 Is it your opinion that the
 8 pharmaceutical composition requires that there
 9 be an effective amount of NR in the
 10 composition?
 11 **MR. ABRAMIC:** Objection. Same
 12 objection.
 13 **A.** So first, I wasn't asked to opine
 14 on that.
 15 **Q.** Okay. But I'm asking you today.
 16 Is that your understanding of Claim 1, that it
 17 requires that there be an amount that can be
 18 deemed an effective amount, meaning that it
 19 causes a certain effect with respect to a
 20 disease state?
 21 **MR. ABRAMIC:** Objection. Scope.
 22 **A.** When you ask me that question, I
 23 think that's not part of Claim 1 at all.
 24 Sorry, I said this very bluntly. I think maybe
 25 you confused the concept of the patent claim

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1 and the ultimate drug. That's maybe where the
 2 confusion comes from.
 3 **Q.** Okay. But you said that Claim 1
 4 requires the NR to be the active ingredient in
 5 the pharmaceutical composition, right?
 6 **A.** If a composition, pharmaceutical
 7 composition is active, and then in that case NR
 8 is the active ingredient.
 9 **Q.** And in order to know whether or
 10 not the NR is active, you first need to
 11 establish what activity you're trying to bring
 12 about; is that right?
 13 **MR. ABRAMIC:** Objection. Asked
 14 and answered.
 15 **A.** So, yes, we talked about this
 16 before, when we talk about specific therapeutic
 17 index or therapeutic area, therapeutic
 18 activity, then one has to do this experimental
 19 testing to show, in that particular case, that
 20 particular indication, how much activity NR
 21 exhibits.
 22 **Q.** In your opinion, Claim 1 requires
 23 that NR be present as an active ingredient,
 24 correct?
 25 **MR. ABRAMIC:** Asked and answered.

Page 30

1 **A.** So again, Claim 1 is about a
2 composition, and the composition has
3 therapeutic or preventative effect, and NR is
4 the active ingredient.
5 **Q.** Does the NR need to be in an
6 amount sufficient to effectively bring about
7 that therapeutic or preventative effect?
8 MR. ABRAMIC: Objection. Asked
9 and answered. Scope.
10 **A.** As I said, that's not part of
11 Claim 1. And the patent did describe the
12 process to establish maybe the amount for each
13 individual indication or disease -- amount
14 required to treat certain disease or
15 indication.
16 **Q.** But if NR is the active ingredient
17 in a pharmaceutical composition that brings
18 about a therapeutic effect, isn't it the case
19 that the amount of the NR in that composition
20 is sufficient to bring about that therapeutic
21 effect?
22 I'm not understanding how those
23 two things can't be true.
24 MR. ABRAMIC: Same objection.
25 **A.** So my understanding of patent law

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1 is you can have a claim, and those limitations,
2 those are for the limitation of a claim, and
3 very common myself and other people see the
4 claim is this claim like Claim 1, it just
5 claims the entity, the chemical entity itself,
6 without specifying the dose or amount in the
7 pill as you were discussing.
8 **Q.** But your interpretation of active
9 ingredient means that the composition actually
10 has a function, right? It brings about an
11 effect?
12 **A.** Yes. So a pharmaceutical
13 composition -- active ingredient must bring
14 some effect. The active ingredient must have
15 an effect, otherwise it won't be called active
16 ingredient.
17 **Q.** Right. So there must be enough
18 active ingredient in the pharmaceutical
19 composition in order to bring about the effect,
20 correct?
21 MR. ABRAMIC: Objection. Asked
22 and answered. Scope.
23 **A.** Again, I think where maybe we're
24 maybe the drug development concept here and the
25 patent mixed together. So my understanding --

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1 I'm sorry to say it that way.
2 My understanding here, we're
3 talking about a patent case. In a patent case
4 they talk about a chemical entity, a molecule
5 in some sense. It's a concept, that structure,
6 one would develop the drug, and each drug is
7 approved by the FDA. It requires dosing amount
8 in the pill for a certain disease.
9 By the way, here we're talking
10 about patent is my understanding I was asked to
11 opine on, is the chemical entity active
12 ingredient, which in this case is NR.
13 So the reason I couldn't answer
14 your question is the dosing is related to a
15 specific drug, in my view, for drug
16 development. That's related to the patent, but
17 not the patent Claim 1 about, in my opinion.
18 **Q.** Do you know how much NR must be
19 present in the composition for the NR to be an
20 active ingredient?
21 MR. ABRAMIC: Objection. Asked
22 and answered.
23 **A.** I think we talked about this
24 before. As a drug, not in a patent case, but
25 in a drug development case, the amount of NR

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1 required to treat a certain disease or prevent
2 certain conditions may vary, and that needs to
3 be found out by experimental approach.
4 Again, in my view, that's not part
5 of Claim 1.
6 **Q.** I want to return to a hypothetical
7 question I asked before, because I don't think
8 the record is clear on this.
9 If I came to you with a pill, and
10 I said I'm trying to figure out whether or not
11 this pill falls within the scope of Claim 1,
12 whether it's covered by Claim 1 or not, what
13 sort of experiments would you do to answer that
14 question? How would you tell?
15 MR. ABRAMIC: Objection to form.
16 **A.** Whether a pill is covered in Claim
17 1 or not?
18 **Q.** Yes.
19 **A.** Again, I'm not one to ask to opine
20 on, I guess it's called infringement or
21 whatever, right? So I'm not asked to do that.
22 **Q.** Okay. Well, imagine the pill is
23 in the prior art, then. Okay? And I say, I
24 found this prior art pill, and I'm trying to
25 figure out whether or not this pill anticipates

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1 Claim 1. Okay? Here's the pill. Can you help
 2 me figure that out? What would you do?
 3 **A.** That's an interesting question.
 4 So what I -- first, I would fully understand
 5 Claim 1. Then to understand the prior art, I
 6 need to see whether NR is present in the pill,
 7 whether it is available, and whether conferred
 8 activity people reported or observed.
 9 **Q.** And what sort of activity would
 10 need to be reported or observed for you to feel
 11 that the pill could be covered by Claim 1?
 12 **A.** That's not for me to decide
 13 activity. It's what they want to claim or
 14 report the activity. Then I need to show
 15 evidence whether the experimental procedure
 16 shows NR, without NR. There are many, many
 17 complicated experiments one has to conduct to
 18 see, for example, whether NR, in the absence of
 19 NR, whether the same effect is observed or not.
 20 It's, you know, hundreds and thousands of
 21 experiments one has to conduct, and there's
 22 always caveats how to interpret the data.
 23 But one experiment I think one
 24 must do is to remove NR from that pill, and
 25 they have everything else in that pill, and

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1 test it, and see whether the same activity is
 2 still being observed and whether it's the same
 3 degree of activity.
 4 That's, at least, I think
 5 scientifically that's a requirement to
 6 establish whether that pill has the activity of
 7 NR.
 8 **MR. YOUNKIN:** Why don't we take a
 9 five-minute break.
 10 (Recess taken at 9:40 a.m. and
 11 reconvening at 9:53 a.m.)
 12 **BY MR. YOUNKIN:**
 13 **Q.** Dr. Zhou, I'd like to ask you a
 14 few more hypotheticals.
 15 **A.** Sure.
 16 **Q.** Okay. Imagine that I come to you
 17 with a pill that has ten milligrams of NR in
 18 it. Okay? And the question is, does this pill
 19 anticipate Claim 1? Okay?
 20 You run some experiments and
 21 determine that my ten milligram pill does not
 22 have any kind of therapeutic or preventative
 23 effect. Okay? You would conclude, am I right,
 24 that the pill does not anticipate Claim 1?
 25 **MR. ABRAMIC:** Objection to the

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1 hypothetical.
 2 **A.** Since it's a hypothetical
 3 question, I want to make sure I understand the
 4 question first. So you're saying that you
 5 would -- there's a pill with a certain amount
 6 of NR in it?
 7 **Q.** Ten milligrams.
 8 **A.** Ten milligrams. And it did not
 9 show any effect -- did or did not show any
 10 effect?
 11 **Q.** Did not. Your testing established
 12 that there is no therapeutic or preventative
 13 effect brought on by taking this pill.
 14 **A.** So this is a very broad question.
 15 I think I probably cannot answer that question,
 16 because therapeutic effect is not just one
 17 term. Therapeutic effect has many, many
 18 indications.
 19 **Q.** But why can't you answer the
 20 question?
 21 **A.** Because when you say therapeutic
 22 effect, there's no generic term for therapeutic
 23 effect. Therapeutic effect, there's always
 24 some specific indication of disease. So I
 25 cannot answer that question, even hypothetical.

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1 **Q.** I want you to assume as part of
 2 the hypothetical that you concluded that there
 3 is no therapeutic or preventative effect.
 4 **A.** As I said, the scientific
 5 rationale won't allow me to conclude that way.
 6 **Q.** So you're saying you could never
 7 reach the conclusion that a pill does not have
 8 an active -- that a pill does not bring about a
 9 therapeutic or preventative effect?
 10 **MR. ABRAMIC:** Objection to form.
 11 Scope.
 12 **A.** It's not whether I cannot or can.
 13 The question, the term "therapeutic effect" is
 14 used too broadly or too narrowly in this case.
 15 I'm not sure whether it's broadly or narrowly.
 16 So the hypothetical question is
 17 not well defined, the question to me.
 18 **Q.** Well, you used the phrase
 19 "therapeutic or preventative effect" in your
 20 testimony today, right?
 21 **A.** Yes.
 22 **Q.** And what do you mean by that?
 23 **A.** Again --
 24 **MR. ABRAMIC:** Objection. Asked
 25 and answered.

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1 **A.** Again, this is a general term, and
 2 the term "therapeutic effect" is for a certain
 3 preventative effect or therapeutic effect. But
 4 those effects are shown by specific indication
 5 or disease.
 6 **Q.** Let me try to add a little more
 7 detail to the hypothetical.
 8 Let's say that I give you my ten
 9 milligram of NR pill, and I say the question is
 10 whether or not this pill is an effective
 11 treatment of cancer. Okay? And you run your
 12 tests and conclude that the ten milligram pill
 13 has no effect on cancer. Okay?
 14 Would you conclude that the pill
 15 does not have an active ingredient that is
 16 effective to treat cancer?
 17 **MR. ABRAMIC:** Objection to form.
 18 **A.** Again, I know this is a
 19 hypothetical question you asked me. You said
 20 that already. I wasn't asked to opine on that.
 21 So sitting here, to think about
 22 your question, ten milligrams of a pill has ten
 23 milligrams of NR in it, is shown not effective
 24 treating cancer? Is that the hypothetical?
 25 **Q.** Correct.

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1 **A.** Okay. And the question is whether
 2 NR is active pharmaceutical composition?
 3 **Q.** The question is whether or not
 4 that ten milligram pill is covered by Claim 1?
 5 **MR. ABRAMIC:** Same objection.
 6 **A.** Again, I think -- again, I was not
 7 asked to opine on that. Sitting here, my
 8 feeling is maybe the question confuses the
 9 concept of patent claim with drug development.
 10 **Q.** Okay. Let me be clear. I'm only
 11 interested in the patent claims. I'm not
 12 interested in drug development.
 13 **A.** Right.
 14 **Q.** So the only question that I have
 15 here today is whether or not this hypothetical
 16 pill that I'm talking about would or would not
 17 be covered by the claim under patent law? It's
 18 not a drug development question.
 19 Do you understand the question?
 20 **A.** I think. Repeat the question one
 21 more time.
 22 **Q.** So this is our ten milligram --
 23 our pill with ten milligrams of NR. You have
 24 concluded that the ten milligram pill is not
 25 effective in treating cancer. Okay?

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1 And the question is whether or not
 2 the ten milligram pill falls within the scope
 3 of Claim 1 or not?
 4 Can you answer that question?
 5 **MR. ABRAMIC:** Objection to form.
 6 **A.** What do you mean "falls within the
 7 scope of Claim 1"?
 8 **Q.** It means that it is a
 9 pharmaceutical composition comprising
 10 nicotinamide riboside as claimed in Claim 1.
 11 **A.** The question said NR was not
 12 active treating cancer?
 13 **Q.** Correct.
 14 **A.** I'm also not clear about your
 15 question cover in the scope?
 16 **Q.** Okay. You were asked to opine
 17 whether or not the prior art anticipates Claim
 18 1, correct?
 19 **A.** Right.
 20 **Q.** And you understand what it means
 21 for a prior art reference to anticipate Claim
 22 1, correct?
 23 **A.** Right. Yes, I understand.
 24 **Q.** Okay. So imagine that my pill is
 25 a piece of prior art. It was something that

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1 was sold ten years ago. Okay? Or 20 years
 2 ago. And that pill has been shown to be not
 3 effective in treating cancer. Okay?
 4 So now my question is, does the
 5 pill anticipate Claim 1?
 6 **MR. ABRAMIC:** Objection to the
 7 hypothetical.
 8 **A.** So again, for that hypothetical
 9 question, sitting here, because the pill showed
 10 no activity, and the claim has NR as active
 11 ingredient. So this is a hypothetical case
 12 that did not describe elements of the claim.
 13 **Q.** Now, what if the prior art showed
 14 that two of these pills, so 20 milligrams, was
 15 effective in treating cancer. Okay?
 16 So would the two pills together
 17 anticipate Claim 1?
 18 **MR. ABRAMIC:** Objection. Scope.
 19 Hypothetical.
 20 **A.** Two pills together?
 21 **Q.** Right. So we began with a ten
 22 milligram pill, and now I'm saying that what
 23 patients were taking in the prior art were two
 24 of those pills, 20 milligrams, and that when
 25 they took 20 milligrams, it was shown to be

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1 effective in treating cancer.
 2 In that case, would the two ten
 3 milligram pills together anticipate Claim 1?
 4 MR. ABRAMIC: Same objections.
 5 A. Again, so it's a hypothetical
 6 question. And sitting here thinking about it,
 7 I think the issue here is not dosing. It's
 8 whether -- because Claim 1, there's no
 9 limitation of amount. It's the fact it's a
 10 chemical entity, which is NR, is active for
 11 some therapeutic indication. In this case, you
 12 already limit that to cancer treatment, without
 13 other details of the treatment regime.
 14 So regardless of the dosing, if
 15 the chemical entity has an effect, sitting here
 16 now, I may consider that falls to the described
 17 element in Claim 1.
 18 Q. So you would think that the taking
 19 of two ten milligram doses of NR would
 20 anticipate Claim 1 --
 21 MR. ABRAMIC: Objection.
 22 Q. -- under that hypothetical?
 23 MR. ABRAMIC: Objection to the
 24 form and characterization.
 25 A. So again, the question here is not

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1 about the dosing. In my view, it's a certain
 2 dose, certain dose, shows an effect of NR in
 3 treating cancer. That's a relevant effect.
 4 Q. Do you have an opinion about
 5 whether or not the 20 milligram dose would
 6 anticipate Claim 1 under the hypothetical that
 7 I've given you?
 8 MR. ABRAMIC: Same objections.
 9 A. Again, it's not a dosing part.
 10 It's the fact that -- Claim 1 is nothing about
 11 dosing. Claim 1 is about whether this chemical
 12 entity, a certain dose, of course it's implied,
 13 that a certain dose has a certain effect.
 14 Q. And if it was shown that the
 15 chemical entity had an effect at a dose of 20
 16 milligrams in the prior art, that would
 17 anticipate Claim 1, right?
 18 MR. ABRAMIC: Same objections.
 19 A. Again, with all of these caveats,
 20 this compound is available, it's a responsible
 21 tool to cancer treatment and it's not other
 22 things. Sitting here, without -- I didn't have
 23 time to think through that, I would say it
 24 feels like it, the fact that NR at a certain
 25 dose has a therapeutic effect for the described

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1 elements of Claim 1.
 2 Q. What is NR effective at treating
 3 or preventing?
 4 A. Say that again.
 5 Q. What is NR effective at treating
 6 or preventing?
 7 A. Sorry, I didn't get your question?
 8 Q. What can nicotinamide riboside
 9 treat or prevent?
 10 A. Again, that's not what I was asked
 11 to opine on.
 12 Q. Do you know the answer to that
 13 question?
 14 A. So the patent describes -- some
 15 specification of the patent describes certain
 16 diseases that may be treated by NR, but that's
 17 not part of the patent claims.
 18 Q. Does the patent claim show that
 19 the diseases that are mentioned in the
 20 specification can, in fact, be treated with NR?
 21 MR. ABRAMIC: Objection to form.
 22 A. I know we talked about this
 23 before. My understanding of patent law is, you
 24 can claim a chemical entity with the idea it
 25 may reach certain disease or indications, and

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1 then whether they can treat and what dosing,
 2 those are figured out later on, and can be as a
 3 source for the limitation. And again, that
 4 goes into the drug development process, not a
 5 patent.
 6 Q. I'm not asking you about your
 7 understanding of patent law. I'm asking you
 8 about your interpretation of the patent itself,
 9 the document.
 10 A. Okay.
 11 Q. Does the patent, the '086 patent,
 12 show that the diseases that are mentioned in
 13 the specification can, in fact, be treated with
 14 NR? Do you think that the specification shows
 15 that?
 16 MR. ABRAMIC: Objection. Form.
 17 Vague.
 18 A. I cannot recall exactly whether NR
 19 can treat any disease, just mentioning the
 20 patent.
 21 Q. You don't remember whether or not
 22 there were any experiments showing that NR does
 23 or does not treat cancer or some other disease,
 24 you don't remember whether that was in the
 25 specification?

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1 **A.** I don't remember specifically
2 whether the disease treatment was shown in the
3 patent. I do remember it mentioned certain
4 disease potentially can be treated by NR. They
5 also mention a general process of how to do
6 that, for example, by varying amount and
7 experimenting with the dosing, things like
8 that.

9 **Q.** Okay. Your declaration cites
10 dictionary definitions of the term
11 "pharmaceutical," right?

12 **A.** Yes, it did.

13 **Q.** Let's look at Paragraph 30, for
14 example, of your declaration.

15 **A.** Paragraph 30?

16 **Q.** Yes. So in that paragraph, you
17 cite to the McGraw-Hill Dictionary of
18 Scientific and Technical Terms, correct?

19 **A.** Yes.

20 **Q.** And you cite a definition that
21 defines pharmaceutical as "'a chemical produced
22 industrially (medicinal drug), which is useful
23 in preventive or therapeutic treatment of a
24 physical, mental, or behavioral condition.'
25 Do you see that?

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1 **A.** Yes.

2 **Q.** Would you agree with me the '086
3 patent does not disclose any chemicals that are
4 produced industrially?

5 MR. ABRAMIC: Objection to form.
6 Do you mean the entire patent?

7 MR. YOUNKIN: Yes. I mean the
8 entire patent.

9 **A.** What do you mean "industrially"?

10 **Q.** Well, you're the one who cited
11 this definition. So what did you understand
12 this to mean?

13 **A.** In fact, I tried to understand the
14 word "industrially," and looked it up in the
15 dictionary myself. My understanding of
16 "industrially" is to opposite of
17 recreationally. It means there's a purpose,
18 and to me it doesn't mean to me to produce tons
19 and tons of large, larger scale. It means it's
20 produced with a purpose for utility.

21 **Q.** Okay. Is the McGraw-Hill
22 Dictionary of Scientific and Technical Terms,
23 is that something you consult in your research?

24 **A.** I do look up scientific terms
25 among different dictionaries, and this is

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1 probably one of the dictionaries I come across.

2 **Q.** Do you have this dictionary in
3 your office, for example?

4 **A.** I don't have a hard copy anymore.
5 It's all an online.

6 **Q.** But this is a dictionary you can
7 recall consulting this particular dictionary in
8 your work?

9 **A.** This comes up when I searched
10 online, I Google, we all are using that very
11 often, and this is one of the results that come
12 up. This is the dictionary that's more
13 scientific than just layman's dictionary, and I
14 thought this is a good definition in this
15 context.

16 **Q.** But the actual dictionary
17 definition was provided to you by Dartmouth's
18 lawyers, right?

19 **A.** No. We talk about this when I
20 came up with this one myself as well. Plus I
21 search lots of dictionaries myself, and the
22 attorneys ask me to come up with a definition
23 during this process, that this is important,
24 and this is one of the dictionaries, several of
25 the ones, that I used.

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1 **Q.** Let me hand you a copy of the
2 dictionary that you provided with your report.
3 It's Exhibit 2004. You can see from the front
4 page that this document is from the Steptoe &
5 Johnson LLP library, right?

6 **A.** Right. For the lawsuit, it was
7 still based on paper, and we needed to find the
8 paper form, such as the Remington compendium
9 of pharmacy. We cannot just do a screen shot.
10 We needed a paper form, and they produced it.
11 It seems they have a hard copy of this
12 dictionary and they made a copy of it to be
13 included in my declaration.

14 **Q.** Do you dispute nicotinamide
15 riboside is present in milk?

16 **A.** Which milk?

17 **Q.** Let me just ask you generally. If
18 I say to you, do you agree or disagree with
19 this statement; milk is a source of NR.

20 MR. ABRAMIC: Objection. Vague.

21 **Q.** Is that true or false?

22 MR. ABRAMIC: Objection. Vague.

23 **A.** So in science, we always need to
24 look at the conditions. So what I would say,
25 milk, in general, as in general, milk, may or

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1 may not contain NR.
 2 There are cases that show certain
 3 milk contains NR. But other milk, sample, we
 4 call that, individual sample, may not contain
 5 NR.
 6 Q. Can you tell me the name of any
 7 journal article that concluded that milk does
 8 not contain NR?
 9 MR. ABRAMIC: Objection to form.
 10 A. No, I cannot recall any article
 11 saying that.
 12 Q. Okay.
 13 A. But I can also not find any
 14 article established that exhaustively tests all
 15 the milk samples.
 16 Q. Okay. So there's no article
 17 that's tested every single milk sample that's
 18 ever been produced in the world, ever, right?
 19 A. Right.
 20 Q. And because of that, you believe
 21 that you cannot conclude that NR is in milk?
 22 MR. ABRAMIC: Objection to form.
 23 A. As I said, NR may or may not be in
 24 certain milk samples.
 25 Q. What is the basis for your opinion

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1 In every single paper that you
 2 have read that studies the presence of NR in
 3 milk, the researchers concluded that milk
 4 contained NR, correct?
 5 MR. ABRAMIC: Objection. Vague.
 6 A. Yes. In the paper I read, which
 7 are limited in number, where they measure NR
 8 content in milk, and milk NR was present, yes.
 9 Q. I'd like to direct your attention
 10 to the Trammell 1 article, and I'll give you a
 11 copy of it. It's Exhibit 1007.
 12 A. Thank you.
 13 Q. You read this paper in connection
 14 with your work on this case; is that right?
 15 A. Yes, I did.
 16 Q. Okay. This paper was coauthored
 17 by Charles Brenner, correct?
 18 A. I see that, yes.
 19 Q. And he is the sole inventor on the
 20 '086 patent, right?
 21 A. I know he is — yes, he's a sole
 22 inventor on the patent.
 23 Q. I'd like to direct your attention
 24 to the paragraph that bridges the first and
 25 second pages of the paper.

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1 that NR may not be in milk samples?
 2 A. I think I described it in my
 3 declaration, because NR can be degraded by many
 4 pathways. The known pathway is by bacterial
 5 and other microbes, such as fungi, are either a
 6 part of the milk or be contaminated with milk.
 7 And the literature article showed that such
 8 bacteria exists and such pathways exist.
 9 Q. But every single one of those
 10 articles also shows that despite some
 11 degradation, NR is present in the milk samples
 12 that were tested, right?
 13 MR. ABRAMIC: Objection to form.
 14 A. Again, that was only a few, very
 15 few, limited, papers talk about NR content in
 16 milk.
 17 Q. But in every single one of those
 18 papers, every single milk sample that was
 19 tested shows the presence of NR, correct?
 20 MR. ABRAMIC: Objection. Vague.
 21 A. Only one I could find, no more
 22 than ten papers, and all recent papers.
 23 Q. But is the answer to that question
 24 yes? Let me ask it again, because this is
 25 important and I want it to be clear.

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1 A. The first and second page?
 2 Q. Right. So it's the paragraph that
 3 begins, "It has long been known."
 4 A. Yes, I see that.
 5 Q. And then in the second sentence he
 6 says or the authors say, "More recently, it has
 7 been discovered that milk also contains
 8 nicotinamide riboside (NR), another salvageable
 9 NAD+ precursor vitamin."
 10 Do you see that?
 11 A. Yes, I see that sentence.
 12 Q. And you would agree with me that
 13 this article does not say that milk may or may
 14 not contain NR, right?
 15 A. Of course, as I said, it is based
 16 on the report that some milk tested has NR.
 17 That's the report that...
 18 Q. But the title of this article is
 19 "Nicotinamide Riboside is a Major NAD+
 20 Precursor Vitamin in Cow Milk," right?
 21 A. Yes. In science we leave lots of
 22 limitations or conditions out of a title, and
 23 also leave out of the paper, and that's why for
 24 the sake of easy to read. We can't have all
 25 the information in the title.

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1 **Q.** So you think that the only
2 conclusion that one can draw from this paper is
3 that there was NR in the particular samples
4 that were tested, and that's it?
5 **A.** Science is evidence based. So we
6 can only say that much. If we test a sample
7 and we see NR present in that sample, we can
8 say this sample contains NR.
9 **Q.** What does "bioavailable" mean?
10 **A.** Bioavailable means many things at
11 different contexts. Maybe you can give me the
12 context.
13 **Q.** Well, in the context of this
14 patent, I believe a few times in your testimony
15 you've used the phrase or the word "available"
16 in talking about NR, that you would be
17 interested in knowing whether or not the NR is
18 available.
19 So what does that mean to you,
20 when the NR is available?
21 **A.** "Available" to me means if it's
22 present and will convert or transport whatever
23 a process, right, we end up to the endpoint of
24 that process. If I have water in this bottle
25 that's available to me, I can drink it into my

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1 mouth. If it's closed, the cap is closed, it's
2 not available for me to drink.
3 **Q.** Okay. In your opinion, is the
4 nicotinamide riboside in milk orally
5 bioavailable?
6 MR. ABRAMIC: Objection. Vague.
7 **A.** I don't think there is evidence
8 that shows that.
9 **Q.** So you don't know one way or the
10 other?
11 **A.** I don't think there's evidence to
12 show the bioavailable of NR, if present in
13 milk, if it's available to humans, for example.
14 **Q.** Okay. Let me ask you a different
15 way. Let me start with a fundamental question.
16 Do you have an opinion -- this is
17 a yes or no question. Do you have an opinion
18 about whether nicotinamide riboside in milk is
19 orally bioavailable?
20 MR. ABRAMIC: Objection. Vague.
21 **Q.** That's just a yes or no question.
22 Let's first see if you have an opinion on it.
23 **A.** Based on this evidence I've seen
24 so far, I think NR is not available.
25 **Q.** Okay. So you do have an opinion,

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1 and you believe that NR in milk is not
2 bioavailable?
3 **A.** It may not be available.
4 **Q.** I want to make sure that I
5 understand the "may" part of this. Is it your
6 opinion that NR is not bioavailable in milk or
7 may not be bioavailable in milk?
8 MR. ABRAMIC: Objection.
9 **A.** There's no evidence to show either
10 way.
11 **Q.** So what's the answer to the
12 question?
13 **A.** What's the question again? Sorry.
14 **Q.** Sure. Is it your opinion that the
15 NR in milk is not orally bioavailable?
16 MR. ABRAMIC: Objection. Vague.
17 **Q.** That's a yes or no question.
18 MR. ABRAMIC: Vague. Asked and
19 answered.
20 MR. YOUNKIN: We didn't get a
21 clear answer.
22 MR. ABRAMIC: You're trying to
23 make him answer yes or no to a vague
24 question. You can't dictate what his
25 answer is going to be to your question.

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1 **Q.** Is it your opinion that the NR in
2 milk is not orally bioavailable?
3 MR. ABRAMIC: Same objection.
4 **A.** As an expert witness here and a
5 scientist, my opinion only comes from
6 scientific evidence. There's no scientific
7 evidence to show either way NR in milk is
8 bioavailable or not.
9 **Q.** Okay. So then is it your opinion
10 that the NR in milk may or may not be orally
11 bioavailable?
12 MR. ABRAMIC: Same objection.
13 **A.** So based on the evidence, yes,
14 there's no evidence to show either way.
15 **Q.** Okay.
16 **A.** In milk, NR in milk.
17 **Q.** And what is the basis for your
18 opinion that the NR in milk may not be orally
19 bioavailable?
20 **A.** So first, as a scientist, there's
21 a well-established experimental procedure or a
22 set of experimental procedures to test whether
23 a molecule in the mixture is bioavailable. In
24 this case, whether NR in milk is bioavailable.
25 I don't feel pretty clearly that

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1 that experiment has not been conducted, and
 2 then whether the experiment has been conducted,
 3 has not been exclusively show whether NR is
 4 available or not.
 5 Furthermore, there is experimental
 6 evidence shown in this paper suggests NR may
 7 not be bioavailable.
 8 **Q.** Okay. Let's start with the first
 9 part of that answer. What is the nature of the
 10 well-established experimental procedure to test
 11 whether a molecule in a mixture is
 12 bioavailable?
 13 **A.** There's many experiments, and all
 14 the single set of experiments can have caveats.
 15 So that's why we often need multiple sets of
 16 experiments. So just to give you one limited
 17 set of experiments I can think about now.
 18 One has to establish NR is present
 19 in milk, and then we have to label it, to
 20 distinguish that from some other precursors of,
 21 for example, NAD. Then we can use, perhaps,
 22 NAD as an endpoint reading to see whether NR
 23 uptake by human and then convert to NAD+. It's
 24 just one possible experiment one can do.
 25 **Q.** The second part of your answer

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1 stated that there is experimental evidence
 2 shown in this paper, referring to Trammell 1, I
 3 believe, that suggests that NR may not be
 4 bioavailable.
 5 Can you explain what you mean by
 6 that?
 7 **A.** Yes. So the evidence suggests
 8 that NR in milk may not be bioavailable, as
 9 described in my declaration. One piece of
 10 evidence is from this paper shown that in
 11 Figure 2, that NR, NR added to milk, that shows
 12 NR binds to certain components in milk, and
 13 often there's been quite a lot of time
 14 discussed of this fact.
 15 So once a molecule binds to what's
 16 also called protective factor, I think, in the
 17 paper, and that is evidence that suggests that
 18 once you bind the molecule, NR binds to
 19 multiple molecules, the nature of the molecule
 20 NR binds to remains unclear, based on this
 21 paper.
 22 So that evidence suggests to me,
 23 very strong evidence, that NR may not be
 24 available to human, for example.
 25 **Q.** Okay. So the way that this

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1 experiment worked is they had samples of milk,
 2 and then they added NR to the samples; is that
 3 right?
 4 **A.** Yes. They prepared an NR molecule
 5 and added to milk.
 6 **Q.** And then they showed the NR bound
 7 to the milk, right?
 8 **A.** Yes.
 9 **Q.** And you conclude from that that
 10 the data may show that NR is not bioavailable
 11 in milk, right, because of the binding?
 12 **A.** Yeah, because of the binding of NR
 13 to a component of milk suggests that NR in milk
 14 may not be bioavailable.
 15 **Q.** Did the authors of Trammell 1
 16 articulate any conclusions about the
 17 bioavailability of NR in milk?
 18 **A.** I think they mentioned that in
 19 some of the texts, and I disagree with their
 20 statement it's available, because they haven't
 21 conducted experiments I mentioned earlier to
 22 really firmly establish that it is available.
 23 **Q.** So you agree with me that the
 24 authors of Trammell 1 concluded that the NR in
 25 milk is orally bioavailable, correct?

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1 **A.** I cannot recall exactly whether
 2 they mentioned the bioavailability in the
 3 paper. I think they mentioned that. But they
 4 have no experiment to conclude that.
 5 If they ever say something about
 6 that, they are a hypothesis, not a summary of
 7 experimental data.
 8 **Q.** Let's look at the last paragraph
 9 of Trammell 1.
 10 **A.** In the text?
 11 **Q.** In the "Discussion" section. I'd
 12 like to direct your attention to the middle
 13 sentence of the very last paragraph. I'll read
 14 it.
 15 "The ability of milk to bind and
 16 preserve the integrity of NR makes dairy
 17 products potentially good sources of
 18 supplemented NR."
 19 Do you see that?
 20 **A.** Yes.
 21 **Q.** Do you disagree with that
 22 statement?
 23 **A.** I think he's a careful scientist.
 24 He used the word "potentially good sources." I
 25 can read the sentence again. "The ability of

<p style="text-align: right;">Page 62</p> <p>1 milk to bind and preserve the integrity of NR 2 makes dairy products potentially good sources 3 of supplemented NR." 4 Before I go to the word 5 "potentially," I want to just go back one step. 6 So all the experiment has done is NR was added 7 to the milk. He didn't do any experiment about 8 what NR in the milk sample they studied. So 9 that's a caveat we need to be mindful of. I 10 think they are mindful of that as well. 11 So here that word they use 12 "potentially good sources." So they haven't 13 demonstrated in this paper, in my view, 14 scientific evidence that NR in milk is a source 15 of supplement NR at all. So that's why they 16 use the word "potentially," because there's no 17 evidence. 18 Q. But the authors of the article 19 concluded that the binding that they observed 20 was potentially beneficial to the oral 21 bioavailability of milk, correct? 22 MR. ABRAMIC: Objection to form. 23 A. So I need to go back to this one, 24 because this is an important point. 25 First, whether they ever studied</p>	<p style="text-align: right;">Page 64</p> <p>1 two molecules. 2 So the data presented by NMR here 3 to me quite clearly shows the binding or 4 interaction between NR with a known component 5 in the milk. 6 Q. Are you aware of any publication 7 stating that NR in milk is not orally 8 bioavailable? 9 A. As I said, I'm not aware of any 10 study that's been done about NR in milk, the 11 bioavailability. So I don't think there's any 12 evidence to say anyway. I'm not aware of any 13 literature or report of bioavailability of NR 14 in milk. 15 Q. Did you review the prosecution 16 history of the '086 patent? 17 A. I was not asked to review that. I 18 don't remember being asked to review that. 19 That's in a file I may have read somewhere, but 20 I don't remember I was asked to review the 21 file. 22 Q. You understand the prosecution 23 history means the back and forth between the 24 patent applicant and the patent office in the 25 process of getting a patent, right?</p>
<p style="text-align: right;">Page 63</p> <p>1 NR added to the milk, it's not NR present in 2 the milk. So there's a big caveat there. 3 The second one is, they use the 4 word "preserve the integrity of NR." I'm not 5 even sure of the word "preserve the integrity 6 of NR" was accurate, because the chemical shift 7 may actually change the structure of NR. 8 Q. So you disagree with this 9 statement, right? 10 MR. ABRAMIC: Objection to form. 11 A. They are very good scientists. 12 They use the word "potentially." So that 13 suggests to me this is a hypothesis. It would 14 be first tested, and based on the scientific 15 evidence, and this potential may not be true. 16 It may be true, but you need evidence to 17 support that in the future. 18 Q. Are you aware of any data 19 correlating NMR data, like the data shown in 20 Figure 2, with the bioavailability with a 21 nutrient? 22 A. I cannot recall an exact NMR 23 experiment to link bioavailability of nutrient 24 by NMR study. An NMR study here is a common 25 tool to study binding or interaction between</p>	<p style="text-align: right;">Page 65</p> <p>1 A. Yes. 2 Q. I will point out that the 3 prosecution history was marked as an exhibit 4 earlier in the case, but it may not have been 5 cited earlier, so let me just give it to you. 6 This is Exhibit 1003. 7 What I'd like to do is direct your 8 attention to Page 133 of this exhibit. Let's 9 start on Page 132. 10 MR. ABRAMIC: I want to make the 11 record clear. Are you suggesting that 12 this is a file history for this patent? 13 MR. YOUNKIN: This is a file 14 history for the patent application from 15 which this is a continuation of. 16 MR. ABRAMIC: Okay. I just wanted 17 to make the record clear. 18 Q. Do you see on Page 132, there's 19 what's called a Rule 132 declaration? Do you 20 see that? 21 A. I see Rule 132 declaration. 22 Q. And then if you turn to Page 135, 23 you'll see that it's signed by Dr. Charles 24 Brenner? 25 A. Yes, I see his signature here.</p>

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1 Q. Okay. Have you reviewed this
 2 declaration before? Have you seen this before?
 3 A. I cannot recall exactly now
 4 whether I reviewed this. I did remember
 5 reviewing a declaration by Dr. Brenner.
 6 Q. Okay. Why don't you take a minute
 7 to take a look at it, and see if it refreshes
 8 your recollection about whether you reviewed
 9 this before.
 10 A. The whole document?
 11 Q. No, no. It's just on Page 132 to
 12 135.
 13 A. Okay. This is what I can recall
 14 now. I remember, as I recall, I see data
 15 similar to Figure 1 and Figure 2. I cannot
 16 recall exactly what this document formats or
 17 not, but I see some data similar to this.
 18 Q. Do you see in this declaration Dr.
 19 Brenner explains that he prepared compounds of
 20 nicotinamide riboside in milk; is that right?
 21 A. I see that, yeah, on Page 132, he
 22 mentioned each compound was prepared in 20
 23 milliliter of lactaid milk.
 24 Q. And then he writes in Figure 1, "I
 25 show that nicotinamide riboside is stable for

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1 at least 24 hours at room temperature in milk,"
 2 right?
 3 A. Yes, I see that.
 4 Q. Okay. And then in Paragraph 3, he
 5 says, "Each formulation was ingested by a human
 6 subject"?
 7 A. Yes.
 8 Q. And in Paragraph 5, at the end, he
 9 concludes from the experimental data that NR is
 10 orally bioavailable, correct?
 11 A. Where?
 12 Q. In Paragraph 5 he says, "From the
 13 confirmatory data provided herein, it can be
 14 concluded that NR is detectable in plasma, NR
 15 increases within the first ten minutes after
 16 ingestion, and NR unexpectedly is more orally
 17 available than nicotinamide to produce NAD and
 18 NADP in white blood cells in the 80-minute
 19 experiment."
 20 Do you see that?
 21 A. Yes. That's what I explained
 22 before. In this case he labeled NR and NR was
 23 added to the milk. So what the data really
 24 showed here is NR added to the milk is orally
 25 available shown on this experiment or NR added

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1 to the milk is not -- may or may not be the
 2 same NR originally present in the milk. That's
 3 why the experiment is not conclusive.
 4 Q. But the binding that was shown in
 5 the Trammell paper that we just discussed did
 6 not interfere with the bioavailability of the
 7 NR in milk, correct?
 8 MR. ABRAMIC: Objection to form.
 9 A. I'm not sure that's the same milk
 10 or not. Again, in that experiment and in this
 11 study, both NR are added to the milk. I just
 12 want to make sure that's clear, that NR was
 13 added to the milk, and that's different than NR
 14 in the milk.
 15 Q. I understand that. I'm asking
 16 about the binding. I understood you to be
 17 suggesting that the Trammell article showed
 18 binding, and that you thought that the binding
 19 might interfere with the oral bioavailability
 20 of milk; is that right?
 21 A. Might, yes.
 22 Q. And the Brenner declaration shows
 23 that the binding of -- any binding that occurs
 24 between milk and the added NR does not
 25 interfere with the oral bioavailability of NR?

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1 MR. ABRAMIC: Objection to form.
 2 Vague.
 3 A. No. The data shows here is more
 4 orally available than nicotinamide. NR is more
 5 orally available than nicotinamide.
 6 I need to go back and look back at
 7 this more carefully whether they had done that.
 8 The question is whether NR binds the milk is
 9 still available, but maybe less available,
 10 whether it interferes with the availability. I
 11 need to go back and look at the data.
 12 But the statement here, if I just
 13 restate his statement, is more orally available
 14 than nicotinamide.
 15 So what he said there, binding may
 16 not prevent from being available, but whether
 17 binding interfered with availability, I don't
 18 know whether from the data that shows that or
 19 not.
 20 Q. The binding did not destroy the
 21 bioavailability, correct?
 22 A. The looks from this data shows
 23 that, yes, the added NR.
 24 Q. This is a new exhibit that we're
 25 marking. We've labeled it 1025.

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1 (Document marked as Exhibit 1025
 2 for identification)
 3 **Q.** So we've given you a document
 4 that's been labeled Exhibit 1025. It's an
 5 article by Katrina Bogan and Charles Brenner
 6 entitled "Nicotinic Acid, Nicotinamide, and
 7 Nicotinamide Riboside: A Molecular Evaluation
 8 of NAD+ Precursor Vitamins in Human Nutrition."
 9 Do you see that?
 10 **A.** I see that.
 11 **Q.** Is this a document you've ever
 12 read before?
 13 **A.** As I said, I don't recall whether
 14 I read this specific article. I was aware of
 15 Dr. Brenner's work.
 16 **Q.** Okay. I'd like to turn your
 17 attention to a sentence in here in particular,
 18 and see whether you agree with it or not. So
 19 this is on Page 11 of the paper.
 20 **A.** Page 11 of the paper?
 21 **Q.** Yes. Do you see there's a section
 22 called "Prospects for NR as a Supplement"?
 23 **A.** Yes, I see that section.
 24 **Q.** Okay. The second sentence of that
 25 section says, "Like Na and Nam, NR is a natural

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1 product found in milk, which is incorporated
 2 into the intracellular NAD+ pool, and thus
 3 could be used as a general supplement,
 4 potentially for people who have adverse
 5 reactions to Na or Nam."
 6 Do you see that?
 7 **A.** I see that sentence.
 8 **Q.** Okay. Do you agree with that
 9 sentence?
 10 **MR. ABRAMIC:** Objection. Form.
 11 **A.** Not completely. As I said,
 12 there's a certain set of experiments. So
 13 there's a lot of limitation of this statement
 14 not expressed here. There are certain steps
 15 that can be done more to the nature of the NR
 16 or NR environment not mentioned here. So
 17 there's lots of steps.
 18 This particular statement there's
 19 some leap of steps in here. It can be true if
 20 only certain conditions are included in this
 21 statement.
 22 **Q.** And what conditions need to be
 23 included?
 24 **A.** There's lots of things. For one
 25 is, I mentioned before, whether NR is naturally

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1 present in milk, if it's there, whether it's
 2 bioavailable, there's no data to show that.
 3 When NR is released from milk,
 4 which people have done this by harsh treatment
 5 to milk, that NR outside of the environment of
 6 milk has been shown -- or even added back to
 7 milk -- has shown to be bioavailable.
 8 But if you show NR in the milk is
 9 incorporated into intracellular NAD+ pool as
 10 people or human, I don't think such experiments
 11 have been conducted. So that conclusion cannot
 12 be drawn or maybe the statement should be more
 13 -- has more limitation to it.
 14 **Q.** I'd like to draw your attention to
 15 the Goldberger article that's the subject of
 16 your declaration, but I can give you a copy of
 17 it.
 18 Do you recall whether or not the
 19 Goldberger article discusses how the milk that
 20 was given to the dogs was prepared?
 21 **A.** Maybe I should see that. I
 22 remember one of the articles, there are two
 23 Goldberger articles. One is Goldberger and
 24 Goldberger and Tanner. One of the articles I
 25 can recall is mentioned such like homemade,

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1 fresh made. I cannot recall exactly which
 2 paper it was mentioned or mentioned in both
 3 papers.
 4 **Q.** Okay. Let's look at this one, the
 5 one that I've given you. This is 1005. And
 6 let's look at Page 20 of 71.
 7 **A.** We refer to this as Goldberger,
 8 right or Goldberger or Tanner?
 9 **Q.** This one is just Goldberger.
 10 **A.** On Page 20?
 11 **Q.** 20 of 71.
 12 **A.** This is for a dog?
 13 **Q.** Correct. You'll see that in
 14 experiment 7, he says that it was a test of
 15 fresh skim milk, right?
 16 **A.** Yes.
 17 **Q.** And he goes on to say, "The milk
 18 when delivered to us was freshly separated,"
 19 right?
 20 **A.** Yes.
 21 **Q.** And he said that "this milk in a
 22 two-quart glass jar was allowed to stand in an
 23 icebox for not more than 24 hours before being
 24 used," right?
 25 **A.** Yes.

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1 **Q.** Is it your opinion that
2 contaminants in the milk used by Goldberger
3 completely degraded the NR in the milk during
4 this 24-hour period?
5 MR. ABRAMIC: Objection. Form.
6 **A.** There's no determination or
7 experiment that was done to determine whether
8 NR was present, and there's no experiment
9 reporting this whether NR -- whether it's being
10 degraded or being measured in this paper.
11 **Q.** And without such experiments, you
12 can't say one way or another whether or not the
13 NR was present in the milk; is that right?
14 **A.** There's no experiments that were
15 done to measure NR content.
16 **Q.** And because of that, you cannot
17 say one way or another whether or not there was
18 NR in milk; is that right, NR in the milk?
19 **A.** As I said, there's no measurement.
20 **Q.** I know that you know there wasn't
21 a measurement. I'm trying to understand the
22 implication of that on your opinion.
23 So because there was no
24 measurement, it's your opinion, is it not, that
25 you cannot say one way or another whether or

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1 not the milk that was used in this experiment
2 contained NR?
3 **A.** Right, I cannot say whether the
4 milk contains NR. I cannot say how much of
5 degradation of NR occurs under these
6 conditions. It can still occur, because ice,
7 microbes, can still act on NR if NR is there.
8 **Q.** Do you recall that we saw in the
9 Brenner declaration that was filed in the
10 patent office that Brenner reported that
11 nicotinamide riboside is stable for at least 24
12 hours at room temperature in milk?
13 **A.** In what milk? In the lactaid
14 milk?
15 **Q.** Well, he doesn't say what milk.
16 He says in milk.
17 **A.** He said lactaid milk. I'm not
18 sure what source of lactaid milk. Can I go
19 back?
20 **Q.** Sure. It's Exhibit 1003, Page
21 132.
22 **A.** As I said, here it says only 20
23 mLs of lactaid milk. I'm not sure what's the
24 source of lactaid milk. Is that from a store
25 or from a farm. I'm not sure exactly what

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1 lactaid milk is.
2 **Q.** But the sentence about stability
3 is, "I show nicotinamide riboside is stable for
4 at least 24 hours at room temperature in milk,"
5 right?
6 **A.** This means the milk, in
7 particular, lactaid milk.
8 **Q.** That's not what he says, right?
9 **A.** This is how scientist state,
10 because given the context, when we say milk, it
11 doesn't mean every milk. It means the milk he
12 uses in this experiment. That's the only thing
13 we can say in science.
14 Right here, in milk, this milk is
15 the lactaid milk they use in the experiments.
16 **Q.** I'm going to give you a new
17 exhibit. This is 1023.
18 (Document marked as Exhibit 1023
19 for identification)
20 **A.** So to answer your question --
21 **Q.** There's no question pending.
22 So we've given you a new document
23 that has been marked 1023. I'll just direct
24 your attention to the first page. This is a
25 document that was submitted with the Food and

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1 Drug Administration.
2 **A.** I don't recall...
3 **Q.** You haven't seen these.
4 **A.** Okay.
5 **Q.** But just to sort of orient you a
6 little bit, this is a document that was
7 submitted to the Food and Drug Administration
8 by ChromaDex.
9 **A.** Okay.
10 **Q.** Have you ever been involved in
11 these sort of regulatory filings in the course
12 of your work?
13 **A.** Not from my work, but I work with
14 a pharmaceutical company, and also in the other
15 lawsuits, I have seen some of these documents.
16 **Q.** Okay. I'd like to turn your
17 attention to Page 22 of this document, using
18 the typed in numbers.
19 **A.** The very bottom one?
20 MR. ABRAMIC: The bottom right.
21 **Q.** I'm sorry, I meant the times new
22 Roman in the center. It has been stamped 35.
23 The stamping was not done by us. This is how
24 the document existed as FDA.
25 **A.** Okay.

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1 **Q.** So you can see that in this
2 section, it's called "History of Use and
3 Intended Use," right?
4 **A.** Yes.
5 **Q.** And the first section is "History
6 of Use: Natural Occurrence of Nicotinamide
7 Riboside (NR) in Foods and Dairy Products,"
8 right?
9 **A.** Yes, I see that.
10 **Q.** And if you skip down to the third
11 sentence, this document that was filed with the
12 FDA says, "Moreover, NR levels in milk do not
13 change significantly when milk is stored at
14 room temperature for 24 hours (Brenner,
15 unpublished)."
16 Do you see that?
17 **A.** Yes, I see that.
18 **Q.** Okay. And there's nothing in this
19 statement that limits the stability to lactaid,
20 for example, right?
21 **A.** Again, any kind of statement like
22 this, this otherwise is not scientific. It
23 only applies to the milk samples it tested. If
24 they haven't tested, you cannot do that. We
25 don't know actually what happened to the milk

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1 that was processed.
2 I actually spent some time to
3 learn about the milk industry myself during
4 this course. The milk process varies
5 dramatically from years back, a different
6 process of treatment.
7 So this is very important, because
8 I think their document shows in milk NR could
9 be degraded by bacteria. So there are reports
10 of that. So milk contamination, we know that's
11 an issue, milk recalls in this country.
12 So the statement only
13 scientifically means the milk has been tested.
14 There's a supplemental material somewhere with
15 the FDA filing and they have to tell where the
16 milk is from and they have to tell the history
17 of the samples, the history of the store, from
18 what vendor, maybe which cow to some degree.
19 **Q.** That's not what they are saying to
20 the FDA. They are saying to the FDA that
21 relying on Brenner's unpublished data, they're
22 telling FDA that NR levels in milk do not
23 change significantly when milk is stored at
24 room temperature for 24 hours.
25 **A.** So for this one, there will be an

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1 FDA examiner, and I am familiar with this
2 process. The sample history has to be
3 documented where this milk is from, how that
4 process, it should be documented. If it were
5 not documented, I'm sure the FDA examiner will
6 ask that. So the information may be in this
7 document or other documents.
8 **Q.** Let me ask you this question,
9 then. Is it your opinion that one could never
10 make the broad statement that NR levels in milk
11 do not change significantly when milk is stored
12 at room temperature for 24 hours?
13 **MR. ABRAMIC:** Objection to form.
14 **A.** I should not make that broad
15 statement. One can say if this milk, for
16 example, the exhaustive tests of a sample meet
17 a certain FDA requirement, for example, just
18 give example, one company has an FDA approved
19 or agriculture department approved the process,
20 and they have all of these monitoring processes
21 in place, and refrigeration and such,
22 conditions like that are met, then we have some
23 certainty that such milk also had been tested
24 for stability of NR in that milk, and then this
25 statement there's always a limitation

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1 associated with such a statement.
2 If I have my own milk cow in my
3 farm, I would not make that statement to my cow
4 unless I tested or I have literature report of
5 a cow or any cow or the cow raised my way in my
6 such environment in Massachusetts, in
7 Wellesley, back yard or Newton for that matter,
8 right, and meet that requirement, otherwise I
9 won't make that statement. I won't extrapolate
10 this information to the cow in my back yard,
11 for example.
12 **Q.** The first sentence of this section
13 says, "Humans are exposed to NR via dietary
14 sources such as milk."
15 Do you see that?
16 **A.** So this in general. If NR in some
17 milk, as we know that. So human -- some people
18 don't drink milk. Some humans are never
19 exposed to NR in milk. They're intolerant. So
20 some humans exposed to some milk which may have
21 NR and that's what the statement about.
22 If a human is exposed to some milk
23 and that milk has NR, that's a statement. It
24 doesn't say everybody has been exposed to milk,
25 right. So not every single human being has

<p style="text-align: right;">Page 82</p> <p>1 been exposed to NR in milk. 2 Q. But the sentence, does it say some 3 humans are exposed to milk which may or may not 4 contain NR, right? 5 A. That's really what it says, right. 6 Q. Well, that's not what it says. It 7 says, "Humans are exposed to NR via dietary 8 sources such as milk," right? 9 A. As an FDA examiner, as a 10 scientist, that's how the sentence should be 11 interpreted. 12 Q. Okay. Let's look at the last 13 sentence of this section or before the table. 14 "Thus, the estimated amount of NR ingested by 15 humans from the equivalent of 710 milliliters 16 per day (three cups) of cow's milk, is 17 approximately" 345 "micrograms per day," right? 18 MR. ABRAMIC: I think it says 19 "545." 20 Q. Oh, yes. 545. Sorry. 21 A. Yes. That's the statement. 22 Q. So the statement is extrapolating, 23 right, and drawing a conclusion about the 24 amount of NR ingested by humans when they drink 25 three cups of cow's milk, right?</p>	<p style="text-align: right;">Page 84</p> <p>1 their evidence in humans, yes, prevents 2 pellagra. 3 Q. And do you agree that black tongue 4 reflects a deficiency in NAD as well? 5 A. Just from reading. I even know 6 less about the chemistry of NAD in dogs. 7 Q. But based on your reading of the 8 literature, that's your understanding, correct? 9 A. Yes. 10 Q. And do you agree Goldberger 11 concluded that skim milk contains the 12 quote/unquote black tongue preventative? 13 A. Yes, that's his statement. 14 Q. And that's because there's 15 something in the milk that increased NAD 16 biosynthesis, right? 17 A. That's the hypothesis. They may 18 be working through another mechanism, but at 19 least that's one of the hypothesis accepted by 20 people and by reading the paper, I agree with 21 that as well. 22 Q. And do you also agree with the 23 hypothesis that the buttermilk that was used in 24 the Goldberger and Tanner article prevented 25 pellagra because something in that buttermilk</p>
<p style="text-align: right;">Page 83</p> <p>1 A. Yes, it's about. We know or you 2 know we have documents that shows different 3 milk, organic and different vendors of milk 4 have different amounts of NR. So this is 5 about. That's why it says "about" there. 6 MR. YOUNKIN: Why don't we take a 7 break. 8 (Recess taken at 11:02 a.m. and 9 reconvening at 11:19 a.m.) 10 BY MR. YOUNKIN: 11 Q. Dr. Zhou, do you agree that 12 pellagra is caused by a deficiency in NAD+? 13 A. I'm not a medical doctor. That's 14 my understanding, deficiency of NAD is at least 15 linked to pellagra. I'm not exactly sure it's 16 causing that or not. 17 Q. But it's linked? 18 A. It's linked. 19 Q. So pellagra reflects an NAD 20 deficiency, correct? 21 A. I think so, yes. 22 Q. And do you agree that the 23 Goldberger and Tanner article concluded that 24 buttermilk prevents pellagra? 25 A. Yes. I looked at a paper and see</p>	<p style="text-align: right;">Page 85</p> <p>1 increased NAD+ biosynthesis? 2 A. Very likely that's the mechanism, 3 yes. 4 MR. YOUNKIN: I have no further 5 questions. 6 MR. ABRAMIC: I have no questions. 7 (Whereupon the deposition 8 concluded at 11:21 a.m.) 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>

<p style="text-align: right;">Page 86</p> <p style="text-align: center;">CERTIFICATE OF DEPONENT</p> <p>I hereby certify that I have read the foregoing pages of my deposition testimony in this proceeding, and with the exception of changes and/or corrections, if any, find them to be a true and correct transcription thereof.</p> <p style="text-align: center;">_____ Deponent</p> <p style="text-align: center;">_____ Date</p> <p style="text-align: center;">NOTARY PUBLIC</p> <p>Subscribed and sworn to before me this _____ day of _____, 20__.</p> <p style="text-align: center;">_____ Notary Republic</p> <p>My Commission Expires: _____</p>	<p style="text-align: right;">Page 88</p> <p style="text-align: center;">ERRATA SHEET</p> <p>PAGE -- LINE -- CORRECTION/REASON</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>
<p style="text-align: right;">Page 87</p> <p style="text-align: center;">ERRATA SHEET</p> <p>PAGE -- LINE -- CORRECTION/REASON</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>	<p style="text-align: right;">Page 89</p> <p style="text-align: center;">ERRATA SHEET</p> <p>PAGE -- LINE -- CORRECTION/REASON</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>

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SUFFOLK, SS.
I, Michael O'Connor, Registered
Merit Reporter/Certified Realtime Reporter,
and Notary Public in and for the
Commonwealth of Massachusetts, do hereby
certify:
That ZHAOHUI SUNNY ZHOU, Ph.D., the
witness whose testimony is hereinbefore set
forth, was duly sworn by me and that such
testimony is a true and accurate record of
my stenotype notes taken in the foregoing
matter to the best of my knowledge, skill
and ability.
IN WITNESS WHEREOF, I have hereunto
set my hand and Notarial Seal this 2nd day
of August 2018.

MICHAEL O'CONNOR, RMR, CRR, CRC
Notary Public
My Commission expires: November 22, 2022

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CERTIFICATE OF DEPONENT

I hereby certify that I have read the foregoing pages of my deposition testimony in this proceeding, and with the exception of changes and/or corrections, if any, find them to be a true and correct transcription thereof.



Deponent



Date

NOTARY PUBLIC

Subscribed and sworn to before me this

_____ day of _____, 20__.

Notary Republic

My Commission Expires: _____

ERRATA SHEET

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PAGE	LINE	CORRECTION/REASON	
<u>9</u>	<u>22</u>	<u>change "invite minutes" to "in vitamins"</u>	transcription error
<u>21</u>	<u>25</u>	<u>change "law, a" to "law, in a"</u>	transcription error
<u>26</u>	<u>18</u>	<u>change "fact" to "effects"</u>	transcription error
<u>55</u>	<u>12</u>	<u>change "bioavailable" to "bioavailability"</u>	transcription error
<u>57</u>	<u>25</u>	<u>change "don't" to "do"</u>	transcription error
<u>62</u>	<u>25</u>	<u>change "whether they ever studied" to "what they studied was"</u>	transcription error
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