

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARLA FOODS AMBA,

Petitioner

v.

LEPRINO FOODS COMPANY,

Patent Owner.

IPR2025-01199
Patent 11,825,860

VIDEO DEPOSITION OF FEDERICO HARTE, Ph.D.
June 26, 2026

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ALSO PRESENT: Houston Woodhouse
Videographer

Pursuant to Notice, the Video Deposition of
 FEDERICO HARTE, Ph.D. taken on June 26, 2026
 at 1400 Wewatta Street, Suite 600, Denver,
 Colorado, commencing at 9:14 AM Mountain
 Time before Annie Sager, Court Reporter and
 Notary Public within and for the State of
 Colorado.

Examination by Ms. Kaiser: 5, 172

Examination by Mr. Krieger: 158

EXHIBIT 1 Dr. Harte Curriculum Vitae 9

EXHIBIT 2 U.S. Patent Application
 Publication US 2019/0274331 A1 59

P R O C E E D I N G S

THE VIDEOGRAPHER: Good morning.

We are on the record. The time is 9:14 AM
June 26th, 2026. We are here today for the
videotaped deposition of Dr. Federico Harte.
The case is being held in the United States
Patent and Trademark Office.

The case caption is Arla Foods
AMBA v. Leprino Foods Company and the docket
number is IPR2025-01199. Today we are
located at 1400 Wewatta Street, Suite 600,
Denver, Colorado, 80202. The court
reporter, Annie Sager. Legal videographer,
Houston Woodhouse. Starting with the
plaintiff's counsel please state your
appearances.

MS. KAISER: I am Jessica Kaiser.
I am counsel for the Petitioner Arla and
with me today is Yuanfeng Gao.

MR. KRIEGER: And Justin Krieger
on behalf of Patent Owner Leprino Foods
Company and with me are Megan Saia,
Alexa Hunter and Kameron Klugh.

(OATH TAKEN.)

FEDERICO HARTE, Ph.D.

1 a witness in the above-entitled matter,
2 after having been first duly sworn,
3 testified under oath as follows:

4 EXAMINATION

5 BY MS. KAISER:

6 Q Good morning, Dr. Harte.

7 A Good morning.

8 Q Can you state your full name for the
9 record, please.

10 A My full name is Federico Miguel Harte.

11 Q And you are currently a professor at
12 Penn State, is that correct?

13 A Well, now I'm starting June 15th I took
14 a leave for a year, but at the time of the
15 declaration I was faculty full-time at Penn State
16 University.

17 Q Okay. It looks like you have some
18 documents with you today.

19 A Yeah.

20 Q Can you let me know what those documents
21 are.

22 A Yeah. I have here with me my
23 declaration. Patent '860. Then I have
24 Bertelsen's patent. I also have the manuscript by
25 Kawasaki. I have a white paper by LeanCreme.

1 Q Is that LeanCreme?

2 A LeanCreme, yeah, sorry, LeanCreme. And
3 then a manuscript by Ozturk.

4 Q And I see that your declaration I think
5 that you have with you it has some tabs in it.

6 A Yeah, yeah, it does, yeah.

7 Q Did you add those tabs?

8 A I added those tabs, yeah.

9 Q Okay. Other than the tabs that are on
10 there are there any other markings or notes in
11 your declaration that you have with you?

12 A Not in my declaration.

13 Q Okay.

14 Are there any notes in the '860 patent
15 that you have with you today?

16 A No. None of the documents have any
17 notes.

18 Q None of the documents that you have with
19 you have any notes?

20 A Well, I have this little notepad with
21 some corrections that I found -- typos that I
22 found in my declaration, yeah.

23 Q Okay. Counsel, can we have a copy of
24 the notes that he brought with him?

25 MR. KRIEGER: Absolutely.

1 BY MS. KAISER:

2 Q Okay. All right.

3 Have you ever been an expert witness in
4 a legal proceeding before?

5 A No.

6 Q And have you ever sat for a deposition
7 before?

8 A No.

9 Q Have you ever been involved in any sort
10 of court proceeding in any way?

11 A No.

12 Q So since this is the first time sitting
13 for a deposition I am just going to give you some
14 ground rules so that we know how to conduct
15 ourselves during this.

16 As you can see, the court reporter is
17 taking down everything that anyone says during the
18 deposition, and that's important so that we can
19 have a clear record, so it's important for you to
20 give audible answers, so yes/no instead of nodding
21 your head.

22 Do you understand that?

23 A Yes.

24 Q Okay. And it's also important for us
25 not to talk over each other. Oftentimes in

1 regular conversations there's a quick kind of give
2 and take, but in deposition it's important for you
3 to let me finish my question before you answer and
4 for me to let you finish your answer before you
5 start -- or before I start talking again.

6 Does that make sense?

7 A I understand.

8 Q Okay.

9 From time to time your counsel
10 Mr. Krieger may object to my questions. That just
11 preserves his objections for the record, so it's
12 important for you to pause and let him make his
13 objections, again, so we don't talk over each
14 other.

15 Does that make sense?

16 A Makes sense.

17 Q And then also in regard to his
18 objections do you understand that you are still
19 required to answer the question even if he objects
20 to it as long as he doesn't instruct you not to
21 answer?

22 A I do understand.

23 Q I will do my best to ask clear
24 questions, but obviously there is a lot of
25 technical terms here and I am not a food scientist

1 by training like you are, so will you let me know
2 if you don't understand a question that I ask you?

3 A Of course, yeah.

4 Q Let's see. So we will also take breaks
5 during the deposition. I will try to take one
6 about every hour. If you need a break more often
7 than that though you can let me know. I will just
8 generally ask you to answer a question if it's
9 pending before we take a break.

10 Is that okay?

11 A I understand, yeah.

12 Q Is there any reason you cannot give
13 truthful and complete testimony today?

14 A No.

15 Q Are you on any medications that would
16 affect your ability to testify today?

17 A No.

18 (EXHIBIT 1 MARKED.)

19 Q I am going to mark an exhibit. We will
20 call this Harte Exhibit Number 1.

21 THE COURT REPORTER: One moment.

22 Okay. Go ahead.

23 A Before we start with the questioning, is
24 it okay if I just go through these typos just to
25 make sure that they are there?

1 Q We will get to a point where we turn to
2 your declaration.

3 A Okay.

4 Q And I will ask you to give me
5 corrections then.

6 A Perfect. Thank you.

7 Q Okay. So Dr. Harte, you have been
8 handed an exhibit that's been marked as Harte
9 Exhibit 1. Do you recognize it?

10 A Yep.

11 Q What is it?

12 A It seems to be my -- let's see. It
13 seems to be a summary of my CV with my
14 publications or some of the publications. I guess
15 this is coming from the website actually from
16 Penn State's website.

17 Q And so this is -- your understanding is
18 that Harte Exhibit 1 is a print-out of your
19 profile on the Penn State website, is that
20 correct?

21 A That is correct, yeah.

22 Q And on the first page of Harte Exhibit 1
23 it lists that you have a BS from the University of
24 Uruguay in agricultural engineering, is that
25 correct?

1 A That is correct, yep.

2 Q What year did you receive that BS
3 degree?

4 A That would be 1996 if memory -- yeah.

5 Q The same year I graduated from college.
6 And then also on Harte **Exhibit 1** it lists that you
7 have a Ph.D. from Washington State University in
8 biological systems engineering, is that correct?

9 A That is correct.

10 Q What year did you receive your Ph.D.?

11 A That is 2002.

12 Q And other than the BS and the Ph.D. that
13 I just asked you about do you have any other
14 post-secondary degrees?

15 A I do not.

16 Q When you got your Ph.D. in biological
17 systems engineering did you complete a thesis?

18 A I did.

19 Q What was generally the subject matter of
20 your thesis?

21 A I would describe it as dairy processing
22 using high pressure.

23 Q And was it processing skim milk?

24 A We were processing both skim milk and
25 whole milk.

1 Q What is skim milk?

2 A Skim milk is a milk where most of the
3 fat has been removed from it.

4 Q And -- go ahead.

5 A It would be similar to whole milk with
6 the exception that most of the fat is removed.

7 Q Generally how much fat is remaining in
8 skim milk?

9 A I would say --

10 MR. KRIEGER: Objection, form,
11 beyond the scope.

12 A I would say around .5 percent. Less
13 than .5 percent.

14 Q And then you said whole milk is
15 different because it has more fat than skim milk?

16 A Exactly right, yeah.

17 Q And how much fat does whole milk
18 typically have?

19 MR. KRIEGER: The same objection.

20 A Well, in this case I would say that it
21 depends whether we are talking about whole milk
22 that is coming from -- let's say straight from the
23 dairy farm or whole milk that we buy in a grocery
24 store.

25 Q Okay. We were talking about your thesis

1 from your Ph.D.

2 A Okay.

3 Q And you mentioned that it was processing
4 whole milk. In that context what percent fat
5 would whole milk typically have?

6 MR. KRIEGER: The same objection.

7 A I do not recall what was the percentage
8 of the whole milk that we were using.

9 Q If we go back to Harte **Exhibit 1** you
10 list areas of expertise. One of those areas is
11 dairy processing, correct? This is on the first
12 page.

13 A Yep.

14 Q And how did you obtain an area of
15 expertise in dairy processing?

16 A Can you clarify the question?

17 Q Sure. So let me take a step back.

18 So on Harte **Exhibit 1** the first page you
19 list three areas of expertise, dairy processing,
20 food rheology and food engineering.

21 Do you see that?

22 A Yep.

23 Q Okay. And my question is as to dairy
24 processing do you consider yourself an expert in
25 dairy processing?

1 A I do.

2 Q Okay. And what is that expertise based
3 on? In other words, how did you come to have that
4 expertise?

5 A Okay. So a lot of the -- my position in
6 the university carries 80 percent research and
7 20 percent teaching, so there is a strong focus on
8 the research that the lab conducts related to the
9 processing of milk and milk products, dairy in
10 general, and I also teach at Penn State of course
11 on dairy processing every spring. I am -- I am
12 the faculty in the food science department at
13 Penn State that teaches dairy processing within
14 the food science department.

15 Q Okay. Thank you for that.

16 After you got your Ph.D. in 2002 what
17 was your next job?

18 A My next job immediately after I finished
19 my Ph.D. I went back to Uruguay in 2002 and I
20 worked in two different universities and did
21 consulting jobs for the dairy industry for two and
22 a half years.

23 Q So that was from 2002 to about 2005?

24 A Yeah.

25 Q And what companies did you do consulting

1 work for when you were in Uruguay from 2002 to
2 2005?

3 A Conaprole. That would be one, and I
4 think that was the one, yeah.

5 Q Okay. And then did you change jobs in
6 around 2005?

7 A Yeah. That is where I went -- a
8 position was open in the University of Tennessee
9 in the food science department, and that is how I
10 started in 2005 as a faculty in the food science
11 department at UTK, University of Tennessee
12 Knoxville also with 80 percent research and
13 20 percent teaching.

14 Q And how long were you at the University
15 of Tennessee?

16 A From 2005 to 2014.

17 Q And where did you go in 2014?

18 A To Penn State University.

19 Q And I believe you said that you're just
20 starting a one-year leave from your teaching
21 position at Penn State, is that correct?

22 A That is correct, yeah.

23 Q So from 2014 until this year, 2026, you
24 have been a professor at Penn State University?

25 A Yeah. Associate professor and then

1 professor.

2 Q Okay. Over the last -- and at your time
3 at -- strike that.

4 At your time at Penn State University
5 your position there as an associate professor and
6 then professor has been about 80 percent research
7 and 20 percent teaching, is that right?

8 A Yeah.

9 Q Over the last five years what has your
10 research focused on in your position at
11 Penn State?

12 MR. KRIEGER: Objection, form.

13 A You mean focus? Can you repeat the
14 question? Sorry.

15 Q Just at a high level I'm trying to
16 understand what your research has generally been
17 about in the last five years.

18 A So I would say that it's been about
19 these topics right there, dairy processing, food
20 rheology and food engineering.

21 Q Okay.

22 And can you tell me a little bit more
23 about what your dairy processing research has
24 involved in the last five years?

25 A Well, so we have been doing research on

1 the function of the casein in the milk, in the
2 binding properties of casein.

3 Q Uh-huh.

4 A In how to separate casein from other
5 components in milk and how to make dairy products
6 with fewer -- fewer ingredients and more natural
7 ingredients under this banner called clean labels,
8 but I can -- I can keep going on with other
9 projects too because it's -- it's very broad the
10 question in my perception broad and the focus on
11 the lab within dairy processing changes depending
12 on what the funding agencies demand, so it's very
13 difficult to say for me that for five years we
14 have been doing one thing and that's it.

15 Q Sure. What is -- what is casein?

16 A Casein is a term used to describe four
17 proteins in milk, alpha-s1, alpha-s2, beta casein
18 and --

19 THE COURT REPORTER: Could you
20 slow down?

21 A I apologize. Alpha-s1 casein, alpha-s2
22 casein, beta casein and kappa casein. These
23 proteins are roughly 80 percent of the total
24 protein in milk and they form an aggregate called
25 casein micelle.

1 THE COURT REPORTER: Casein

2 micelle?

3 A Micelle, yeah. M-I-C-E-L-L-E.

4 Q And if you could just -- I think you
5 said this, but what is casein micelle?

6 A Okay. A casein micelle is an aggregate
7 of casein proteins. There are roughly 5000
8 individual caseins in each casein micelle and
9 there are like roughly 10 to the 14 casein
10 micelles per milk. Casein is what makes milk look
11 white, skim milk look white.

12 Q Okay. And you said that casein
13 typically comprises about 80 percent of the total
14 protein in milk, is that right?

15 A That's correct. Ballpark.

16 Q Ballpark, yes.

17 And is it correct then that
18 approximately the other 20 percent of the protein
19 in milk is made up of whey proteins?

20 MR. KRIEGER: Objection, form.

21 A So when I teach dairy processing we
22 discuss the composition of milk, and as this is a
23 biological system so the percentage is -- is
24 difficult for me to say that is exactly
25 20 percent, but roughly I describe the composition

1 of milk as having roughly 80 percent of casein and
2 20 percent of these general term whey proteins.

3 Q Okay. In the last five years has any of
4 your research at Penn State involved whey
5 proteins?

6 A Well, as we work with caseins we care
7 about what happens with the whey, right? Some of
8 the projects that we are trying to work on that we
9 are working on are about separating the casein
10 from the whey, so we cannot ignore what happens
11 with whey, so it is tremendously relevant to us,
12 yeah. So I would say, yes, it involves whey too.

13 Q Okay.

14 A Yeah.

15 Q What are whey proteins?

16 A So in general terms when we make cheese
17 we are going to -- cheese is probably retaining
18 the caseins, and everything in milk that is not
19 the caseins will be in general term the whey, so
20 it's a really broad term that describes a myriad
21 of proteins that you can find in milk. Usually
22 all the whey proteins are separated from the milk
23 when we make cheese or by other means.

24 Q Are you familiar -- so you talked about
25 making cheese and retaining the caseins and then

1 having everything else go to the whey. Are you --
2 or maybe I'm not characterizing that right, but
3 generally you're separating the caseins from other
4 things when you're making cheese, is that right?

5 MR. KRIEGER: Objection, form.

6 A It is a broad claim, right? But I would
7 say that in the case of making cheese your
8 objective is to retain the casein.

9 Q Okay.

10 A Yeah.

11 Q Are you familiar with using rennit for
12 separation in cheesemaking?

13 A Yes.

14 Q And how does that process work?

15 A Well, in the case of cheesemaking what
16 we do is we first set the milk in what is
17 generally referred to as a cheese bath and we add
18 an enzyme. This enzyme is going to, I would use
19 the word shave or cut, proteolyze kappa casein in
20 the surface of the casein micelle.

21 The kappa casein will be broken
22 in two peptides. One is the glycomacropeptide and
23 the other one is para kappa-casein that remains in
24 the casein micelle. So even though the
25 glycomacropeptide that is part of the casein is

1 released to the whey as we use chymosin. That
2 would be the typical enzyme that is contained in
3 rennet for making cheese.

4 Q Okay.

5 A Does that address -- addresses your
6 question?

7 Q I think so.

8 A Okay.

9 Q You mentioned glycomacropeptide.

10 A Yep.

11 Q I have seen that abbreviated as GMP. Is
12 that consistent with your experience?

13 A Yep.

14 Q So if I refer to GMP, you will know that
15 I mean glycomacropeptide?

16 A Yep.

17 Q That will save me a lot of syllables
18 over the course of the day.

19 A Yep.

20 Q And have you also heard
21 glycomacropeptide referred to as CMP?

22 A Yeah, too, yeah.

23 Q Okay. And is it your understanding that
24 glycomacropeptide is a whey protein?

25 A That's a little bit general. So the

1 issue is that the word "whey" is quite general, so
 2 there are many streams in milk or during the
 3 processing of milk that are called whey, so
 4 whether GMP is or not present in whey it will
 5 depend on the way that -- I am saying "whey" so
 6 many times. It depends on the type of processing
 7 that you are applying, right?

8 If we are talking about sweet
 9 whey, yes, GMP is part of sweet whey. And I'm
 10 referring to sweet whey as the whey that is coming
 11 from the standard processing when you make cheese.

12 Q So -- yeah.

13 A Let me just finish saying that there are
 14 other types of whey. For instance, what is coming
 15 from making greek yogurt where you are not going
 16 to find GMP and it's still referred to as a whey.

17 Q Okay. You mentioned the term sweet
 18 whey.

19 A Uh-huh.

20 Q And that sweet whey is known to contain
 21 GMP, is that correct?

22 A So "sweet whey" is usually the term.
 23 Sweet way is used to describe the whey coming from
 24 the making of cheese, and in that regard sweet
 25 whey or cheese whey and in that regard they --

1 they do contain GMP, yeah.

2 Q Okay.

3 A Between, yeah.

4 Q Is it your understanding that GMP is an
5 inferior source of protein for muscle recovery?

6 MR. KRIEGER: Objection, form,
7 foundation.

8 A Can you repeat the question again?

9 BY MS. KAISER:

10 Q Sure. Is it your understanding that GMP
11 is an inferior source -- strike that.

12 Is it your understanding that people in
13 this art have an understanding that GMP is an
14 inferior source of protein for muscle recovery?

15 MR. KRIEGER: Objection, form,
16 foundation.

17 A Well, I am a food scientist, not a
18 nutritional scientist, so it's for me difficult to
19 elaborate on what I would consider nutrition
20 aspects of GMP, so yeah.

21 Q When looking at whey protein
22 compositions is it your -- do you have an
23 understanding about whether having GMP in those
24 compositions for a food product would be
25 desirable?

1 MR. KRIEGER: Objection, form.

2 A Well, that is in my perception a very
3 general statement. It is very difficult for me to
4 say that it is desirable just on its own. There
5 are a myriad of products coming from milk, a
6 myriad of applications, and I would like to say
7 that -- I would say that depending on the
8 application it would depend whether you want or
9 not GMP in there.

10 Q If I was making a protein drink for
11 athletes would it be -- would there -- would there
12 be known drawbacks to having GMP in that drink?

13 MR. KRIEGER: Objection, form,
14 foundation.

15 A So can you repeat the question?

16 Q Sure. So if -- if we are talking about
17 a product that is say a protein drink for
18 athletes --

19 A Yeah. Uh-huh.

20 Q I'm asking in the art of dairy
21 processing and food science and let's just say in
22 2023 were there known drawbacks to having GMP
23 present in such a product?

24 A In a protein drink?

25 Q Yes.

1 A Okay. So what I say is that --

2 MR. KRIEGER: Objection, form,
3 foundation. Sorry.

4 A Okay. Can you define drawback?

5 Q What do you understand "drawback" to
6 mean?

7 A It's so general that it's difficult for
8 me to -- to say.

9 Q Okay. Would it help if I said negative
10 qualities?

11 A So my understanding is that the flavor
12 profile of a dairy product would change depending
13 on whether GMP is present or not.

14 Q Okay.

15 A Now, whether that is good or not that
16 depends on the consumer, I guess.

17 Q Okay. And so you don't have an opinion
18 about whether that flavor profile with more GMP
19 would be undesirable in a -- in a protein drink?

20 MR. KRIEGER: Objection, form.

21 A My opinion? Well, what I would say is
22 that based on some of the material that I read and
23 it's part of this declaration it seems that most
24 consumers prefer a protein drink that is made with
25 whey coming from cheese that doesn't have GMP due

1 to the flavor profile. Now, whether that is good
2 or not...

3 Q Did you have that understanding prior to
4 reviewing materials for this case or did you
5 develop that understanding as part of this matter?

6 A Well, I have seen -- well, let me
7 recall. As I was reviewing the patent I read -- I
8 took ahold of manuscripts and I tried to locate
9 micelle specifically on the flavor profile and
10 based on the manuscript that I read that is the
11 information that came through, yeah.

12 Q Okay.

13 But you didn't have that understanding
14 prior to reading the challenged patent in this
15 case, is that correct?

16 A So when I teach my course on dairy
17 processing we talk about ingredients and we
18 discuss that some of the ingredients that are
19 offered by the dairy industry -- so there is a
20 myriad of, as I mentioned, products or ingredients
21 that are coming from the processing of milk and I
22 made my students aware that within what we call
23 whey protein, whey protein concentrates and
24 isolates, there is demineralized whey and there is
25 also a low on GMP product, not specifically that

1 there was a flavor profile difference. That I --
2 I read when I started reviewing the patent, yeah.
3 What was the specific -- the GMP -- what was the
4 impact of having low or high GMP in whey.

5 Q In your dairy processing course --

6 A Yeah.

7 Q -- how long have you been teaching about
8 low GMP products?

9 A Oh, recently. This is a -- it's been I
10 would say -- it's difficult for me to say, but
11 it's definitely something very recent that is --
12 that came to market, so difficult for me to say,
13 but it's definitely recent, right?

14 So I would say -- so I -- I
15 taught this spring and we discussed ingredients
16 and I talked about the interest of GMP and GMP
17 being there, so we discussed the topic but not --
18 not specifically on -- on specifically what was
19 the aspect that was happening.

20 Q You said that one of the ingredients
21 that you talked about in your food processing
22 class is WPI?

23 A Whey protein isolates, yeah.

24 Q Okay. And what is WPI?

25 A It's a whey protein isolate.

1 Q And what are the components of WPI?

2 A Mostly the whey proteins in milk usually
3 from sweet whey. I mean whey coming from cheese.
4 In general terms I can't exactly -- there is a
5 boundary between how much protein do you have
6 between WPC and WPI. I would say that WPI has
7 more than maybe 80 percent protein, total protein.
8 And the profile of those proteins would be the
9 profile of sweet whey.

10 Q When you say the profile of proteins
11 what do you mean?

12 A So there is a -- there is a myriad of
13 whey proteins. So when -- when we make cheese and
14 retain the casein and we expel this liquid called
15 whey there are major -- major milk -- major whey
16 proteins like lactoglobulin and lactalbumin, but
17 then there is a whole set of other proteins in
18 there, right?

19 I would say that 50 percent of
20 the whey proteins would be lactoglobulin and
21 20 percent lactalbumin roughly but the -- the
22 profile of these different proteins throughout
23 WPC, so the protein content changes, but the
24 profile remains the same, and when I say the
25 profile is the relative content.

1 Q Okay.

2 So the relative percentages of each whey
3 protein stays the same?

4 A That is what I am trying to say.

5 Q Okay. And so just take, for example, a
6 sweet whey that has 50 percent beta-lactoglobulin
7 and 20 percent alpha-lactalbumin. You would
8 expect then even though the percentage of total
9 protein may be different in the WPI it would still
10 have that 50 percent BLG and 20 percent ALA, is
11 that -- is that right?

12 MR. KRIEGER: Objection, form.

13 A What I am saying is that if the WPC or
14 WPI are coming from cheese whey I expect the
15 relative percent of the different components in
16 the sweet whey to remain in WPI and WPC.

17 Q Okay. And WPC stands for whey protein
18 concentrate, is that right?

19 A That is correct.

20 Q Okay.

21 Sometimes I have seen it referred to
22 with WPC and then a number like WPC30. Have you
23 seen that before?

24 A Let me make a clarification. So my -- I
25 think my previous statement was a little broad,

1 right? So as we process sweet whey into creating
2 WPC and creating WPI their profile will change, so
3 I am going to be careful there, because one thing
4 is to say in general terms, but in this case I
5 want to be careful because numbers matter and
6 words matter, right?

7 So as we add processing steps and
8 we are using different processing operations,
9 depending on the operations that we use, WPI and
10 WPC will have the same profile of proteins that we
11 can have in sweet whey. That is an important
12 clarification.

13 Q Okay. Thank you.

14 A My previous statement was way too
15 general, yeah.

16 Q Okay. And I appreciate that
17 clarification. I want to go back and ask the
18 question --

19 A Yeah. Yeah.

20 Q -- that I just asked you though because
21 I don't think your clarification answered it.

22 A Yep.

23 Q So I was saying I have seen in some
24 publications where WPC also has a number after it
25 like WPC30.

1 A Yep.

2 Q Have you also seen that?

3 A Yeah.

4 Q And when it's WPC followed by a number
5 what does the number typically refer to?

6 A The number typically referred to the
7 protein, the total protein content in that WPC.

8 Q Okay. And so if you had WPC30 that
9 would be 30 percent total protein content, is that
10 right?

11 A Ballpark.

12 Q Ballpark.

13 A Yeah.

14 Q And the same thing for WPC80. It would
15 be ballpark 80 percent protein?

16 A Yeah.

17 Q What is -- what is the typical
18 processing to get from sweet whey to WPC80?

19 MR. KRIEGER: Objection, form,
20 foundation.

21 A Well, it is for me difficult to say that
22 there is a typical process because in most cases
23 we are talking about a series of tangential flow
24 filtration operations that is general with
25 different pore size. Now, what is that a company

1 will choose to do, what set of steps a company
2 will do, it depends on the company.

3 Q Okay.

4 You mentioned filtration operations with
5 different pore sizes.

6 A Uh-huh.

7 Q Are you familiar with the term
8 microfiltration?

9 A I am.

10 Q What is microfiltration?

11 A Microfiltration is a process where --
12 there are in general terms two types of
13 filtration, dead-end filtration and tangential
14 flow filtration. Depending on the pore size that
15 we are using we will have microfiltration,
16 ultrafiltration, nanofiltration and reverse
17 osmosis.

18 It is sometimes difficult to
19 narrowly define where microfiltration starts and
20 finishes versus ultrafiltration because there is a
21 little bit of overlapping. There is overlapping.

22 So I would say that
23 microfiltration starts with a pore size of I would
24 say 0.1 micrometer, but some people refer that as
25 ultrafiltration and it can go up to 2 microns, but

1 again this -- I want to be careful because this is
2 where the definitions do become a little loose.
3 There is overlapping between microfiltration and
4 ultrafiltration, but in general terms we are
5 talking about micron size and sub-micron size for
6 ultrafiltration.

7 Q When you're using microfiltration --

8 A Yeah.

9 Q -- to process or to filter sweet whey --

10 A Yeah.

11 Q Is it correct that the whey proteins
12 would typically pass into the permeate for that
13 microfiltration operation?

14 MR. KRIEGER: Objection, form,
15 foundation.

16 A So every time we have a microfiltration,
17 ultrafiltration, nanofiltration or reverse osmosis
18 process we are changing the profile of the whey
19 proteins. How much and to what extent it will
20 depend on the process, but I would say that the
21 profile is going to change. It is not going to
22 remain exactly the same --

23 Q Okay.

24 A -- in microfiltration, yeah.

25 Q I don't think that that answered my

1 question.

2 A Okay.

3 Q So I want you to listen to the question
4 that I'm asking.

5 A I apologize.

6 Q And see if you can answer it.

7 A Yep.

8 Q So my question was: Is it correct that
9 whey proteins would typically pass into the
10 permeate for a microfiltration operation that's
11 applied to sweet whey?

12 MR. KRIEGER: Objection, form,
13 foundation.

14 A Okay. I would say that that statement
15 would be I would say correct if you say that some
16 whey proteins pass. Some whey proteins don't. I
17 -- I don't want to be absolute regarding all the
18 whey proteins passing through.

19 Q Would it be correct to say that most of
20 the whey proteins would pass into the permeate?

21 MR. KRIEGER: Objection, form,
22 foundation.

23 A Sorry. That is I think too general,
24 yeah.

25 Q Okay. Then you mentioned

1 ultrafiltration.

2 A Yep.

3 Q Do you remember that?

4 A Yes, I do, yeah.

5 Q What would the typical pore size be for
6 ultrafiltration operation?

7 MR. KRIEGER: Objection, form.

8 A I -- I struggle with typical because --
9 but I would say that microfiltration would start
10 at roughly 0.1 micrometer and it would go to --
11 down to 0.001 micrometer, but in that range we
12 start talking about kilodaltons.

13 THE COURT REPORTER: Talking
14 about?

15 A Kilodaltons. And similarly to what I
16 said about microfiltration, the range where
17 ultrafiltration ends or the range in pore size
18 where it begins and ends overlaps on the one side
19 with microfiltration and on the other with
20 nanofiltration.

21 Q If the first processing step for sweet
22 whey is microfiltration, what would a person in
23 this area, that is, dairy processing, understand
24 would be in the permeate?

25 MR. KRIEGER: Objection, form,

1 foundation.

2 A I do think that is way too general of a
3 statement.

4 Q Are you familiar with the term
5 diafiltration?

6 A Yes.

7 Q What is diafiltration?

8 A Diafiltration, so what you do is you
9 have a -- when you do tangential flow filtration
10 you will have a retentate and a permeate.

11 And usually let's say that you
12 have a retentate that you want to continue
13 concentrating or isolating. You can add water and
14 run the filtration again, so it will be like
15 having two tangential flow filtrations one after
16 the other. That is diafiltration.

17 Q Are you familiar with using centrifuging
18 as a process step in dairy processing?

19 A Yes.

20 Q What is centrifuging?

21 A So there are two types of centrifuge
22 processes, a benchtop and then a continued
23 centrifuge. In both cases centrifugal force is
24 used as the basis of separation based on density.
25 So whether we want to separate a -- usually

1 whether it is solid or not the basis for
2 separation using a centrifuge is going to be
3 density. And for that we accelerate and create
4 the G-force, centrifugal force that will promote
5 the separation based on density.

6 Q Can centrifuging also be done in
7 conjunction with filtering?

8 MR. KRIEGER: Objection, form.

9 A There is a -- what is called spin
10 filters where a tube is equipped with a filter and
11 that whole thing is placed inside the centrifuge
12 and that creates a liquid that goes through the
13 filter and a filter cake that stays in the filter,
14 yeah.

15 Q Are you familiar with a processing step
16 of hydrolyzing in dairy processing?

17 A Yes. Sometimes hydrolyzing is a synonym
18 of proteolyzing.

19 Q What hydrolyzing?

20 A In the case of for instance cheesemaking
21 the kappa casein will be proteolyzed by the enzyme
22 so that will be a hydrolysis also a breakdown of
23 the protein.

24 Q What about in the context of whey
25 proteins, are you familiar with using hydrolyzing

1 in the context of whey proteins?

2 A Well, if we refer specifically for
3 instance to patent '860 GMP, one of the methods is
4 to break down GMP. That will be a hydrolysis
5 product.

6 Q And in the '860 patent it talks about
7 using enzymes for selective hydrolyzing, correct?

8 A Uh-huh.

9 Q Are you familiar with pasteurizing?

10 A Yes.

11 Q What is pasteurizing?

12 A Well, pasteurizing, it depends on the
13 context, right? So in general terms
14 pasteurization is a process that intends to reduce
15 the number of vegetative cells in a product.

16 Now, depending on what product
17 you are talking there may be or not specific
18 regulations, right? So again it's usually a
19 thermal process usually, but what are the time and
20 temperatures used and what are the target
21 microorganisms will depend on the product.

22 Q And then are you familiar with
23 denaturing proteins during dairy processing?

24 A Yes.

25 Q What are the ways that someone can

1 denature proteins during dairy processing?

2 A One way is definitely increasing
3 temperature and another way would be applying very
4 high pressure depending on the protein. Those
5 would be two ways to denature. Not every protein
6 will denature though.

7 Q What -- what are some whey proteins that
8 denature?

9 A Lactoglobulin. Lactalbumin. Those are
10 proteins that will denature in milk.

11 Q Okay. When you say lactoglobulin do you
12 mean BLG?

13 A BLG. Sorry. My bad.

14 Q Okay.

15 A Beta-lactoglobulin, BLG. And
16 alpha-lactalbumin, ALA.

17 Q Okay.

18 And BLG and ALA will denature when heat
19 is applied, is that right?

20 A Well, that is a -- a general term,
21 right? Not every heat treatment is going to
22 denature.

23 Q Yeah, I apologize. That wasn't a great
24 question. Let me ask a better question.

25 So when subjected to a sufficiently high

1 temperature for a sufficient period of time BLG is
2 a whey protein that will denature, correct?

3 MR. KRIEGER: Objection, form.

4 A And that is a little general too because
5 I would say yes when the temperature increases to
6 a certain point BLG will denature, but what
7 temperature will -- what is the specific
8 temperature that will denature BLG will depend on
9 the environment too. The presence of other
10 solids, ionic strength, those are factors that
11 effect the temperature or the buffering capacity
12 that the protein will denature.

13 Q And is pH another condition that will
14 effect the temperature at which a protein
15 denatures?

16 A Yes, pH will effect the temperature at
17 which a protein will denature, yeah.

18 Q What happens when BLG is denatured?

19 MR. KRIEGER: Objection, form,
20 foundation.

21 A So what happens is a -- so what I -- so
22 proteins do have primary, secondary, tertiary and
23 quaternary structures, right? Denaturation means
24 a change in secondary and tertiary structure of
25 the protein. So the fact that it's changing means

1 denaturation, but what is it that you get and what
2 is that will happen it will depend on the -- it's
3 difficult for me to generalize and say this is
4 what happens when it denatures.

5 Q Are you familiar with the term protein
6 aggregation?

7 A Yeah.

8 Q What is protein aggregation?

9 A In general terms it is when two proteins
10 remain close together as an entity.

11 Q Does protein aggregation occur as part
12 of denaturization?

13 A Not necessarily.

14 Q Okay.

15 A Not necessarily.

16 Q When BLG is denatured does it -- does
17 the denaturization change the amino acid sequence
18 of the protein?

19 MR. KRIEGER: Objection, form,
20 foundation.

21 A Denaturization itself should not, right,
22 because as I mentioned denaturization -- the term
23 denaturization means changes in secondary and
24 tertiary structure. Denaturization is not changes
25 in the primary structure. That would be

1 hydrolysis/proteolysis.

2 Now, after it denatures what
3 happens after that it may lead to proteolysis, but
4 the denaturization itself -- the term
5 "denaturization" is used to describe changes in
6 secondary and tertiary structures.

7 Q Okay.

8 And changes in the secondary and
9 tertiary structures of a protein like BLG don't
10 change its amino acid sequence, right?

11 MR. KRIEGER: Hold on. Objection,
12 form.

13 A As I mentioned before, there is a
14 delicate -- the -- the definition of
15 denaturization means changes in secondary and
16 tertiary structure. That's the definition.

17 Now, what happens right after
18 denaturization, a protein may be prone to
19 proteolysis because -- so the structure the -- the
20 function of a protein depends on the structure.
21 So if we are changing a structure then those
22 changes may determine later on easier or not as
23 easier proteolysis. Am I making myself clear?

24 Q I think so, but what I'm trying to
25 understand -- so I'm taking your definition of

1 denaturization.

2 A Uh-huh. Yeah.

3 Q So the changes to the secondary and
4 tertiary structures.

5 A Yep.

6 Q And what I'm trying to understand then
7 is what that means as a practical matter. So what
8 -- other than just that change in structure are
9 there any other changes that happen? So sort of
10 taking that background to the question.

11 A Yeah.

12 Q What I'm asking is if you just look at
13 the denaturization, so the changes to the
14 structures that we've talked about.

15 A Uh-huh.

16 Q Not considering downstream processing.

17 THE COURT REPORTER: Just one at a
18 time.

19 A I apologize.

20 Q Yeah. So not considering downstream
21 processing. I'm wondering just with
22 denaturization alone does that change the amino
23 acid sequence of the protein?

24 MR. KRIEGER: Objection, form.

25 A So the sequence of amino acids is

1 described as the primary structure of a protein.
2 So if -- again, using my definition or the
3 definition that I'm providing that denaturization
4 means changes in the secondary and tertiary --
5 and/or tertiary structures of protein,
6 denaturization doesn't require or is not within
7 the definition that denaturization implies a
8 change in amino acid sequence.

9 Q Okay. And then again using that same
10 definition of denaturization, considering only
11 that step, does denaturization change the
12 molecular weight of the protein?

13 MR. KRIEGER: Objection, form.

14 A So it is a tricky question, so let me
15 elaborate. As I mentioned, the -- the function of
16 a protein will depend on the structure, right, in
17 any structure, primary, secondary, tertiary or
18 quaternary structure.

19 So there are reactive groups
20 inside a protein that may not be -- or groups that
21 may be prone to reaction that maybe just may not
22 be reactive because they are buried inside a
23 structure. So as we denature a protein -- pick a
24 protein. So we may expose those reactive groups,
25 so right immediately after the denaturization

1 those reactive groups may, for instance, form
2 disulfide bonds and that would change -- that will
3 put two proteins together by a covalent bond and
4 that will change the molecular weight.

5 Q Okay.

6 But I'm just -- so you're talking about
7 things that can happen after denaturization.

8 A But immediately after.

9 Q Okay.

10 A That depend on the environment where the
11 protein is.

12 MR. KRIEGER: Jessica, we have
13 been going about an hour.

14 Q Okay. I just have a couple more
15 questions to finish this. So let's take BLG as an
16 example.

17 A Uh-huh.

18 Q When BLG is denatured does its molecular
19 weight change?

20 MR. KRIEGER: Objection, form,
21 foundation.

22 A So I can say the following. If I am
23 using electrophoresis to determine molecular
24 weight of lactoglobulin and I expose lactoglobulin
25 to conditions leading to denaturization and

1 potential aggregation, beta-lactoglobulin may or
2 may not depending on the environment that it's
3 being exposed to form disulfide bonds.

4 So in that regard I may see a
5 change in molecular weight. For instance, the
6 band corresponding to lactoglobulin may go to
7 18 kilodaltons to 36 kilodaltons because it is
8 forming a disulfide bond so -- but we are talking
9 about two lactoglobulins together, right?

10 Also, if the protein is being
11 exposed for instance to -- reactive groups are
12 being exposed, there may be oxidation. There may
13 be exposure to proteolysis, but it's not the
14 denaturization itself. It's the fact that the
15 protein is changing, right? Hopefully.

16 Q Okay. Let me make sure that I
17 understand.

18 A Yeah.

19 Q So the denaturization itself doesn't
20 change the molecular weight, but there can be
21 subsequent chemical reactions that could change
22 the molecular weight, is that correct?

23 A So let me try to clarify here.
24 Denaturization itself is about changes in
25 secondary and tertiary structure. Those changes

1 may have consequences right away, so not -- not
2 downstream. As the protein denatures things may
3 happen because the function is changing. So it
4 may be seen as denaturization created these
5 changes, but it's by definition denaturization is
6 about the changes in secondary and tertiary
7 structure.

8 Q Okay. Let me -- let me ask the question
9 a slightly different way.

10 A Yeah.

11 Q The changes in secondary and tertiary
12 structures themselves that are part of -- or that
13 are denaturization --

14 A Uh-huh.

15 Q Those changes don't change the molecular
16 weight of the protein?

17 MR. KRIEGER: Objection, form.

18 A Clarify the question again and let me
19 see if I can.

20 Q Sure. Let me ask it again.

21 A Yeah.

22 Q So taking BLG as an example so it's more
23 concrete.

24 A Yep.

25 Q So when BLG is denatured the changes to

1 the secondary and tertiary structures, so the
2 structure changes themselves don't change the
3 molecular weight?

4 MR. KRIEGER: Objection, form.

5 A Well, those changes are the reason why a
6 protein may go to proteolysis or to -- so by
7 definition denaturization means changes in
8 secondary and tertiary structure, but those
9 changes do have consequences, so you can say that
10 denaturization may be the trigger to this.

11 It's difficult for me to -- to be
12 absolute because the changes that may happen to a
13 protein are directly linked to denaturization, but
14 by definition the denaturization is a change in
15 secondary and tertiary structure. That mean --
16 that doesn't mean that it doesn't have
17 consequences.

18 Q Right. I understand that because you
19 have said that several times.

20 A Yeah.

21 Q So I understand that there could be
22 consequences.

23 A Yep.

24 Q What I am trying to understand is not --
25 not what the consequences are, but just the

1 structure changes. I'm trying to understand
2 whether the structure changes themselves cause a
3 change to molecular weight.

4 Do you understand the question that I'm
5 asking?

6 A So if you are telling me that
7 denaturization is a change in molecular weight I
8 would say denaturation is a change in secondary
9 and tertiary structure. If you tell me that
10 denaturization may promote changes in molecular
11 weight I would say yes.

12 Q Okay.

13 A So hopefully the difference is clear.

14 Q Okay. So -- so what I understand you to
15 be saying is denaturization is a change in
16 structure, not a change in molecular weight?

17 A Secondary and tertiary structure.

18 Q Secondary and tertiary structure. So
19 let me start over.

20 What I understand you to be saying is
21 that denaturization is -- is changes in secondary
22 and tertiary structure, not molecular weight, but
23 that denaturization can promote changes in
24 molecular weight, is that correct?

25 MR. KRIEGER: Objection, form and

1 mischaracterizes testimony.

2 A I wouldn't say promote. There can be a
3 direct consequence. Hopefully -- again, it's a
4 subtle difference, right?

5 So there is a definition of
6 denaturization that since the -- since the
7 function of a protein depends on the structure and
8 when I say function is whatever happens with the
9 protein, as I denature the function changes and
10 one of the changes may be a loss in molecular
11 weight or a change in molecular weight so -- but
12 it's not that downstream something will happen.
13 It is happening -- it may happen as the protein
14 denatures, but the definition of denaturization
15 doesn't imply that something like that will
16 happen. The definition is narrow. It's how it
17 changes in secondary and tertiary structure.

18 Q Okay. And I just want to be clear. I'm
19 not trying to trick you or put words in your
20 mouth. When I asked you a question earlier your
21 answer was if you tell me that the denaturization
22 may promote changes in molecular weight, I would
23 say yes, so hopefully the difference is clear.
24 And then I was just trying to clarify the
25 difference that you were making.

1 A Okay. Yeah, well, then maybe my
2 statement was too general, right? So what I was
3 trying to say is that there is a definition of
4 denaturization changes in secondary and tertiary
5 structure. What happens with the protein right
6 after or down the stream it will be a consequence
7 of denaturization.

8 Q Okay. I think we can take a break now.

9 THE VIDEOGRAPHER: Off the record

10 10:23.

11 (BREAK TAKEN.)

12 THE VIDEOGRAPHER: Back on the

13 record 10:38.

14 BY MS. KAISER:

15 Q Welcome back, Dr. Harte.

16 A Thank you.

17 Q During the break did you talk to anybody
18 about the substance of your deposition?

19 A No.

20 Q Okay. Earlier before the break we were
21 talking about sweet whey. Do you remember that?

22 A Yep.

23 Q And you said -- I might say this
24 slightly wrong, but you said that sweet whey is
25 the whey that is -- comes from cheesemaking, is

1 that right?

2 MR. KRIEGER: Objection, form.

3 A The -- the whey that is coming out from
4 cheesemaking is usually referred to as sweet whey
5 or cheese whey.

6 Q Okay.

7 A Right before nothing is being done.

8 Q And do you have an understanding of the
9 typical pH of sweet whey?

10 MR. KRIEGER: Objection, form.

11 A Well, that's a little general because it
12 really depends on the cheese that is being made,
13 right? There is a myriad of cheeses out there.
14 As a very general -- well, there are tons of
15 cheeses out there, so I would prefer not to say
16 that there is a typical pH.

17 Q Okay.

18 So in your opinion there's not a typical
19 pH for sweet whey?

20 A In the cheese that we make during my
21 teaching we usually have a pH in the whey of
22 around -- below 5.6 and about 5.2. But that's the
23 cheese that we make in the pilot plant.

24 Q Okay.

25 A I'm not saying that is not important. I

1 am saying that it depends on the cheese that you
2 are making.

3 Q Okay. I understand.

4 A Yeah.

5 Q In dairy processing are you familiar
6 with clarifying steps?

7 A Yes.

8 Q What is a clarifying step?

9 A So it is a general term, right?
10 Clarification is used as a -- as a means to remove
11 something that is big or very -- again,
12 clarification is not a -- it doesn't describe just
13 a single process all over, right, every time I
14 would say, but it is a general term generally used
15 to describe a process where something that is,
16 quote, unquote, big is removed while other major
17 changes in whatever you have are not happening.

18 Q Are you familiar with the term cheese
19 fines?

20 A Yes.

21 Q What are cheese fines?

22 A Cheese fines are usually referred to as
23 the relatively large particles that are coming
24 with the whey or the sweet whey that is part of
25 cheesemaking.

1 Q Can a clarifying step be used to remove
2 cheese fines from sweet whey?

3 A Well, as I mentioned, clarification is
4 not a single processing operation, right? So if
5 only fines are being removed from the cheese whey
6 that would be typically a process called
7 clarification where the fines are being removed,
8 but it depends on the process that you are working
9 on. Make sense?

10 Q Yes. And earlier we talked about
11 microfiltration and ultrafiltration. You remember
12 that?

13 A Uh-huh.

14 Q Are ultrafiltration steps used to
15 concentrate the amount of protein in sweet whey?

16 MR. KRIEGER: Objection, form,
17 foundation.

18 A That is a bit general. So as I
19 mentioned before, microfiltration and
20 ultrafiltration and nanofiltration and also
21 reverse osmosis are not just used always for the
22 same objective, right? So whether you're using
23 for a given objective that -- it's difficult to
24 generalize and say, well, it's always this way,
25 right?

1 Q Okay.

2 And maybe I can ask the question a
3 little bit differently. Can ultrafiltration be
4 used to concentrate the amount of protein in sweet
5 whey?

6 MR. KRIEGER: Objection, form.

7 A Can ultrafiltration be used to
8 concentrate the proteins in sweet whey? It can.
9 I'm not saying that it is necessary, but it can.

10 Q We talked about clarification being used
11 to remove cheese fines from sweet whey.

12 A Uh-huh.

13 Q Can clarification also be used to remove
14 bacteria from sweet whey?

15 A I would say that is -- that is too much
16 of a generalization for clarification. I would
17 say that is most -- I would say yes for fines.
18 For bacteria that will be too much of a
19 generalization.

20 Q What processes are used to remove
21 bacteria from sweet whey?

22 A Bacteria from sweet whey? To remove or
23 to destroy bacteria?

24 Q So either, to remove or destroy.

25 A Okay. So vegetative bacteria are

1 sensitive to temperature, right, depending on the
2 bacteria what temperature and what time will it be
3 used. In the U.S. the pasteurization of milk is
4 defined as in most cases 72 degrees C for
5 15 seconds and that reduces the bacteria -- the
6 viable bacterial content in milk, so a thermal
7 process can be used to reduce the bacterial count.

8 Now, there are applications. I
9 -- I don't know in the case of sweet whey where
10 microfiltration has been -- microfiltration is a
11 very -- since the range is wide, I am aware of
12 processes where microfiltration is being used to
13 reduce bacterial counts. I can't say that I have
14 seen those in whey, in sweet whey.

15 Q So just generally in dairy processing
16 microfiltration can be used to reduce bacterial
17 count?

18 A Oh, sorry. I wouldn't say that it is
19 typically used in dairy processing. It can be
20 used as technology is available.

21 Q What is butterfat?

22 A Butterfat is -- is the concentrated or
23 aggregated milk fat. It's a general term, right?

24 Q Okay. And do you know what cream is?

25 A Yep. So cream is a -- cream is defined

1 by the code of federal regulations, so there are
2 different types of cream. It usually implies
3 concentrating milk to create a liquid that has a
4 relatively high content of milk fat. For
5 instance, usually we are talking about 36 to
6 40 percent milk fat. But there are -- if you go
7 to the code of federal regulations you will see
8 several types of creams, yeah.

9 Q And are you familiar with lactose?

10 A Yes.

11 Q What is lactose?

12 A Lactose is a disaccharide typically
13 found in milk. The concentration would be around
14 5 percent. It's the sugar in milk. Glucose and
15 galactose.

16 THE COURT REPORTER: Pardon?

17 A Glucose and galactose.

18 Q We talked about alpha-lactalbumin or ALA
19 earlier.

20 A Uh-huh.

21 Q Is ALA considered a whey protein?

22 A Yes.

23 Q And then we talked about
24 beta-lactoglobulin or BLG earlier. Is BLG
25 considered a whey protein?

1 A Yes. Now, the term "whey" again it
2 depends on where the whey is coming from. I would
3 say in sweet whey, right? For instance, if you
4 are making greek yogurt that whey is going to have
5 very little protein.

6 Q Okay. So maybe to ask a better
7 question, is ALA considered whey protein in sweet
8 whey?

9 MR. KRIEGER: I'm sorry. Can you
10 go back? I'm not sure that she captured
11 that last answer correctly. Do you recall
12 what your last sentence was?

13 THE WITNESS: No. About glucose
14 and galactose?

15 MR. KRIEGER: Do you mind if I
16 just read his last sentence? I just feel
17 like she didn't get that correctly.

18 MS. KAISER: Let me do it.

19 MR. KRIEGER: Okay. Go ahead.

20 Q So the way that the last sentence got
21 captured was: If you are making greek yogurt that
22 whey is going to have protein. I think -- I think
23 what you said is that whey is going to have little
24 protein, is that right?

25 A Yeah, very little protein.

1 Q Okay.

2 A Yeah.

3 THE COURT REPORTER: Thank you.

4 A Yeah.

5 Q Yeah. Thank you, Justin. Okay.

6 And then let me go back to my question
7 because I was trying to incorporate your
8 clarification.

9 A Yeah.

10 Q So is ALA considered whey protein in
11 sweet whey?

12 A Yes.

13 Q Okay. And is BLG considered whey
14 protein in sweet whey?

15 A Yes.

16 Q Have you been named as an inventor on
17 any U.S. patents?

18 A Yes.

19 Q Do you know how many?

20 A Three.

21 Q I'm sorry?

22 A Three.

23 (EXHIBIT 2 MARKED.)

24 Q Okay. I am going to mark another
25 exhibit as Harte Exhibit 2.

1 A Thank you.

2 Q Dr. Harte, you have been handed a
3 document that's been marked as Harte Exhibit 2.

4 A Uh-huh.

5 Q Do you recognize it?

6 A Yeah.

7 Q What is it?

8 A This is a patent on the stabilization of
9 carrageenan free chocolate milk coming from my
10 lab.

11 Q Coming from what?

12 A My lab.

13 Q Your lab?

14 A Yeah.

15 Q Got it.

16 Do you see at the top it has a
17 Publication Number U.S. 2019/0274331 A1?

18 A Yeah.

19 Q And then on the first page if you look
20 where it says inventors the first named inventor
21 is Federico Miguel Harte.

22 A Uh-huh.

23 Q Do you see that?

24 A Yep.

25 Q And that's you, correct?

1 A That is me, uh-huh.

2 Q Okay.

3 Just generally what does this patent
4 application publication relate to?

5 A This is about stabilization of cocoa to
6 make chocolate milk without the use of
7 carrageenan.

8 Q And this patent application publication
9 was based on experiments that you performed in
10 your lab, is that right?

11 A That is correct.

12 Q I want to direct you to the claims that
13 are at the back of the patent, so the last page
14 which is labeled as 11. Let me know when you're
15 there.

16 A Claims. Okay. Yeah. 11. Yep.

17 Q And you understand that the numbered
18 paragraphs at the end of a patent are the patent
19 claims?

20 A Yes.

21 Q Okay.

22 Do you see claim 6 that starts a method
23 for preparing shelf-stable k-carrageenan free
24 chocolate milk?

25 A Uh-huh. Yes.

1 Q And then it goes on to say "the method
2 comprising." Do you see that?

3 A Yes.

4 Q Do you have an understanding of what the
5 word "comprising" means in the context of patent
6 claims?

7 A Well, I am not a lawyer, right, so --
8 and I -- I receive advice from the office of
9 technology management at Penn State.

10 What I understand is that it uses
11 these elements. Now, whether that -- I am
12 hesitating here because I don't recall whether it
13 excludes other elements. That I don't recall.

14 Q Okay.

15 A Yeah. And I -- I do apologize. I am
16 not a lawyer so it's -- these are legal terms that
17 are difficult, yeah.

18 Q Okay.

19 If you go to in Harte **Exhibit 2** which is
20 your patent application publication --

21 A Yes.

22 Q And if you go to paragraph 82.

23 A What page?

24 Q It starts on page 6.

25 A Yes.

1 Q So just take a second and read
2 paragraph 82 to yourself and let me know when
3 you're done.

4 A 82. Okay. Yes.

5 Q Okay. And if you look on page 7 --

6 A Yes.

7 Q So I'm still in paragraph 82.

8 A Uh-huh.

9 Q And most of the way down do you see that
10 it refers to beta-LG?

11 A Yes.

12 Q Is it your understanding that that's
13 referring to beta-lactoglobulin or BLG?

14 A Yes.

15 Q Okay.

16 And do you see that it says,
17 "Denaturization of whey proteins, especially BLG
18 has been reported at temperatures above
19 77 degrees C."

20 Do you see that?

21 A I can see.

22 Q And then it goes after some citations it
23 goes on and said, "And processing temperatures in
24 this disclosure were significantly higher (85 to
25 92 degrees C)."

1 Do you see that?

2 A I see, yep.

3 Q And so is it your understanding that the
4 processing temperatures in the experiments that
5 are in Harte Exhibit 2 were 85 to 92 degrees C?

6 A That is correct.

7 Q Okay. If you go to paragraph 91 that is
8 on page 8.

9 A Yes.

10 Q Take a second or a minute to read that
11 paragraph and then let me know when you're done.

12 A Yes.

13 Q Okay.

14 If you look about five lines down there
15 is a sentence that starts "due to the high
16 temperatures."

17 A Uh-huh.

18 Q Do you see that?

19 A Yes.

20 Q And that sentence reads, "Due to the
21 high temperatures used during the processing of
22 all chocolate skim milks, complete whey protein
23 denaturation occurred evidenced by the lack of BLG
24 monomers in gels ran under non-reducing
25 conditions."

1 A Yes.

2 Q And is it your understanding that the
3 high temperatures that are referenced here in
4 paragraph 91 is the 85 to 92 degrees C that we saw
5 in paragraph 82?

6 A Let's see. So I need a minute because
7 there were two instances of high temperature in
8 this.

9 Q Okay.

10 A I want to make sure that both of them
11 are included there. Yes, 85 to 92.

12 Q Thank you. You can put that aside.

13 All right. I want to transition to one
14 of the documents I think you already have in front
15 of you which is Exhibit 1001 which is the '860
16 patent.

17 A Yep.

18 Q Justin, would you like a copy?

19 MR. KRIEGER: I think we're good.

20 Thank you.

21 Q Okay. All right. Dr. Harte,
22 Exhibit 1001 is U.S. Patent 11,825,860 B1.

23 A Uh-huh. Uh-huh.

24 Q Do you see that?

25 A Yes.

1 Q Are you familiar with the '860 patent?

2 A Yes.

3 Q Okay.

4 And the '860 patent is the patent about
5 which you have provided opinions in this matter,
6 correct?

7 A That is correct.

8 Q Okay.

9 So I want to direct your attention both
10 to Figure 1 of the '860 patent as well as the
11 description of that figure that starts at column 6
12 around line 3.

13 A Uh-huh.

14 Q So do you have both of those available
15 to you?

16 A Yeah. Uh-huh. Yes.

17 Q If you look in column 6 around line 14.

18 A You said column 6? Okay. Line 14.

19 Yeah.

20 Q Okay. And you see here it's discussing
21 Figure 1, correct?

22 A It starts with "the whey compensation."

23 Q Right. Right. But if you look -- so
24 I'm just trying to orient you.

25 A Figure 1. Yeah.

1 Q So starting at about line 3 it's
2 describing Figure 1.

3 A Yes.

4 Q And then at line 14 it mentions whey
5 composition feedstock.

6 A Uh-huh. Uh-huh.

7 Q And it says that that whey compensation
8 feedstock may be obtained from a cheesemaking
9 process.

10 A Uh-huh.

11 Q Do you see that?

12 A Yes.

13 Q So when that whey composition feedstock
14 is obtained from a cheesemaking process that would
15 be sweet whey or cheese whey, correct?

16 A I agree.

17 Q Okay.

18 In looking at the description of
19 Figure 1 is it your understanding that the whey
20 composition feedstock is the output of block 102
21 in Figure 1?

22 MR. KRIEGER: Objection, form.

23 A Can you repeat the question, please?

24 Q So I just want to make sure that we have
25 the same understanding of Figure 1, so I'm asking

1 about your understanding of that figure.

2 A Uh-huh.

3 Q So is it your understanding that the
4 whey composition feedstock that is described in
5 column 6 is the output of block 102 in Figure 1?

6 MR. KRIEGER: Objection, form.

7 A Okay. So it says "Filter enzymatically
8 coagulated cheese whey." Right? That is what
9 Figure 1 says. So it says "the whey composition
10 feedstock utilized herein may be obtained from a
11 cheesemaking process" which would be that. "A
12 whey protein concentrate, a whey protein isolate,
13 such as derived from cow's milk, or a combination
14 thereof." Whey protein isolate.

15 Q And maybe just to assist so let me --
16 let me -- I don't want to interrupt you if you
17 have --

18 A No, go ahead.

19 Q Okay.

20 A Yeah.

21 Q If you look at column 6 line -- starting
22 at line 29.

23 A Uh-huh.

24 Q It says, "For instance, in some
25 embodiments, the whey protein feedstock may be a

1 whey protein retentate filtered 102 from sweet
2 whey." And then it goes on.

3 Do you see that?

4 A Yes.

5 Q And so in the embodiments where the whey
6 protein feedstock is a retentate filtered 102 from
7 sweet whey, that's the output of block 102 in
8 Figure 1, correct?

9 A I wouldn't say so. It's difficult. So
10 a -- I wouldn't say so because this is -- it says
11 a whey protein retentate so -- and what is coming
12 from Figure 1 is cheese whey. So line -- let me
13 see. "In some embodiments, the whey protein
14 feedstock may be a whey protein retentate." I
15 wouldn't say that a whey protein retentate is the
16 same as an enzymatically coagulated cheese way.

17 Q So if you go to Figure 1 if you look at
18 block 102 it says "Filter enzymatically coagulated
19 cheese whey."

20 Do you see that?

21 A Filter enzymatically coagulated cheese
22 whey. Oh, there is a -- okay. Yeah. Yeah. So
23 it says filter. So this is not cheese whey. It's
24 cheese whey that has been filtered. So in that
25 case it says filter -- well, it doesn't -- filter

1 enzymatically coagulated.

2 Well, from the figure I should read the
3 description a little better. This sounds like
4 it's not clear whether -- filter enzymatically
5 coagulated cheese whey. Give me a minute. So
6 let's see. Filter enzymatically coagulated cheese
7 whey. Reduce native --

8 THE COURT REPORTER: Please speak
9 out loud.

10 A Yeah. So it is -- it is for me
11 difficult to understand what this filter is here.
12 It says enzymatically coagulated cheese whey.
13 This is cheese whey that has been enzymatically
14 coagulated, so I need to check whether -- filter
15 enzymatically coagulated --

16 Q So Dr. Harte --

17 A Yes.

18 Q Just so we don't drive the court
19 reporter crazy, if you're thinking to yourself,
20 then anything you say out loud she has to take
21 down.

22 A Sure.

23 Q So if you're sort of noodling things to
24 yourself, yeah.

25 A It makes sense.

1 Q Okay.

2 A Thank you. So let me read the paragraph
3 slowly. Okay. So what was the question again?

4 Q Let me ask you a different question.
5 When is the last time you reviewed the
6 '860 patent prior to today?

7 A Yesterday.

8 Q Did you review the entire patent?

9 A No, not the entire patent.

10 Q Okay.

11 A Yeah.

12 Q When is the last time you reviewed the
13 entire patent?

14 A I would say -- read the entire thing? I
15 don't recall. Maybe -- maybe a month ago.

16 Q Okay.

17 How many times have you read the '860
18 patent from front to back?

19 A At least twice.

20 Q Okay.

21 Did you think that in forming your
22 opinions in this matter it was important to
23 understand the figures?

24 A Yes.

25 Q Okay. And so did you in forming your

1 opinions review Figure 1?

2 A I did.

3 Q Okay. And so do you have an
4 understanding of what Figure 1 shows?

5 A I do.

6 Q Okay. And so Figure 1 shows step 102 as
7 filter enzymatically coagulated cheese whey?

8 A Yes.

9 Q What does that mean?

10 A So this is a whey that is coming from
11 the making of cheese. So when it says
12 enzymatically coagulated that means that rennet
13 has been used to coagulate this -- this milk into
14 cheese.

15 Q Okay.

16 A Yeah.

17 Q And what does the filter part mean?

18 A Well, filter, it doesn't say what type
19 of filtration this is, so my assumption here is
20 that this is a very course filter. It doesn't say
21 microfiltration. It doesn't say ultrafiltration.
22 Oh. Well, let -- let me clarify that so -- and I
23 do apologize.

24 So the byproduct of this process
25 is reduce native GMP levels, right, in cheese

1 whey. So that -- that byproduct cannot be just
2 done by just a course -- a filter, right? What I
3 am trying to say this is not a clarification
4 process, and I apologize for the confusion. So
5 this is in my perception tangential flow
6 microfiltration because the byproduct that is
7 coming is reduced native GMP in cheese whey as a
8 retentate, right?

9 Q Okay.

10 A Yeah.

11 Q And so having had a chance to look at
12 Figure 1, and I encourage you to look at the whole
13 thing if you need the context to answer my
14 questions, going back then to step 102 what is
15 your understanding of filter enzymatically
16 coagulated cheese whey? And maybe just to ask a
17 more clear question --

18 A Yeah. Yeah.

19 Q So it's your understanding that that's
20 not a course filtration step I think you said?

21 A Which one?

22 Q 102.

23 MR. KRIEGER: Objection, form.

24 A So -- so what I'm saying is in Figure 1
25 what it shows as a byproduct is reduce native GMP

1 cheese whey retentate. That means this is not a
2 -- any filtration process. Certainly not a
3 clarification process, right, because the
4 composition is changing.

5 Q And I want to understand why you're
6 saying it's not a clarification process. Would it
7 be correct that in a clarification process you
8 wouldn't -- so in a clarification process what is
9 in the retentate?

10 MR. KRIEGER: Objection, form,
11 foundation.

12 A Okay. What I am trying to say here is
13 that in a clarification process what we are trying
14 to do in the case of -- as I mentioned before,
15 clarification means different things in different
16 processes, right?

17 In the case of cheesemaking a
18 clarification process is such where the fines are
19 being removed. In this case the byproduct --
20 well, the product that is coming as a retentate is
21 -- is different, right? So it's not just -- we
22 are not just removing fines. In that sense this
23 is not a clarification process.

24 Q Okay.

25 And you wouldn't, for example, reduce

1 native GMP from cheese fines?

2 MR. KRIEGER: Objection, form,
3 foundation.

4 Q If you were looking to make a whey
5 protein composition.

6 MR. KRIEGER: The same objection.

7 A That was a long question. Can you
8 clarify the question?

9 Q So I'm trying to understand why it
10 wouldn't make sense to you for step 102 to be a
11 clarification process.

12 A Oh.

13 Q And so what I -- so what my question is:
14 You said the reason is because it talks about in
15 the next step reducing native GMP levels in cheese
16 whey retentate.

17 A Uh-huh.

18 Q And so my question is: Is the reason
19 why that means step 102 is not a clarification
20 process is because the sort of solids that you
21 pull out from a clarification process are not
22 something that you would then reduce GMP from to
23 make a whey protein composition?

24 A What I am trying to say here is that a
25 clarification process will be such where something

1 that is big and very different from -- "very
2 different" is such a loose term, but something
3 that is extremely big is being removed without
4 really changing the composition of the liquid
5 usually done by centrifugation, but it can be also
6 done by a very, very course filtration. But as
7 Figure 1 is showing, the output of this process is
8 a reduced native GMP cheese whey retentate, so
9 that for me is an indication that this is a
10 different process.

11 Q If you go to claim 8 which is on
12 column 23.

13 A In '860?

14 Q Yes. We are still in Exhibit 1001 which
15 is the '860 patent.

16 A Claim 8. Yes.

17 Q The first step of the method of claim 8
18 is filtering cheese whey from enzymatically
19 coagulated milk into a cheese whey retentate -- or
20 retentate and a permeate.

21 Do you see that?

22 A Filtering cheese whey into a cheese whey
23 retentate and a permeate. Yes. Uh-huh.

24 Q Is it your understanding that the
25 filtering step of claim 8 cannot be a

1 clarification step?

2 MR. KRIEGER: Objection, form.

3 A Based on the definition that I -- I just
4 mentioned, I wouldn't call this a clarification
5 step.

6 Q Is it your opinion that in claim 8 a
7 process that has a clarification step followed by
8 a filtering step could not meet claim 8?

9 MR. KRIEGER: Objection, form,
10 foundation, legal conclusion.

11 A Can you repeat the question?

12 Q Sure.

13 So I'm asking if all of the other
14 limitations of claim 8 were met, okay, so just
15 take -- take as my hypothetical that all of the
16 method steps of claim 8 are performed in a
17 process. Okay?

18 And prior to the filtering step, so that
19 is prior to filtering the cheese whey into a
20 cheese whey retentate and a permeate we add a
21 clarifying step. Does adding the clarifying step
22 mean that that process no longer practices claim 8
23 in your opinion?

24 MR. KRIEGER: Objection, form,
25 foundation, beyond the scope.

1 MS. KAISER: How is it beyond the
2 scope?

3 MR. KRIEGER: You are asking him
4 to render a legal opinion regarding
5 infringement which he's not even an
6 attorney. He has not provided opinions
7 regarding infringement at all.

8 MS. KAISER: Okay. I am not
9 asking about --

10 MR. KRIEGER: Well, you asked. It
11 goes well beyond the scope.

12 Q Can you answer my question?

13 A Can I answer the question?

14 MR. KRIEGER: You can answer it if
15 you can.

16 A Okay. What I'm saying is that we are
17 talking about cheese whey here, so as long as we
18 can continue calling this cheese whey, so if the
19 process that is in between this filtration step
20 and the original cheese whey doesn't change the
21 composition of the cheese whey that means if it's
22 just removing fines we can still call this a
23 cheese whey. That's my fine distinction here. So
24 as long as we can call it a cheese whey then we
25 can continue with claim 8.

1 THE COURT REPORTER: We can
2 continue with?

3 A With claim 8. Is it okay if I take a
4 break?

5 Q Of course, yeah.

6 MR. KRIEGER: Let's go off the
7 record.

8 THE VIDEOGRAPHER: Off the record
9 11:27.

10 (BREAK TAKEN.)

11 THE VIDEOGRAPHER: Back on the
12 record 11:36.

13 BY MS. KAISER:

14 Q Dr. Harte, you have in front of you your
15 declaration which is Exhibit 2005.

16 A Yes. Yes, I do.

17 Q Okay. If you turn to page 11 of your
18 declaration.

19 A Do you mind if we go --

20 Q Let me just ask you. Since it's
21 following up let me just ask you these questions
22 and then we will do that. That would probably be
23 a good thing to do before lunch.

24 A Okay.

25 Q So if you can turn to page 11 of

1 Exhibit 2005 and let me know when you're there.

2 A Ready.

3 Q Okay.

4 Do you see that there is a section
5 that's labeled "cheese whey retentate" and "cheese
6 whey retentate composition."

7 A Yes.

8 Q Okay. And then under that section do
9 you see paragraph 37?

10 A Yes.

11 Q And the first sentence of that paragraph
12 reads, "In my opinion, a POSITA would understand
13 that a 'cheese whey retentate' is the portion of
14 cheese whey that is captured by the filter after
15 the initial filtration of the cheese whey and a
16 cheese whey permeate passes through the filter."

17 Do you see that?

18 A Yes, I do.

19 Q Okay. What do you mean by initial?

20 A So when the filtration starts.

21 Q Okay. And so going back -- and if it's
22 easier you have reproduced claim 8 on the
23 preceding page in paragraph 32 of Exhibit 2005.

24 A Uh-huh.

25 Q And that -- that first step, the

1 filtering cheese whey step, it uses the term
2 cheese whey retentate.

3 Do you see that?

4 A For 38, right?

5 Q So I'm -- I'm pointing you back to
6 claim 8 which is reproduced in your declaration in
7 paragraph 32 if it's easier.

8 A Yes.

9 Q Okay.

10 And the first step of the method of
11 claim 8 is filtering cheese whey from
12 enzymatically coagulated milk into cheese whey
13 retentate and a permeate.

14 Do you see that?

15 A Yes, I do.

16 Q And so it's your opinion as I understand
17 it based on paragraph 37 that the cheese whey
18 retentate must be the portion of the cheese whey
19 that is captured by the filter after the initial
20 filtration of the cheese whey, correct?

21 A "After the initial filtration of the
22 cheese whey." Cheese whey retentate is the
23 portion of the cheese whey that is captured by the
24 filter after the initial filtration. I apologize.
25 I just did what you told me not to do.

1 Q That's okay. Let me ask.

2 A Yeah.

3 Q Let me ask you my question again so that
4 we have a clear record.

5 A Yes.

6 Q Is it your opinion as shown in
7 paragraph 37 that the cheese whey retentate in
8 claim 8 must be the portion of the cheese whey
9 that is captured by the filter after the initial
10 filtration of the cheese whey?

11 A Yes. After the initial filtration of
12 the cheese whey, yes.

13 Q And so based on that if a clarification
14 step occurred in claim 8 before the filtration
15 step and that clarification step was performed by
16 filtering then that couldn't perform the filtering
17 step because now -- let me strike that and ask a
18 better question. Sorry.

19 So it's your opinion that the filtering
20 step has to be the first filtering step. In other
21 words, the filtering step of claim 8 has to be the
22 first filtering step performed on the cheese whey?

23 MR. KRIEGER: Objection, form.

24 A As long as we call it a cheese whey that
25 is the step that we should follow. Now, if there

1 is clarification being done and there are no --
2 and only fines are being removed we can call that
3 a cheese whey.

4 Q Okay. So you could -- so it's your
5 opinion that you could have a filtering step and
6 as long as the permeate of that filtering step was
7 still a cheese whey that then you could perform a
8 subsequent filtering step and that could still be
9 -- strike that. Let me use your words.

10 So one of your opinions in this case is
11 that in the Bertelsen reference that because the
12 first filtration step is a microfiltration step
13 and what is -- well, sorry. Let's just -- let's
14 just go from a figure, so if you go to page 27 of
15 your declaration.

16 A Yes.

17 Q And feel free to look at other -- other
18 paragraphs if you need to orient yourself. But
19 you see on page 27 there is a figure that adds
20 steps -- let me -- let me start over.

21 A Yes.

22 Q On page 27 there is -- of your
23 declaration which is Exhibit 2005 there is a
24 figure which shows steps of Bertelsen's process in
25 the top portion above the dotted redline and then

1 part of the Nielsen 785 process --

2 A Yes.

3 Q -- below the dotted redline, is that
4 correct?

5 A Yes.

6 Q Okay.

7 And it's your understanding that the
8 process that's depicted in the figure starts with
9 cheese whey from standard cheese production,
10 correct?

11 A Sweet whey, yes.

12 Q Sweet whey. And that sweet whey then is
13 subjected to microfiltration with a 1.2-micron
14 filter, correct?

15 A Yes.

16 Q And that filtration step, the
17 microfiltration step results in a permeate and a
18 retentate?

19 A That is correct. Uh-huh.

20 Q And the permeate from the
21 microfiltration step is then subjected to an
22 ultrafiltration step?

23 A Based on this figure, yes.

24 Q And that ultrafiltration step then
25 results in a retentate and a permeate, correct?

1 A Correct.

2 Q And it's your opinion that what is shown
3 as the lactose-depleted UF retentate cannot be the
4 "cheese whey retentate" of claim 8, is that
5 correct?

6 A Based on this figure there is a
7 microfiltration step that generates a permeate.
8 So this is being -- this is, in my opinion, no
9 longer cheese whey.

10 Q Okay.

11 And so the answer to my question then is
12 that it's your opinion that what is shown as the
13 lactose depleted UF retentate is not a "cheese
14 whey retentate" in the context of claim 8?

15 A What I'm -- what I'm saying here is that
16 cheese whey and sweet whey are terms refer to the
17 whey coming from cheesemaking. If there are
18 processes after that we are no longer talking
19 about cheese whey.

20 It -- it does become complicated
21 because there is such a widespread use of the term
22 "whey" that it creates confusion, right? But what
23 I'm saying here is that if there is a process that
24 is changing something in the cheese whey beyond
25 just removing fines we can no longer call that

1 cheese whey.

2 Q So if you look at paragraph 72 which is
3 the paragraph after the figure on page 27.

4 A Yes.

5 Q You say, "It is my opinion that
6 Nielsen 785/Bertelsen does not satisfy claim 8.2."
7 Continuing onto the next page. "Because, as shown
8 in the corrected Bertelsen flow chart, the BLG
9 isolate powder is actually made from a
10 microfiltration permeate."

11 Do you see that?

12 A Yes.

13 Q And so is it your understanding that
14 doctor -- strike that.

15 You understand that petitioner's expert
16 is named Dr. Etzel?

17 A I do.

18 Q And you have read his declaration in
19 this case?

20 A I did.

21 Q Did you review the transcript of his
22 deposition?

23 A I did.

24 Q Okay.

25 And you understand that it's Dr. Etzel's

1 opinion that the lactose depleted UF retentate
2 teaches cheese -- the cheese whey retentate of
3 claim 8, correct?

4 A You are asking me if that is what he
5 said?

6 Q I am asking you if that's your
7 understanding of his opinion.

8 A It would be better if we can go to his
9 declaration and read that part again.

10 Q Okay.

11 So as -- as you sit here right now you
12 don't have an understanding of what Dr. Etzel
13 mapped the cheese whey retentate of claim 8 to in
14 Bertelsen?

15 A I do. But on what Dr. Etzel did was --
16 Bertelsen is a bit confusing in terms of what did
17 they do. So Dr. Etzel tried in his best judgment
18 to come up with this flow chart, right? Now, what
19 he -- what did he specifically say about lactose
20 depleted UF retentate that I would like to read
21 again in his declaration just to make sure.

22 Q Well, let me ask you this.

23 A Yeah.

24 Q Is it -- let's assume for sake of
25 argument --

1 A Yeah.

2 Q -- that what Dr. Etzel said was the
3 cheese whey retentate was an ultrafiltration
4 retentate in Bertelsen.

5 You disagree with that, correct?

6 A Can you say that again?

7 Q Sure.

8 A Yeah.

9 Q I am saying assume that Dr. Etzel said
10 in his opinions that in Bertelsen the
11 ultrafiltration retentate teaches the cheese whey
12 retentate of claim 8.

13 You disagree with that, correct?

14 MR. KRIEGER: Objection, form.

15 A What I'm saying here is that in the step
16 in this figure where -- what is being fed in the
17 ultrafiltration tangential flow system based on
18 this diagram I would not consider that cheese whey
19 any longer because based on what I see here this
20 is not just a clarification step, so there -- this
21 is not just removing fines. And for that is that
22 I say, well, what it says here is cheese whey
23 permeate is not -- is no longer just cheese whey
24 or sweet whey.

25 Q Okay.

1 A It's a permeate.

2 Q So I want you to listen to the question
3 that I am asking.

4 A Yeah.

5 Q Because I am not asking you why you
6 disagree with something. I am only asking if you
7 disagree with something, so it's a yes/no
8 question.

9 A Okay.

10 Q Okay.

11 So my question is: If Dr. Etzel said
12 that the UF retentate in Bertelsen teaches a
13 cheese whey retentate, you would disagree with
14 that, correct?

15 MR. KRIEGER: Objection, form.

16 A So if -- if Dr. Etzel is saying that
17 what is shown here as cheese whey permeate is the
18 same as cheese whey I would disagree with that.

19 Q You're not answering my question,
20 Dr. Harte.

21 A Okay.

22 Q I am saying if Dr. Etzel said that a UF
23 retentate in Bertelsen teaches the cheese whey
24 retentate in claim 8, you disagree with that,
25 correct?

1 MR. KRIEGER: Objection, form,
2 asked and answered.

3 MS. KAISER: He hasn't answered
4 it.

5 MR. KRIEGER: He has. You just
6 don't like his answer, but he has answered
7 it.

8 MS. KAISER: It's a yes or no
9 question.

10 MR. KRIEGER: Objection.

11 Q Or let me ask you a different question.
12 Would you agree that the UF retentate in
13 Bertelsen teaches the cheese whey retentate of
14 claim 8?

15 A I go back to my comment before. What I
16 am trying to say here and what I'm saying is that
17 since there is a microfiltration step as shown in
18 the figure on page 27 I wouldn't call that cheese
19 whey permeate cheese whey or sweet whey. I -- I
20 would call it as it says in there cheese whey
21 permeate.

22 Q Okay. Let me ask you a different
23 question.

24 A Yeah.

25 Q In the figure that is reproduced or that

1 is -- is shown on page 27 of your declaration is
2 there a cheese whey retentate?

3 A It shows a cheese whey retentate, yes.

4 Q Okay. And what is that cheese whey
5 retentate?

6 A That is the portion that is -- doesn't
7 pass through the filter, through this
8 microfiltration unit as the cheese whey goes
9 through.

10 Q Okay. In the figure that you've
11 produced on page 27 of your declaration --

12 A Yes.

13 Q -- other than the microfiltration
14 retentate is there any other cheese whey retentate
15 as that term is used in claim 8 of the '860
16 patent?

17 A What I see in this figure is that there
18 is sweet whey that has been micro-filtered using
19 tangential flow filtration to create a cheese way
20 retentate and a cheese way permeate.

21 Q I don't think that answered my question.
22 So what I'm asking you is you've identified one
23 cheese whey retentate.

24 A Yes.

25 Q That is the microfiltration retentate.

1 A Uh-huh.

2 Q I am asking if there are any other
3 cheese whey retentates in the figure on page 27 of
4 your declaration.

5 A Based on this figure, no. There is only
6 one cheese whey retentate.

7 Q Okay. Thank you.

8 And so if you look at paragraph 73 of
9 your declaration.

10 A Yes.

11 Q You say -- this is towards the bottom of
12 that paragraph: The "concentrated UF whey protein
13 retentate" is not a "cheese whey retentate."

14 Do you see that?

15 MR. KRIEGER: I'm sorry. Where is
16 that?

17 Q Paragraph 73.

18 A I see that, yeah.

19 Q Do you still agree with that statement?

20 A Okay. So everything starts from sweet
21 whey and then a -- there is a microfiltration step
22 where a cheese whey retentate and a cheese whey
23 permeate is being created. So I would say that as
24 it's written here this cheese whey permeate is no
25 longer -- sorry. The cheese whey -- both the

1 cheese whey retentate and the cheese whey
2 permeates are no longer -- cannot be called just
3 cheese whey.

4 Q So my question is: You have a statement
5 in paragraph 73 that says "the concentrated UF
6 whey protein retentate."

7 Do you see that in the figure on
8 page 27?

9 A Yeah.

10 Q "Is not a cheese whey retentate."

11 A Yes.

12 Q As you sit here right now do you still
13 agree with that statement?

14 A I do.

15 Q Okay.

16 A Yeah.

17 MR. KRIEGER: Good time to break
18 for lunch?

19 MS. KAISER: I was going to let
20 him do his corrections.

21 MR. KRIEGER: Okay. Very good.

22 Q Dr. Harte, before we break for lunch, I
23 think you told me that you had some corrections
24 for your declaration.

25 A I do, yeah.

1 Q And are those corrections what's marked
2 by the tabs in your declaration?

3 A Some of them are, but these are just
4 markings. I -- I did put markings on each of the
5 grounds just to make sure that I was precise.

6 Q Okay. The tabs in your declaration,
7 they signify the start of each ground, is that
8 right?

9 A The tabs on the top are the grounds, and
10 then these are the corrections.

11 Q I see.

12 A Yeah.

13 Q Okay. And so do you have five
14 corrections?

15 A Well, there is one correction that
16 appears in two places, so there are a total of
17 four corrections.

18 Q Okay.
19 What is the first correction that you
20 would like to make to your declaration?

21 A Yeah. The first one would be in
22 page ii, the table of contents.

23 Q Okay.

24 A So in item 13C it reads, "Ozturk,
25 Kawasaki, and LeanCreme do not teach of suggest."

1 And it says "or." It should say "or suggest."

2 Q Okay.

3 A And that of course repeats in page 66,
4 C. Instead of "of" it should be "or."

5 Q Thank you.

6 A Yeah.

7 Q What is the second correction you would
8 like to make?

9 A The second -- page 4 and paragraph 14,
10 line 4. It reads "caseins" and there is a
11 parentheses and it says alpha-s2, comma, alpha-s2.
12 It should be alpha-s1 and then alpha-s2.

13 Q Okay. Thank you. What is the third
14 correction you would like to make?

15 A Yeah. Number 3 would be page 34. I
16 will get there.

17 Q Okay.

18 A So if we go to paragraph 86, the second
19 sentence, it reads, "A POSITA would understand
20 that centrifugation process used by Bertelsen is
21 not a membrane process and is not
22 microfiltration." And what I would like to do
23 there is to add "as described in patent '860."
24 Right?

25 Q Okay.

1 A And then the next one will be page 64.
2 Yeah, let me get there. So after the table in the
3 fourth line it says, "evident from Hinkova
4 Table 7." I think "Table 7" should be removed
5 because it is there. Exhibit 1013, 6, Table 7.

6 Q So you just want it to say "as evident
7 from Hinkova."

8 A Just remove "Table 7."

9 Q Okay.

10 A Yeah. Exhibit 1013 is Hinkova.

11 Q Okay. Any other corrections?

12 A No, that's -- that's it, yeah.

13 Q Okay. A few -- I have a couple of
14 questions about your corrections.

15 A Yes.

16 Q So the correction that you made to the
17 heading --

18 A Yes.

19 Q -- to say teach or suggest, what is your
20 understanding of what it means for a reference to
21 teach or suggest something?

22 A Well, again, as I mentioned before, I am
23 not a lawyer, right? So in this case these three
24 references are not telling me that these --
25 greater than 50 percent -- 50 -- whey percent of

1 denatured whey protein.

2 Q Okay.

3 Do you have an understanding of the
4 difference between a reference teaching something
5 and a reference suggesting something?

6 A Teaching or suggesting? Well, I would
7 say whether it's explicitly said or it's somehow
8 suggested that that is the case, but again I am
9 not a lawyer so --

10 Q Okay. And then in paragraph 86.

11 A Let me get there. Yes.

12 Q So you wanted to add to: A POSITA would
13 understand that centrifugation process used by
14 Bertelsen is not a membrane process and is not
15 microfiltration "as described in the '860 patent."

16 A Yes.

17 Q What are you referring to by "as
18 described in the '860 patent."

19 A So the '860 patent is about tangential
20 flow filtration, and Bertelsen is using dead-end
21 filtration which is let's say in general terms
22 beyond the scope of what we are discussing here.

23 It may be confusing, but the
24 patent '860 doesn't say anything or it's -- the
25 patent '860 is not about dead-end filtration.

1 It's all about tangential flow filtration even
2 though it's not explicitly stated in the patent.

3 Q Okay.

4 And so is it your opinion then that in
5 claim 8 when it says "filter" that must only be
6 tangential flow filtration?

7 A Yes.

8 Q Okay. All right. If lunch is here I
9 think we can break.

10 THE VIDEOGRAPHER: Off the record

11 12:03.

12 (BREAK TAKEN.)

13 THE VIDEOGRAPHER: Back on the
14 record 12:38.

15 BY MS. KAISER:

16 Q Dr. Harte, I wanted to see if you could
17 get your declaration back out and turn to page 27.
18 This is the figure that we have been talking about
19 that represents Bertelsen's process and Nielsen
20 785's process.

21 A Yes, I am there.

22 Q Okay. So earlier we were talking about
23 microfiltration retentate that you have labeled as
24 cheese whey retentate.

25 Do you recall that?

1 A Yes.

2 Q Okay.

3 So in the microfiltration retentate in
4 the figure on page 27 of your declaration what is
5 that retentate comprised of?

6 A I would prefer not to elaborate. It
7 will be -- it will be a little too general for me
8 to say. It will be important to run an analysis
9 and understand what is there. If there is nothing
10 in between the sweet whey -- if there were no
11 fines removed. My guess is that there will be
12 some fines in there.

13 Q Okay.

14 A But discussing the -- the composition of
15 both the cheese whey retentate and the permeate
16 would be -- without having an analysis would be
17 difficult to do.

18 Q Okay.

19 So as you sit here right now you don't
20 have an opinion about what is in the
21 microfiltration retentate in the figure that's on
22 page 27 of your declaration?

23 A Well, in general terms, but that's why
24 in general terms I would say, again, if there is
25 no -- nothing in between the sweet whey that is

1 coming to the microfilter, and as I mentioned
2 fines, and this is a 1.2 micro filter, so I guess
3 some bacteria may be there and maybe proteins from
4 whey too, right?

5 So that is where it becomes a
6 little bit difficult when it comes to things that
7 are borderline or that they can aggregate, so
8 whatever is huge is going to be there, but then
9 when it comes to the widths of it, it becomes more
10 difficult.

11 Q So would it be common to perform a
12 clarification step that removes cheese fines with
13 a 1.2-micron filter?

14 MR. KRIEGER: Objection, form.

15 A Well, it depends on what the operation
16 is, what type of cheese is being made. Usually
17 what is done is it's being used a centrifugal
18 separator, a continuous centrifugal separator to
19 remove those fines. I would expect the filter to
20 be a little larger when it comes to removing fines
21 than this.

22 Q Okay.

23 So you said if there was no
24 clarification step before the 1.2 micron filter
25 then you would expect cheese fines to be in the

1 retentate, correct?

2 A In that --

3 MR. KRIEGER: Objection, form.

4 A In this specific diagram if there was no
5 clarification step I would expect to see -- to
6 find fines in this cheese whey retentate.

7 Q And then you said bacteria could be in
8 the cheese whey retentate as well?

9 A Well, bacteria, if I recall -- while we
10 are talking about -- there are bacteria that can
11 be between 2 to 3 microns, so some may be there.
12 Some may go forward to the cheese whey permeate.
13 It's difficult for me to be definitive where the
14 bacteria are going to be.

15 Q Okay.

16 Anything else you would expect to be in
17 the cheese whey retentate besides fines and
18 bacteria?

19 MR. KRIEGER: Objection, form.

20 A As I mentioned before, without an
21 analysis it's difficult to know, and that is why I
22 do struggle with it, right, so --

23 Q Is there a certain -- oh, sorry. Go
24 ahead.

25 A If there was only -- so as I mentioned

1 before, I don't think this is just a clarification
2 step, so that is why I struggle to call it cheese
3 whey, so this is a retentate and a permeate and I
4 would need an analysis of those two specifically
5 for the components in whey where are they going
6 with this specific micron size.

7 Q Okay.

8 Is there a specific molecular weight of
9 particles -- or of compounds that you would expect
10 to pass through a 1.2-micron filter in the context
11 of cheese whey?

12 MR. KRIEGER: Objection, form.

13 A Can you repeat the question, please?

14 Q Sure.

15 And maybe just to orient you if you go
16 to paragraph 69 of your declaration.

17 A Yes.

18 Q You say, "From my experience, GMP would
19 not be removed in this microfiltration step
20 because GMP has a very low molecular weight
21 (around 7 kilodaltons) that would permeate the
22 1.2-micron filter."

23 Do you see that?

24 A I can see that, yep.

25 Q So I am wondering what -- what in your

1 experience what the threshold would be for
2 molecular weight that would pass through a
3 1.2-micron filter.

4 A Well, it is -- it is difficult to answer
5 because as I think we discussed before depending
6 what is being done to these proteins or components
7 in milk they tend to aggregate or not, right? So
8 it's not just the molecular weight of any
9 individual protein. That is why I do struggle to
10 -- to respond here.

11 Q Okay. You can set the declaration aside
12 for the moment.

13 A Yes.

14 Q And I want to go back to the '860 patent
15 which is Exhibit 1001.

16 A Yes.

17 Q So if we go back to column 6 of the '860
18 patent and you recall earlier that in column 6 the
19 '860 patent is discussing Figure 1.

20 Do you remember that?

21 A Yes.

22 Q Okay. I want to direct you to -- it's
23 the third full paragraph, but it starts "for
24 instance" and it starts around line 29 of
25 column 6.

1 A Yes. Yes.

2 Q If you go further down that paragraph it
3 says, "In embodiments, the whey protein retentate
4 may be concentrated using ultrafiltration, or
5 other methods as known in the art."

6 Do you see that?

7 A Yes.

8 Q When the whey protein retentate is
9 concentrated does it still remain a whey protein
10 retentate in your opinion?

11 A Well, this is where in my opinion things
12 become dicey, right? Because if we assume that
13 only water is being removed and nothing else, not
14 even salt, well, then we can say that only water
15 has been removed, but depending on the processes
16 that are being used this concentration may affect
17 the composition of this whey protein.

18 Q And when you say affect the composition
19 of the protein --

20 A Yeah.

21 Q -- it sounds like you're not including
22 in that the percentage of total protein. In other
23 words, if it's concentrated it's going to have a
24 higher total protein percentage, correct?

25 MR. KRIEGER: Objection, form.

1 A Can you repeat the question?

2 Q Sure.

3 So when -- in column 6 at about line 35
4 when it says the whey protein retentate may be
5 concentrated utilizing ultrafiltration, is it your
6 understanding that means that the percentage of
7 protein will be higher after it's been
8 concentrated?

9 A I would say that probably the
10 concentration will be higher, but the composition
11 is difficult to say because --

12 Q What's the distinction?

13 MR. KRIEGER: Sorry. Were you
14 finished?

15 A I was going to add that we have a
16 profile of proteins, right? And as we do a
17 filtration process like this and we concentrate
18 probably some of the proteins may go into the
19 permeate and some of the proteins will remain in
20 the retentate. So as I indicated before, it is
21 not just water that is being -- if we were to be
22 sure that there is only water being removed I
23 would say, well, it is the same.

24 Q So is it your opinion then that if
25 during ultra -- I'm sorry.

1 If during concentration components other
2 than water are removed then after concentration it
3 would no longer be a whey protein retentate?

4 A Okay. The term whey protein, a whey
5 protein retentate can be a ton of different
6 things, right? Still a whey protein. It doesn't
7 mean that it will be the same whey protein. It
8 still -- it is still whey protein.

9 Q So Figure 1 in step 103 uses the term
10 "cheese whey retentate."

11 A Cheese whey retentate, yes.

12 Q Do you see that?

13 A Yes.

14 Q If prior to reducing native GMP the
15 cheese whey retentate is concentrated would it no
16 longer be a cheese whey retentate?

17 A I don't have a definite answer there
18 because as I mentioned before as long as -- the
19 only case where I would say it is a -- still
20 remains a cheese whey is where only fines are
21 being removed.

22 Q And water, right?

23 A To a limited extent in this case because
24 this is -- in the -- the objective of
25 clarification is to remove fines. So as you

1 remove fines, you are also removing a little bit
2 of water, but it's not a concentration process or
3 at least let's say that the objective is not to
4 concentrate anything.

5 Q Okay.

6 A So fines do have water. In that sense
7 things may be concentrating. I am just trying not
8 to be absolute.

9 Q No, I understand. Yeah, I appreciate
10 your precision. So if we look at Figure 1.

11 A Yes.

12 Q And you're filtering the enzymatically
13 coagulated cheese whey in step 102, right?

14 A Yes. Uh-huh.

15 Q And then from that you get a cheese whey
16 retentate?

17 A Yes.

18 Q That you then reduce the native GMP
19 levels in step 103, correct?

20 A That is correct, yep.

21 Q Okay. So my question is: Say we put a
22 box in Figure 1. We will call it 102A so it's
23 between step 102 and 103.

24 A Uh-huh.

25 Q And in step 102A we concentrate the

1 cheese whey retentate by removing water. Then in
2 step 103 could we still say that we're reducing
3 native GMP levels in cheese whey retentate or
4 could we not because we have removed water?

5 MR. KRIEGER: Objection, form.

6 A It is -- we are -- I think we are
7 entering into hypotheticals. So cheese whey is
8 what is coming from the making of cheese. It's
9 usually referred -- if I am running clarification
10 steps where I am only removing fines, I would call
11 it still cheese whey because there is very limited
12 water being removed.

13 Q Uh-huh.

14 A Now, if we are continuing doing this
15 process where we keep removing water, again, this
16 is somehow hypothetical. I would call it like
17 maybe a cheese whey concentrate.

18 Q Okay. And so going back then to
19 column 6.

20 A Yes.

21 Q So in about line 35 when it says, "The
22 whey protein retentate may be concentrated using
23 ultrafiltration," then you would say it sounds
24 like that's no longer the retentate. Now it's a
25 concentrate. Is that fair?

1 A Well, but here it says whey protein,
2 right? And as I mentioned the term "whey protein"
3 is being so loosely defined in general terms that
4 this is still whey protein, right? So we have
5 whey protein concentrates and whey protein
6 isolates.

7 Q Okay. Let's maybe take it in the
8 context of claim 8 then if you go to that which is
9 at column 23.

10 A Where? Sorry.

11 Q Column 23.

12 A 23. Yes.

13 Q It's the last page of the patent.

14 A Yes. Uh-huh.

15 Q So you remember earlier we talked about
16 the filtering step.

17 A Yes.

18 Q Where you filter into a cheese whey --

19 A Yes.

20 Q -- retentate and permeate?

21 A Yes.

22 Q And then after that next you have a
23 reducing native GMP in the cheese whey retentate
24 to form a reduced GMP cheese whey retentate.

25 A Yes.

1 Q So if after the filtering step you
2 included a concentrating step where you removed
3 water and then it was the concentrated cheese whey
4 that you did the reducing step to, in your opinion
5 would you be still reducing GMP in a cheese whey
6 retentate?

7 MR. KRIEGER: Objection, form.

8 A I would call it a reduced GMP in a
9 concentrated cheese whey.

10 Q Okay.

11 And what if you -- in between the
12 filtering step and the reducing step what if you
13 diluted it by adding water, so you took the
14 retentate and you diluted it by adding water and
15 then in that diluted composition you reduced the
16 native GMP, would you then -- would it be your
17 opinion that you have reduced GMP in a cheese whey
18 retentate?

19 MR. KRIEGER: Objection, form.

20 A So this is cheese whey that is subject
21 to microfiltration and has a retentate, and then
22 water is being added, so that will be a
23 diafiltrated cheese whey, right?

24 So what I'm trying to say here is
25 originally there is cheese whey, but there is

1 diafiltration in this case, so water is being
2 added. So I do not know if I would -- I would
3 call a cheese whey retentate where -- where water
4 is being added still a cheese whey retentate.

5 Q Okay.

6 A Yeah.

7 Q If you go to column 15 of the patent.

8 A Column 15. Yes.

9 Q And we are still in Exhibit 1001 which
10 is the '860 patent.

11 A Column 15. Yep.

12 Q Okay. You're at column 15?

13 A Yes.

14 Q Okay.

15 Do you see where about two-thirds of the
16 way down it says Example 1?

17 A Yes.

18 Q Okay.

19 And so in Example 1 it says, "A reduced
20 GMP denatured whey protein composition was made
21 using a whey protein composition (WPC) that is
22 greater than 25 percent protein on a dry weight
23 basis from sweet whey of mozzarella cheesemaking."

24 Do you see that?

25 A Yes.

1 Q Okay. And then it says, "The process
2 begins with WPC retentate (80 percent protein on
3 dry basis) that is concentrated using
4 ultrafiltration of pasteurized sweet whey
5 separated from cheese curd."

6 Do you see that?

7 A Yes.

8 Q Would you consider WPC retentate to be a
9 cheese whey retentate as that term is used in
10 claim 8?

11 A No. A WPC retentate is a WPC retentate.

12 Q What's the difference between a cheese
13 whey retentate and a WPC retentate?

14 A A cheese whey retentate comes from the
15 -- it is the retentate from tangential flow
16 filtration of cheese whey.

17 Q And what is a WPC retentate?

18 A I would call this -- this whey protein
19 concentrate a pasteurized sweet whey retentate.
20 If I understand there is sweet whey that then has
21 been pasteurized, and then the only process that
22 is happening is this ultrafiltration membrane that
23 is going to generate two streams, a permeate and a
24 retentate.

25 So before concentration what's

1 coming there would be a -- so this has -- so the
2 WPC has also a concentration step apparently,
3 concentrated, so right after the ultrafiltration
4 step I would have two streams, pasteurized sweet
5 whey retentate and pasteurized sweet whey
6 permeate, and then there is a concentration step
7 to create WPC. So no, WPC would not by itself be
8 a sweet whey retentate.

9 Q Okay. Thank you for that explanation.
10 So maybe I just want to walk through the process
11 that is described in Example 1 --

12 A Yep.

13 Q -- and make sure that I understand it
14 correctly.

15 A Yep.

16 Q So based on what you described I
17 understand that you would have sweet whey of
18 mozzarella cheesemaking and that you would
19 separate that into a retentate and a permeate, is
20 that right?

21 A Yes.

22 Q And the retentate would be the WPC
23 that's 25 -- greater than 25 percent protein?

24 A Wait. Let me go again to the example.

25 Q This is on column 15.

1 A So can you repeat the process again?

2 Q Sure.

3 So based on what you described, I
4 understand you would have sweet whey from
5 mozzarella cheesemaking that you would separate
6 into a retentate and a permeate, is that right?

7 A Pasteurized sweet whey.

8 Q Pasteurized sweet whey.

9 A Yeah.

10 Q But otherwise what I said is correct?

11 A Well, this is pasteurized sweet whey.

12 Q Okay. Let me ask it again.

13 So in Example 1 you would have
14 pasteurized sweet whey of mozzarella cheesemaking
15 process that you would separate into a retentate
16 and a permeate, is that correct?

17 A That is correct, yes.

18 Q Okay.

19 And the retentate would be WPC that is
20 greater than 25 percent protein on a dry weight
21 basis, is that correct?

22 A Well, there is a concentration step
23 here. So what comes from the first step of the
24 ultrafiltration membrane, I would call that
25 pasteurized sweet whey retentate.

1 Q Okay.

2 A Now -- yeah. If there are further
3 concentration steps then I would no longer call
4 that a pasteurized -- sorry -- a pasteurized sweet
5 whey retentate.

6 Q Okay. So in Example 1 --

7 A Yes.

8 Q -- after the first filtration step on
9 the pasteurized sweet whey you would have a
10 pasteurized sweet whey retentate?

11 A Yes.

12 Q Then Example 1 describes concentrating
13 that retentate using ultrafiltration to create
14 WPC80, is that correct?

15 A I would say using diafiltration, right?
16 So there should be several concentration steps to
17 get to 80 percent.

18 Q Okay.

19 But in Example 1 the pasteurized sweet
20 whey retentate is concentrated and through a
21 series of concentration steps ultimately becomes
22 WPC80. Is that how you understand Example 1?

23 A Yes.

24 Q Okay. And then it says starting at
25 about line 51: The 80 percent WPC (WPC80)

1 retentate is transferred to a temperature
2 controlled holding tank and kept cold at
3 45 degrees C or -- I'm sorry -- 45 degrees F or
4 less.

5 Do you see that?

6 A Yes.

7 Q And then it goes on and says, "Where it
8 is mixed with water to make a 14 percent protein
9 solution."

10 Do you see that?

11 A Yes.

12 Q And the -- so being mixed with water
13 would be a dilution step, correct?

14 A Yes.

15 Q And then the last sentence of that
16 paragraph says, "The diluted whey protein solution
17 remains in the holding tank at about 45 degrees F
18 or less until the addition of protease enzymes."

19 Do you see that?

20 A Yes.

21 Q And is it your understanding that adding
22 the protease enzymes in Example 1 is -- reduces
23 GMP in the diluted whey protein solution?

24 A Yes. That following paragraph,
25 selectively hydrolyzes GMP.

1 Q So in Example 1 the solution that is --
2 strike that. In Example 1 the solution in which
3 GMP is reduced, is that solution a cheese whey
4 retentate in your opinion?

5 A As it reads in the patent it's a diluted
6 whey protein solution. It doesn't refer to as a
7 cheese -- as I mentioned, there are several steps
8 in between and I tried to keep -- well, in my
9 opinion cheese whey is what is just coming from
10 the making of cheese so any -- any modification
11 other than removing fines makes this thing a
12 different -- we should use a different name.

13 Q Okay.

14 A Yeah.

15 Q And so it follows then that your opinion
16 would be that Example 1 of the '860 patent doesn't
17 meet the limitations of claim 8?

18 MR. KRIEGER: Objection, form.

19 Q Is that correct?

20 A Oh, okay. So what I am saying is that I
21 don't recall here -- let me check the claim again.
22 What I'm saying here is that in Example 1 the
23 enzyme that will hydrolyze GMP is being added to a
24 diluted whey protein solution. Whether -- whether
25 that meets the limitations or not of claim 8, that

1 I don't know.

2 Q So in Example 1 is the step reducing
3 native GMP in the cheese whey retentate to form a
4 reduced GMP cheese whey retentate composition
5 performed?

6 MR. KRIEGER: Objection, form,
7 beyond the scope.

8 A In Example 1 the enzyme is being added
9 to a diluted whey protein solution.

10 Q So the answer to my question is no?

11 MR. KRIEGER: The same objection.

12 A What is the question again?

13 Q In Example 1 is the reducing native GMP
14 in the cheese whey retentate to form a reduced GMP
15 cheese whey retentate composition performed?

16 MR. KRIEGER: Objection, form,
17 beyond the scope.

18 A In Example 1 GMP is being -- sorry --
19 the enzyme is being added to diluted whey protein
20 solutions.

21 Q So in your opinion GMP is being reduced
22 in a diluted whey protein solution and not in a
23 cheese whey retentate, is that correct?

24 MR. KRIEGER: Objection, form,
25 beyond the scope.

1 A In this case the enzyme is being added
2 to a diluted whey protein solution.

3 Q And in your opinion the diluted whey
4 protein solution is not a cheese whey retentate, is
5 that correct?

6 MR. KRIEGER: Objection, form,
7 beyond the scope.

8 A A -- a dilute -- this diluted whey
9 protein solution -- this diluted whey in
10 Example 1, the diluted whey protein solution is
11 not a cheese whey --

12 Q Retentate?

13 A -- retentate.

14 Q Okay.

15 Going back to Example 1, I want to talk
16 about the reducing step, so this starts in about
17 line 61-ish where in the paragraph that says
18 "addition of one or more enzymes." Let me know
19 when you're with me. Column 15.

20 A I'm there.

21 Q Okay.

22 So it says, "One or more protease
23 enzymes began an incubation phase of protein
24 hydrolysis that selectively hydrolyzes GMP in the
25 whey protein mixture."

1 Do you see that?

2 A I apologize. You said column 15?

3 Q Yes.

4 A And line?

5 Q Around 61-ish. It's the -- the last
6 partial paragraph in the column. It starts
7 "addition of one or more enzymes."

8 A Oh. But you said addition of one or
9 more proteolytic or something enzymes.

10 Q Let me start at the beginning.

11 A Yeah.

12 Q Okay.

13 So it says, "Addition of one or more
14 enzymes, in this case, one or more protease
15 enzymes began an incubation phase of protein
16 hydrolysis that selectively hydrolyzes GMP in the
17 whey protein mixture."

18 Do you see that?

19 A Yes.

20 Q What does it mean that it selectively
21 hydrolyzes GMP?

22 A Okay. There are enzymes that have
23 specificity and enzymes that are generally
24 proteolytic. For instance, chymosin is specific
25 for kappa casein.

1 THE COURT REPORTER: Is specific

2 for?

3 A Kappa casein. Trypsin or pepsin are
4 enzymes that are not as specific. So when it says
5 selectively hydrolyzes GMP is that in this case
6 the enzyme that is being used is specific for GMP.

7 Q Okay.

8 And then you see that that sentence goes
9 on to say, "Leaving the other whey protein such as
10 alpha-lactalbumin and beta-lactoglobulin largely
11 unhydrolyzed."

12 Do you see that?

13 A Yes.

14 Q Sorry for the pronunciation.

15 Do you have an understanding of what it
16 means by largely unhydrolyzed?

17 A So what is the question again?

18 Q I am wondering if you have an
19 understanding of what "largely unhydrolyzed"
20 means.

21 A I am speculating here. Again,
22 selectivity is not a -- there are degrees of
23 selectivity, right? So in this case what I am
24 assuming is that the enzyme that it's using to
25 proteolyze GMP -- all the activity for GMP or it

1 prefers GMP. It doesn't mean that it may not to
2 some degree hydrolyze also lactalbumin and
3 lactoglobulin.

4 Q So in Example 1 the specific protease
5 enzyme selectively hydrolyzes GMP, but at least to
6 a small degree it may also hydrolyze ALA and BLG,
7 is that correct?

8 MR. KRIEGER: Objection, form.

9 A That may be the case. Also it may be
10 the case that milk has natural enzymes in there
11 that maybe this is referring to natural enzymes in
12 milk that may be partially hydrolyzing
13 lactoglobulin and lactalbumin.

14 Q In Example 1 in the hydrolyzing step
15 that reduces GMP --

16 A What page again?

17 Q I'm still in Example 1.

18 A Yes.

19 Q So we're still in column 15 and 16.

20 A Okay.

21 Q So in Example 1 the enzymatic process
22 that reduces GMP, does it involve any filtration?

23 MR. KRIEGER: Objection, form.

24 A So in Example 1 there are filtration
25 steps to getting to -- filtration and

1 diafiltration steps to get to diluted whey
2 protein, a diluted whey protein solution, upon
3 which this enzyme is being added. So if you're
4 saying that there is a filtration step related to
5 adding the enzyme the answer would be no.

6 Q So I want to go back to claim 8 which is
7 on column 23 in the last page of the '860 patent.

8 A Yes.

9 Q And I want to focus on the reducing step
10 again so that step reads: Reducing native GMP in
11 the whey -- I'm sorry.

12 Reducing native GMP in the cheese whey
13 retentate to form a reduced-GMP cheese whey
14 retentate composition.

15 A Uh-huh.

16 Q Do you see that?

17 A Yes.

18 Q Do you have an opinion on how the scope
19 of that limitation would change if the word
20 "composition" was removed?

21 A So the way that I understand these is
22 that we have a -- we can have a cheese whey
23 retentate and then if anything is being added,
24 let's say an enzyme in this case is being added,
25 what we have is a cheese whey retentate

1 composition. So the fact that we add an enzyme
2 makes it a cheese whey retentate composition as
3 opposed -- as a cheese whey retentate.

4 Q So would it be your opinion then that if
5 the word "composition" was removed from the
6 reducing step that the reducing step could not be
7 performed by using an enzyme?

8 MR. KRIEGER: Objection, form and
9 beyond the scope. He did not provide
10 testimony regarding this issue. And I am
11 going to instruct him not to answer. If you
12 want to call the board, you can, but this
13 goes to motion to amend issues that he did
14 not testify about.

15 MS. KAISER: Okay. Let's call the
16 board.

17 MR. KRIEGER: Okay.

18 MS. KAISER: Let's go off the
19 record.

20 THE VIDEOGRAPHER: Off the record
21 1:21.

22 (BREAK TAKEN.)

23 THE VIDEOGRAPHER: Back on the
24 record 1:27.

25 BY MS. KAISER:

1 Q Dr. Harte, all right, so I understand
2 that your counsel is not going to -- is not going
3 to maintain his objection or at least he is not
4 going to maintain his instruction not to answer,
5 so I am going to ask you the question again.

6 A Yes.

7 Q So referring to claim 8 of the '860
8 patent which is on column 23, and again I'm
9 talking about the reducing step, so my question
10 is: Is it your opinion that if the word
11 "composition" was removed from the reducing step
12 that the reducing step could not be performed by
13 using an enzyme?

14 MR. KRIEGER: Object to the form.

15 A So a -- a cheese whey retentate is part
16 of a cheese whey retentate composition, so then in
17 my opinion removing the word "composition"
18 wouldn't make a difference in this case.

19 Q So it's your opinion that composition
20 doesn't add anything to the --

21 A No. What I am saying is that this is a
22 reduced whey composition. Let me go back to what
23 it says here. This is a reduced GMP cheese whey
24 retentate composition and this is a reduced GMP
25 cheese whey retentate.

1 Q Okay.

2 A So removing the word "composition"
3 should not change what this is saying. The
4 opposite would be maybe different.

5 Q So just for the record you said -- you
6 were holding your hands out wide and you said, out
7 wide, is a cheese whey or, I'm sorry, is a reduced
8 GMP cheese retentate composition, and then you
9 moved your hands narrower and you said this is a
10 reduced GMP cheese whey retentate. Is that right?

11 A Yes. In other words, reduced cheese GMP
12 -- in other words a -- a reduced GMP cheese whey
13 retentate composition. Let me restate that. A
14 reduced GMP cheese whey retentate is part of a
15 reduced GMP cheese whey retentate composition, so
16 it wouldn't matter whether the word "composition"
17 is there.

18 Q So I understood you earlier to say that
19 a cheese whey -- I'm sorry -- that a reduced GMP
20 cheese whey retentate composition allows for the
21 addition of components like an enzyme, is that
22 right?

23 A Yes.

24 Q Okay.

25 And so if the reducing limitation of

1 claim 8 were changed to say reducing native GMP in
2 the cheese whey retentate to form a reduced GMP
3 cheese whey retentate, so omitting the word
4 "composition" then is it your opinion that that
5 would not allow for addition of components like an
6 enzyme?

7 MR. KRIEGER: Objection, form,
8 asked and answered.

9 A What I am saying is that if you have a
10 reduced -- you can say that -- okay. That when
11 you have a reduced GMP -- let me get back to it.
12 A reduced GMP cheese whey retentate. When you add
13 an enzyme you can add an enzyme there and it will
14 become a reduced GMP cheese whey retentate
15 composition.

16 Q Right. But if you don't have -- in the
17 claim you don't have the word "composition" then
18 you can't add an enzyme, right? Because you are
19 not making a reduced GMP cheese whey retentate
20 composition. You are only making a reduced GMP
21 cheese whey retentate.

22 Do you agree with that?

23 MR. KRIEGER: The same objection.

24 A What I am saying is that a reduced GMP
25 cheese whey retentate is part of a reduced GMP

1 cheese whey retentate composition.

2 Q I understand that.

3 A Yeah.

4 Q What I am saying is assume that the
5 claim term now no longer uses the word
6 "composition" so just "composition" is out. Okay?

7 A Yeah.

8 Q So now what you are making instead of a
9 reduced GMP cheese whey retentate composition,
10 you're not making that anymore. What you're
11 making now is a reduced GMP cheese whey retentate.

12 A Okay.

13 MR. KRIEGER: The same objection.

14 A What I am saying is that when you talk
15 about a reduced GMP -- let me get back. When you
16 talk about a reduced GMP cheese whey retentate
17 composition you can also say reduced GMP cheese
18 whey retentate.

19 Q Okay.

20 So in your opinion there is no
21 difference between a reduced GMP cheese whey
22 retentate and a reduced GMP cheese whey retentate
23 composition? Is that your testimony?

24 MR. KRIEGER: Objection, form.

25 A A reduced GMP cheese whey retentate is

1 part of a reduced cheese whey retentate
2 composition if that makes sense. So -- so a
3 reduced GMP cheese whey retentate is not a reduced
4 GMP cheese whey composition, but a reduced GMP
5 cheese whey retentate composition is a reduced GMP
6 cheese whey retentate.

7 Q So what do you mean when you say a
8 reduced GMP cheese whey retentate is not a reduced
9 GMP cheese whey composition?

10 A Because as -- as I indicated before, a
11 reduced GMP cheese whey retentate composition has
12 a reduced GMP cheese whey retentate, but the other
13 way around is not the case. So a reduced GMP
14 cheese whey retentate doesn't have a reduced GMP
15 cheese whey retentate composition.

16 Q Because it can't include additional
17 components?

18 A Once you add additional components to a
19 reduced GMP cheese whey retentate you get a
20 reduced GMP cheese whey retentate composition.

21 Q Okay. Thank you.

22 Did you tell me before you have the
23 Bertelsen reference there, Exhibit 1006?

24 A Yes, I do, yeah.

25 Q Okay. Can you get that in front of you?

1 A Yes.

2 Q Justin, do you need a copy?

3 MR. KRIEGER: No, I'm good.

4 Thank you.

5 MS. KAISER: Okay.

6 MR. KRIEGER: Actually, I will
7 take one. Thank you.

8 Q Okay. Exhibit 1006 is International
9 Publication Number WO 2018/115520 A1.

10 Do you see that?

11 A Yes.

12 Q And the first named inventor is
13 Hans Bertelsen. Do you see that?

14 A Yes.

15 Q So if I refer to Exhibit 1006 as
16 "Bertelsen" you will understand that that's what I
17 mean?

18 A Yes.

19 Q Okay.
20 When is the last time you reviewed the
21 Bertelsen reference?

22 A Do you mean back-to-back? Maybe a month
23 ago, yeah.

24 Q When's the last time you reviewed any
25 portion of Bertelsen?

1 A Yesterday and the day before.

2 Q And you understand that Bertelsen is
3 generally about the crystallization of BLG, is
4 that fair?

5 A Yes.

6 Q Okay. If you go to page 25 of
7 Bertelsen.

8 A I am there.

9 Q Okay.
10 Do you see at about line 23 it says,
11 "Step B of the method involves crystallizing at
12 least some of the BLG of the supersaturated whey
13 protein solution."

14 A Yes.

15 Q And then if you go down a little bit to
16 about line 31 do you see it says: The
17 crystallization of BLG of step B may involve e.g.
18 or -- I'm sorry. Let me start that over.

19 "The crystallization of BLG of step B
20 may e.g. involve one or more of the following."

21 Do you see that?

22 A Yes.

23 Q And then there is a list of four items.
24 Waiting for crystallization to take place,
25 addition of crystallization seeds, increasing the

1 degrees of supersaturation of BLG even further,
2 and/or mechanical stimulation.

3 Do you see that?

4 A Yes.

5 Q So is it your understanding that in the
6 crystallization of BLG in Bertelsen seeding is
7 optional?

8 A Well, based on what is being said here
9 it says "as an example." So what it is that
10 Bertelsen thinks is optional or not that is
11 difficult for me to say.

12 Q Okay. If you look at page 27 --

13 A Page 27. Yes.

14 Q If you look at about line 13 you see it
15 says, "In some preferred embodiments of the
16 invention step B involves waiting for the BLG
17 crystal to form. This may take several hours and
18 is typically for a whey protein solution which is
19 only slightly supersaturated with respect to BLG
20 and to which no crystallization seeds have been
21 added."

22 Do you see that?

23 A Yes.

24 Q So would you agree that Bertelsen at
25 least discloses some embodiments without seeding?

1 A Let me read it again. It is difficult
2 for me to say here because it says waiting for BLG
3 crystals to form, and then it says that it may
4 take several hours. I don't know if this is what
5 he intends to do. Maybe he's just saying that it
6 just takes several hours.

7 Q And it says no crystallization seeds
8 have been added, right?

9 A Right. But it's difficult for me to say
10 whether Bertelsen is -- is instructing me to do
11 this. It says waiting for crystals to be formed.
12 And then it says that if there are no crystals
13 being added or seeded, and maybe he's trying to
14 tell me here that crystals should be added and the
15 solution should be supersaturated.

16 Q So you don't have an opinion then one
17 way or the other as you sit here right now about
18 whether seeding is required in Bertelsen's
19 examples?

20 MR. KRIEGER: Objection, form.

21 A What I am trying to say is that it is
22 difficult for me to say based on this paragraph
23 that seeding is optional.

24 Q Okay. If you go to page 57.

25 A At least it's not being explicitly said.

1 Q Okay. If you go to page 57.

2 A I'm there.

3 Q Okay.

4 You see the first sentence on this page
5 says, "Lactose depleted UF retentate derived from
6 sweet whey from a standard cheese production
7 process and filtered through a 1.2-micron filter
8 was used as feed for the BLG crystallization
9 process."

10 Do you see that?

11 A Yes.

12 Q And it's your opinion as I understand it
13 that this means that the 1.2-micron filter
14 happened before the UF filtration in Bertelsen's
15 process, is that correct?

16 A That is my understanding, but the -- the
17 patent is somehow confusing there, so I am
18 following Dr. Etzel's clarification, right? So he
19 -- he mentioned the microfiltration step was done
20 before the filtration, but the patent is somehow
21 confusing, yeah.

22 Q Is it possible that the -- or could this
23 sentence also be interpreted to say that the UF
24 retentate itself is then filtered through a
25 1.2-micron filter?

1 A So based on the way this is written, but
2 as I mentioned it -- it gives room for confusion.
3 There is microfiltration and then ultrafiltration.
4 Now, that is confusing. What is the -- whether it
5 gives room to a combination it is -- it is
6 confusing, yeah.

7 Q Okay.

8 If the ultrafiltration step happened
9 before the microfiltration step then would you
10 agree that Bertelsen's process begins with a sweet
11 whey or a cheese whey retentate?

12 MR. KRIEGER: Objection, form.

13 A So -- so as I mentioned before, I call
14 sweet whey what comes from making of cheese and
15 didn't have any processing before any filtration
16 step unless we are talking about clarification for
17 just fines removals where in that case it is
18 commonly known still as a sweet whey.

19 Q Okay. I -- I understand that. I think
20 you have testified to that already.

21 A Yeah.

22 Q My question was a little bit different.
23 So assume that the ultrafiltration step is the
24 step that happens first.

25 A Yes.

1 Q Then would you agree that Bertelsen's
2 process begins with cheese whey retentate?

3 MR. KRIEGER: Objection, form,
4 foundation.

5 A As I mentioned it is -- it is confusing,
6 so I am -- this is a hypothetical. So the process
7 that is based on what is written, the process that
8 -- and I think it seems to be correct or it seems
9 to be correct is probably the one that is being
10 followed here is microfiltration followed by
11 ultrafiltration.

12 If there -- hypothetically if
13 there is a step where sweet whey is being
14 processed by any means of filtration,
15 microfiltration, ultrafiltration, nanofiltration
16 what is -- what would come out from that
17 filtration process would be a cheese whey
18 retentate and a cheese whey permeate.

19 Q Okay.

20 And going back to the sentence that's
21 the first sentence on page 57 of Bertelsen, would
22 you agree that that sentence refers to the lactose
23 depleted UF retentate as the feed for the BLG
24 crystallization process?

25 A Can you repeat the question again?

1 Sorry.

2 Q Yeah, of course. So I'm again looking
3 at the first sentence on page 57 of Bertelsen.

4 A Yes.

5 Q Do you agree that sentence refers to the
6 lactose depleted UF retentate as the feed for the
7 BLG crystallization process?

8 A Yes, although again this sentence is
9 confusing.

10 Q Okay. Do you want to take a break here?

11 MR. KRIEGER: Sure.

12 THE VIDEOGRAPHER: Off the record.

13 1:49.

14 (BREAK TAKEN.)

15 THE VIDEOGRAPHER: Back on the
16 record 2:06.

17 BY MS. KAISER:

18 Q Dr. Harte, I am going to hand you an
19 exhibit that has been previously marked as
20 Exhibit 2017.

21 Do you recognize this document?

22 A Yes.

23 Q And you see that this is an article from
24 the Korean Journal for Food Science and Animal
25 Resources?

1 A That is correct.

2 Q Okay. And this is an exhibit that you
3 cite in your declaration, correct?

4 A Yes.

5 Q Okay.

6 And the title of this article is
7 "Experimental and Modeling Study of the
8 Denaturization of Milk Protein by Heat Treatment."

9 Do you see that?

10 A Yes.

11 Q Okay.

12 I wanted to direct your attention to
13 page -- it's page 3 of the document, but page 46
14 of the article.

15 A Yes.

16 Q And there is a heading that says
17 "Results and Discussion."

18 Do you see that?

19 A Yes.

20 Q And if you look in the second column
21 it's about halfway down. It says, "With the
22 increase of the heat treatment temperature."

23 Do you see that?

24 A Let me get -- yeah, with the increase,
25 yeah.

1 Q Okay.

2 And that says, "With the increase of the
3 heat treatment temperature whey protein bands
4 almost disappeared when the temperature especially
5 higher than 85 degrees C at lane 4, 5 and 6 which
6 showed that almost all of the whey protein
7 denatured."

8 Do you see that?

9 A Yes.

10 Q What does it mean by lane 4, 5 and 6?

11 A So if you take a look on the figure it
12 says here -- let's go back to Figure 1. Figure 1
13 has different electrophoresis gels and it refers
14 to the numbers 1, 2, 3, 4, 5, 6, 7, 8. Those are
15 the lanes. Lane 4, 5 and 6 in this case.

16 Q And lane 4, 5 and 6 are whey protein
17 bands, is that right?

18 A Let me see. In this case, no. The lane
19 is showing caseins and whey proteins too.

20 Q Okay. What are electro -- you said
21 electrophoresis gels?

22 A Electrophoresis, yeah.

23 Q What are they?

24 A So the term would be SDS gel
25 electrophoresis. Sorry. SDS polyacrylamide gel

1 electrophoresis probably.

2 This is a gel that is subject to
3 a current. So you put a liquid containing your
4 proteins on top of these lanes, and because of the
5 current and because of the proteins being charged
6 the proteins are going to be moving. And the
7 speed at which they move it's pretty much
8 proportional to their size, so smaller proteins
9 are going to move faster than larger proteins.
10 Then the current is removed and the proteins are
11 stained and that is how you get these lanes,
12 right?

13 Q Can the SDS gel electrophoresis
14 differentiate between different kinds of proteins?

15 A That -- that is a generalization. It
16 can differentiate between some proteins, but
17 between others it cannot. If the -- if the
18 molecular weight is somehow similar or if the
19 molecular weight -- molecular weight range of that
20 specific gel is not appropriate for the size of
21 the proteins it is difficult to differentiate,
22 yeah.

23 Q Can you use SDS gel electrophoresis to
24 test for the presence of BLG?

25 A It's regularly done, yeah.

1 Q Can you use SDS gel electrophoresis to
2 test for the presence of ALA?

3 A Yes.

4 Q And what is the detection limit for BLG
5 using SDS gel electrophoresis?

6 MR. KRIEGER: Objection, form,
7 foundation.

8 A SDS in general we are usually talking
9 about micrograms per mil when it comes to -- but
10 it is very general. I -- I don't remember top of
11 my head specifically for lactoglobulin.

12 Q Okay.

13 Can you use SDS gel electrophoresis to
14 test for the presence of -- of GMP?

15 A Well, again, you need to make sure that
16 the gel that you are using has the proper
17 molecular weight for GMP. GMP has a molecular
18 weight of roughly 7 kilodaltons, so most gels that
19 for instance we use in the lab to separate
20 proteins in milk are outside the range of GMP, but
21 there are gels that you can specifically buy for
22 GMP --

23 Q Okay.

24 A -- and peptides in general, yeah.

25 Q If you go to page 4 of Exhibit 2017

1 which is page 47 of the article, and let me know
2 when you're there.

3 A Page 47. Yes.

4 Q Okay. If you look at the top of the
5 right -- or I'm sorry. The top of the left-hand
6 column you see it says, "The result of the ratio
7 of denatured whey protein during heat treatment."

8 A Uh-huh.

9 Q Figure 1 indicated that as heat treated
10 temperature rise the increased rate of whey
11 protein denaturation degree was essentially absent
12 in the PAGE patterns of several heat-treated
13 samples -- severely heat treated samples. Sorry.

14 Do you see that?

15 A Yes.

16 Q And then do you see it says the
17 denaturation degree of whey protein increased from
18 28.34 percent to 45.37 percent as the heat
19 treatment time extended from 65 C to 85 C for
20 ten minutes?

21 Do you see that?

22 A Yes.

23 Q And then it says almost all whey protein
24 denatured at 95 degrees C for ten minutes.

25 Do you see that?

1 A Yes.

2 Q Okay. If you look down at figure 2
3 which is on that same page.

4 A Uh-huh.

5 Q Do you see the graph that is in the
6 bottom right, so it's graph D?

7 A Yes.

8 Q And if you look in the caption it says
9 denaturation rate -- for D it says denaturation
10 ratio. Whey proteins of heat treated 75 degrees C
11 white squares. 85 degrees C, black circles.
12 95 degrees C, white triangles.

13 Do you see that?

14 A Yes.

15 Q And so is it your understanding that the
16 top line in 2D is at 95 degrees C?

17 A Yes.

18 Q And when you look at that top line and
19 -- so let me just take a step back. In 2D the
20 X-axis is time in minutes.

21 Do you see that?

22 A Yes.

23 Q And then the Y axis is denaturation
24 degree and percentage. Do you see that?

25 A Yes.

1 Q Okay.

2 So directing your attention back to the
3 95 degrees C line, do you see that at 10 minutes
4 the denaturation degree appears to be somewhere
5 between 90 and 100 percent?

6 A Yes.

7 Q And is that consistent then with what I
8 just read from the text above that says almost all
9 whey protein denatured at 95 degrees C for
10 ten minutes?

11 MR. KRIEGER: Objection, form.

12 A Yeah. "Almost all" is -- it's a general
13 term. I would like -- I would prefer to use the
14 number, right, whatever number they get here.

15 Q Okay.

16 What would you estimate the denaturation
17 degree is in figure 2D at 10 minutes at
18 95 degrees C?

19 A I would say between 90 and 100.

20 Q Okay.

21 And then the graph also in 2D shows
22 denaturation degree for 5 minutes.

23 Do you see that?

24 A Yes.

25 Q And at 95 degrees for five minutes it

1 appears to me that's around 90 percent, is that
2 fair?

3 A Yes.

4 Q Okay.

5 And if you look at 85 degrees C it
6 appears that at 5 minutes and 85 degrees C it
7 would be somewhere around 65 percent, is that
8 fair?

9 A Between 60 and 70 percent, yeah.

10 Q Okay.

11 And so if we took a temperature that was
12 say 90 degrees C you would -- for five minutes in
13 figure 2D you would expect that to be somewhere
14 between 70 percent and 90 percent denaturation, is
15 that fair?

16 MR. KRIEGER: Objection, form.

17 A Again, you said 90 degrees C for
18 five minutes?

19 Q Yes.

20 A And it should be -- I would say that it
21 should be between 60 to 70 percent and 90 percent.

22 Q Okay.

23 A Uh-huh.

24 Q We talked a little bit in Exhibit 2017
25 about SDS gel electrophoresis.

1 Are there other methods that people of
2 skill in the art have used to test for the
3 presence of whey proteins?

4 A Liquid chromatography would be one.
5 Capillary electrophoresis would be -- would be
6 another one.

7 Q Does the liquid chromatography have the
8 same detection limit for BLG as SDS gel
9 electrophoresis?

10 MR. KRIEGER: Objection,
11 foundation.

12 A In general terms, liquid chromatography
13 has a higher resolution or higher detection limit
14 -- better detection limit. A better detection
15 limit versus electrophoresis.

16 Q Would it be fair to say that the
17 detection limit for whey proteins varies depending
18 on the type of testing that you use?

19 A Yes. The detection limit of any
20 analytical tool -- so different analytical tools
21 do have in general terms different detection
22 limits, so yes, it's fair.

23 Q We were talking about sweet whey
24 earlier.

25 A Yes.

1 Q And you talked about, I think, some of
2 the components of sweet whey, and prior to a
3 clarification step I think you said that sweet
4 whey can include cheese fines, is that right?

5 A Yes.

6 Q And sweet whey can also include
7 bacteria?

8 A Yes.

9 Q And sweet whey includes whey proteins,
10 correct?

11 A Yes.

12 Q And those whey proteins typically
13 include ALA?

14 A Yes.

15 Q And BLG?

16 A Yes.

17 Q And GMP?

18 A If the whey is coming from cheese, if it
19 is cheese whey, yes.

20 Q Okay. And anything else that is
21 typically present in sweet whey?

22 A There is some lactose residual fat.
23 There may be a myriad of different proteins in
24 there, right? We talked about the main ones.
25 Chances are there will be some residual casein in

1 there too. The big ones definitely are the ones
2 that you mentioned.

3 Q Okay. If I wanted to remove or reduce a
4 specific whey protein from sweet whey --

5 A Yes.

6 Q -- we talked about one way to do that
7 being enzymatic hydrolyzing, correct?

8 A Yeah. We talked about GMP and enzymatic
9 hydrolysis.

10 Q Okay.

11 A GMP is a peptide.

12 Q Okay.

13 Could I -- so we talked about using
14 enzymatic hydrolysis to reduce GMP in sweet whey.

15 A Yes.

16 Q Could I also use enzymatic hydrolysis to
17 reduce BLG in sweet whey?

18 A I am not aware of an enzyme that is
19 specific to lactoglobulin to BLG.

20 Q Okay.

21 A But if I -- I can remove or I can, I
22 guess, reduce BLG together with other proteins
23 using general enzymes or non-specific enzymes.

24 Q Can I use enzyme hydrolysis to reduce
25 ALA in sweet whey?

1 A Again, I am not --

2 MR. KRIEGER: Objection, form.

3 A I am not aware of an enzyme that is
4 specific to ALA, but there are known specific
5 enzymes that will hydrolyze ALA together with
6 other proteins.

7 Q If I wanted to remove ALA from sweet
8 whey what processing steps could I use to remove
9 ALA?

10 A So there are -- remove or isolate ALA?

11 Q Let's say reduce the amount of ALA.

12 A Okay.

13 MR. KRIEGER: Objection, beyond
14 the scope.

15 A So it -- it seems that the method that
16 Bertelsen is using where BLG is crystallized
17 favors the crystallization of BLG versus ALA.

18 Q And what's your basis for saying that?

19 A Because in Bertelsen's -- he or she
20 specifically or they specifically talk about BLG
21 crystallization.

22 Q Okay. Let's take a short break. I
23 might be getting pretty close to being done.

24 THE VIDEOGRAPHER: Off the record

25 2:42 -- or 2:24.

(BREAK TAKEN.)

THE VIDEOGRAPHER: Back on the
record 2:37.

BY MS. KAISER:

Q Dr. Harte, I want to direct your
attention back to your declaration which is
Exhibit 2005.

A Yes.

Q Okay. If you could turn to page 64 and
let me know when you're there.

A Yes.

Q So this is the page where you had a
correction earlier to remove Table 7 from the end
of paragraph 146.

Do you remember that?

A That's correct, yep.

Q Okay. And Table 7 -- well, strike that.
It's your understanding that Hinkova
uses a .1 micron filter, is that right?

A Yeah. They use a 5 kilodalton and
.1 micron and .5 micron.

Q Okay. Do you see in paragraph 147 you
talk about rejection factors?

A Yes, that is correct, yeah.

Q What does "rejection factor" mean?

1 A That would be the amount of a given
2 component that is not going to go through the
3 membrane, so it will remain in the retentate.

4 Q And so for example for GMP if it has a
5 62.6 percent rejection factor then 62.6 percent of
6 the GMP would go into the retentate, is that
7 right?

8 A Yes.

9 Q And that means that approximately
10 37.4 percent would go into the permeate, is that
11 right?

12 A Yes.

13 Q And in paragraph 147 you talk about
14 rejection factors for GMP, ALA and BLG.

15 Do you see that?

16 A Yes.

17 Q Are there micro -- in microfiltration
18 can you have 100 percent rejection rate for GMP,
19 ALA or BLG?

20 MR. KRIEGER: Objection, form.

21 A Can you repeat the question?

22 Q Sure. In microfiltration --

23 A Yes.

24 Q -- is it possible to have 100 percent
25 rejection rate for GMP?

1 MR. KRIEGER: The same objection.

2 A So as -- as 147 the line right there,
3 the paragraph is showing it is very difficult to
4 talk about absolutes when it comes to -- to these
5 tangential flow filtration devices. So for
6 instance in this case GMP rejection is 62 to 77
7 when it is the same GMP, so it will be difficult
8 for me to say that there is one -- being so
9 absolute. It would be a little hypothetical I
10 would say.

11 Q Is there a pore size that you could
12 identify at which you would get 100 percent
13 rejection rate for GMP?

14 A If we were using like reverse osmosis
15 where only water and some salts are going through
16 I would say the rejection rate would be
17 100 percent for pretty much any peptide or
18 protein.

19 Q Okay.

20 What about for microfiltration? Is
21 there any pore size in the microfiltration range
22 that would give 100 percent rejection rate for GMP
23 that?

24 A I don't know.

25 Q You don't know?

1 A Uh-uh.

2 Q Okay.

3 What about for ALA, is there any pore
4 size in the microfiltration range that would give
5 100 percent rejection rate for ALA?

6 A The same thing. I don't know.

7 Q Okay.

8 And what about for BLG, is there any
9 pore size in the microfiltration range that would
10 give 100 percent rejection rate for BLG?

11 A The same thing. I would say I don't
12 know.

13 Q Okay.

14 And how about for ultrafiltration range,
15 is there any pore size in the ultrafiltration
16 range that would give 100 percent rejection rate
17 for GMP?

18 A Well, as Table 7 is showing, there is a
19 membrane here that is 5 kilodaltons. That will be
20 considered for being ultrafiltration, and there is
21 no 100 percent rejection rate. All the GMP is
22 larger than 5 kilodaltons.

23 Q And it's also true in that Table 7 that
24 for ALA you don't have 100 percent rejection rate
25 for 5 kilodaltons, correct?

1 A Well, again, there is a range, right?
2 It's giving us 96.7 plus minus 5.7. So the true
3 rejection rate can be anywhere from in this case
4 let's say 91 to 100, the true rejection rate.

5 Q You said --

6 A Yeah.

7 Q I'm sorry. Go ahead.

8 A But the same applies to in this case CMP
9 or GMP. There is a standard deviation, and what
10 this test is showing is that it can be anywhere in
11 that range.

12 Q Okay.

13 A Yeah.

14 Q You've talked a number of times today
15 about how -- that it's hard to talk in absolutes.

16 Do you think that generally scientists
17 don't expect filtration to absolutely filter every
18 molecule of something even if the rejection rate
19 were approaching 100 percent?

20 MR. KRIEGER: Objection, form.

21 A That would be too general to say what
22 the scientists would agree upon.

23 Q If you had a filtration operation --
24 well, strike that. All right. What did you do to
25 prepare for your deposition today?

1 A So I read my declaration. I went over
2 the exhibits that I used for my declaration, and I
3 came here -- today is Friday -- Wednesday and
4 Thursday.

5 Q Did you meet with anyone on Wednesday
6 and Thursday of this week?

7 A Yeah. I met with Justin. On Wednesday
8 I met with Justin and with Megan. And on Thursday
9 with Justin and Megan and Alexa and the summer
10 intern was there too, Kameron.

11 Q Okay.

12 On Wednesday how many hours
13 approximately did you meet with counsel?

14 A We started around 9 and we finished I
15 would say around 3.

16 Q Okay.

17 And on Thursday how many hours did you
18 meet with them?

19 A Similar, so 9-ish to 2.

20 Q In preparing for your deposition did you
21 review any materials that are not cited in your
22 declaration?

23 A I did not.

24 Q How -- how did you prepare your
25 declaration in this case?

1 MR. KRIEGER: I am going to object
2 and instruct the witness not to answer on
3 the basis of privilege.

4 Q Did you draft your declaration for this
5 matter yourself?

6 MR. KRIEGER: Again, I object on
7 the basis of privilege and instruct the
8 witness not to answer.

9 Q Did you collaborate with anyone in
10 drafting your declaration for this proceeding?

11 MR. KRIEGER: You can answer that
12 question, but be careful not to disclose any
13 attorney-client communications or strategy
14 discussed in our meetings.

15 A So as I mentioned before, words do
16 matter, so in parts of this declaration where
17 things were ambiguous or not clearly stated in
18 that I did collaborate with someone to make sure
19 that the message that I was trying to confer was
20 there.

21 Q How much time did you spend drafting
22 your declaration in this proceeding?

23 A Numbers do matter, but I -- I can only
24 say a lot of time in this case. It is difficult
25 for me to pinpoint a number because it wasn't done

1 in a single, so I would say straight work I would
2 say maybe 10 hours.

3 Q Okay.

4 A Yeah.

5 Q When did you first start drafting your
6 declaration?

7 MR. KRIEGER: Objection,
8 relevance.

9 A It's difficult to pinpoint because it
10 happened during the springtime and I was teaching
11 at the same time two courses which it was really a
12 busy time in the spring.

13 Q Did you speak directly with anyone at
14 Leprino when you were preparing your expert
15 declaration?

16 A No. No.

17 Q Did you speak with anyone at Leprino
18 when you were preparing for your deposition today?

19 A No.

20 Q During any of the breaks during this
21 deposition did you speak with anyone about the
22 substance of your testimony?

23 A No.

24 Q Okay. I pass the witness.

25 MR. KRIEGER: Okay. We can go off

1 the record.

2 MS. KAISER: Yeah.

3 THE VIDEOGRAPHER: Off the record
4 2:50.

5 (BREAK TAKEN.)

6 THE VIDEOGRAPHER: Back on the
7 record 3:22.

8 EXAMINATION

9 BY MR. KRIEGER:

10 Q Good afternoon, Dr. Harte.

11 We just have a few questions we'd like
12 to ask you to help clarify a few points from your
13 testimony today. Okay?

14 A Yes.

15 Q So earlier today Ms. Kaiser was asking
16 you some questions regarding Example 1 from
17 Exhibit 1001, the '860 patent.

18 Do you recall that line of questioning?

19 A Yes.

20 Q And could you please pull up that
21 exhibit and take a look?

22 A Example 1, right?

23 Q Correct.

24 A What page was Example 1?

25 Q It is column 15.

1 A Fifteen? Okay. Yep.

2 Q And before we talk about this we also
3 discussed today something called WPC.

4 Do you recall that?

5 A Yes.

6 Q What is -- in the field, in this field,
7 what does WPC stand for?

8 A Whey protein concentrate.

9 Q Okay. And the term "WPC" is used in
10 Example 1 here, correct?

11 A That is correct.

12 Q And what does -- if you can tell what
13 does that stand for in Example 1?

14 A It reads whey protein composition.

15 Q Is a whey protein composition different
16 than a whey protein concentrate?

17 A It is.

18 Q How is it different in light of the text
19 of Example 1 here?

20 A Well, in light of the example here it
21 reads whey protein composition greater than
22 25 percent protein on a dry weight basis from
23 sweet whey of mozzarella cheese. So -- and this
24 is not a WPC, yes. Usually we discuss as a whey
25 protein concentrate, right? This will be

1 basically same as sweet whey of mozzarella cheese.

2 Q And in your discussions with Ms. Kaiser
3 what was your understanding at that time of what
4 WPC meant in the context of Example 1?

5 A Yeah. I was -- again, I -- I just used
6 WPC as it stands as a whey protein concentrate.

7 Q So in light of that understanding
8 Ms. Kaiser asked you the following question at one
9 point. She said: But in Example 1 the
10 pasteurized sweet whey retentate is concentrated
11 and through a series of concentration steps
12 ultimately becomes WPC80. Is that how you
13 understand Example 1? And you testified "yes."

14 Do you agree with that position now in
15 view of your understanding that WPC in Example 1
16 means whey protein composition and not whey
17 protein concentrate?

18 A Yeah. This is sweet whey, so it's
19 similar to sweet whey instead of a whey protein
20 concentrate.

21 Q And so when ultimately Ms. Kaiser asked
22 you the question of whether claim 8 read on
23 Example 1, I believe you answered in the negative,
24 but in view of your new understanding is that an
25 accurate answer?

1 A I would say that the -- the starting
2 point is sweet whey, right? So we are not
3 starting from a whey protein concentrate. We are
4 starting from sweet whey in this case based on the
5 acronym that is being used is WPC, but it refers
6 to sweet whey.

7 Q So in light of that is it your view that
8 claim 8 reads on Example 1 or no?

9 A I think so, yes.

10 Q I'd next like to ask you about some
11 testimony you had today -- okay. I'm sorry.
12 Before I move on, this example also refers to
13 WPC80.

14 Do you see that?

15 A Yes.

16 Q And is it fair to characterize that as a
17 cheese whey retentate or no?

18 A Yes.

19 Q Let's talk about ALA denaturation which
20 you talked about today in the context of
21 Exhibit 2017, and this is on page 47 if you could
22 pull that up, please.

23 A Yes.

24 Q You spent some time discussing with
25 Ms. Kaiser specifically --

1 MS. KAISER: Where are you? I'm
2 so sorry.

3 MR. KRIEGER: I'm sorry.
4 Exhibit 2017.

5 MS. KAISER: Give me a second.

6 MR. KRIEGER: Take your time.

7 MS. KAISER: You transitioned so
8 quickly. Okay. And what page?

9 MR. KRIEGER: 47.

10 MS. KAISER: Thank you. Got it.
11 I'm with you again.

12 BY MR. KRIEGER:

13 Q Okay. And you discussed with Ms. Kaiser
14 Figure 2 and specifically Figure 2D.

15 Do you recall that line of testimony?

16 A Yes.

17 Q Could you please take a moment and just
18 read to yourself the legend under Figure 2.

19 A It says: Figure 2. Native PAGE and
20 ratio of denatured whey proteins at different time
21 in heat-treated milk. A, B and C native PAGE of
22 whey proteins of heat-treated milk at 75
23 degrees C, 85 degrees C, 95 degrees C
24 respectively. Lane 1, casein. Lane 2, whey
25 protein. Lane 3, raw milk. Lanes 4 to 8,

1 5 minutes, 10 minutes, 15 minutes, 20 minutes,
2 25 minutes, 30 minutes. D, denaturation ratio.
3 Whey proteins of heat-treated 75 degrees C, white
4 squares. 85 degrees C, black circles. 95
5 degrees C, white triangles.

6 Q Okay.

7 And so you can see here based on this
8 legend at the -- in bold at the bottom of page 47
9 of Exhibit 2017 that these native PAGE and ratio
10 results are based on heat-treated milk, is that
11 correct?

12 A That is correct.

13 MS. KAISER: Objection, leading.

14 If you could pause to let me make my
15 objections as well I would appreciate it.

16 BY MR. KRIEGER:

17 Q What is the composition that the
18 materials shown in Figure 2 are based on?

19 A The composition would be the composition
20 of milk.

21 Q Okay.

22 And would you expect milk would denature
23 similarly or differently from WPC?

24 A Differently.

25 Q And why is that?

1 A Because the rate of denaturation of
2 proteins both -- or any protein, but specifically
3 lactoglobulin and lactalbumin, BLG and ALA depends
4 on the environment where they are present. ALA is
5 extremely sensitive to -- the denaturation of ALA
6 is sensitive to the presence of calcium, so in
7 that regard ALA it's a protein that responds to
8 the environment when it comes to thermal
9 denaturation.

10 Q And in your opinion would milk be
11 expected to denature similarly or differently
12 relative to WPPC?

13 MS. KAISER: Objection, outside
14 the scope.

15 MR. KRIEGER: You can answer.

16 A Relative to?

17 Q WPPC.

18 MS. KAISER: The same objection.

19 A So as I mentioned before, every time we
20 change the environment we need to run these
21 studies again because the denaturation temperature
22 and time is subject to the environment where the
23 proteins are.

24 Q And would you expect proteins in milk to
25 denature differently to the proteins in WPI?

1 MS. KAISER: Objection, beyond the
2 scope, form.

3 A I would.

4 Q At the first full paragraph on the left
5 column of page 47 of Exhibit 2017 you can see that
6 it says whey proteins (alpha-LA and beta-LG).

7 Do you see that?

8 A Yes.

9 Q What is alpha-LA?

10 A Alpha-lactalbumin.

11 Q What is beta-LG?

12 A Beta-lactoglobulin.

13 Q Okay.

14 So what does this parenthetical tell
15 you, if anything, about what they're referring to
16 when they say whey proteins in this Exhibit 2017?

17 A Yeah. They are generalizing all the
18 whey proteins as if they were only
19 alpha-lactalbumin and beta-lactoglobulin.

20 Q Are these the only proteins you would
21 expect to see in milk?

22 A No.

23 MS. KAISER: Objection to form.

24 Q Are there other proteins in addition to
25 ALA and BLG that you would expect in milk?

1 A Oh, yes. There is bovine serum albumin
2 and a range of proteins like lactoferrin and other
3 proteins in milk.

4 Q Do all of those proteins denature at the
5 same rate as ALA and BLG to your knowledge?

6 MS. KAISER: Objection to form.

7 A No.

8 Q Can you expand on that? Why is that?

9 A So each protein has a different behavior
10 when it comes to how it responds to the
11 environment and temperature, so generalizing
12 denaturing conditions from one protein to another
13 or from one environment to another it's something
14 very difficult to do.

15 Q Let's turn now to your patent document
16 that Ms. Kaiser was asking you some questions
17 about and I think it's Deposition **Exhibit 1**.

18 A Two.

19 Q Two? Sorry. It's Deposition **Exhibit 2**.
20 Do you have that in front of you?

21 A Yes, I do, yeah.

22 Q Could you please turn to paragraph 91.

23 A Yes.

24 Q So you had a discussion with Ms. Kaiser
25 regarding this paragraph and I believe

1 specifically the second full sentence that states,
2 "Due to the high temperatures used during the
3 processing of all chocolate skim milks, complete
4 whey protein denaturation occurred evidenced by
5 the lack of B-1G monomers in gels ran under
6 non-reducing conditions." And it refers to
7 Figure 9A.

8 Do you see that?

9 A Yes, I do, yeah.

10 Q What was your conclusion with respect to
11 the term "denaturation occurred." What was the
12 basis for that conclusion?

13 MS. KAISER: Objection to form.

14 Q Let me restate that. You said complete
15 whey protein denaturation occurred. Do you see
16 that?

17 A I do.

18 Q What was that statement based on?

19 A Based on tracking what happened with
20 beta-lactoglobulin.

21 Q Was that based on any proteins other
22 than BLG?

23 A No. In this case we just tried
24 lactoglobulin.

25 Q Did you also consider ALA denaturation?

1 MS. KAISER: Objection, leading.

2 A Well, based on what I -- what this
3 figure refers to also what I recall what you can
4 see in Figure 9A is that there is residual
5 alpha-lactalbumin there, so I would say this was a
6 little bit of a generalization because we are
7 concluding something based on what happens with
8 lactoglobulin when the figure is showing bands for
9 alpha-lactalbumin.

10 Q Dr. Harte, if you look down below that
11 sentence I just read.

12 A Uh-huh. Yeah.

13 Q There is a sentence that says, "Under
14 reducing conditions B-1G monomers were observed
15 again as expected."

16 A Yes.

17 Q "Along with thicker A-1A bands
18 associated to the bottom phase in chocolate milks
19 indicating that partial denaturation of A-1A
20 occurred too."

21 Do you see that?

22 A Yes.

23 Q What does that statement mean that
24 partial denaturation of 1A occurred?

25 A Yeah. It shows -- this refers to

1 Figure 9A and B and what these figures are
 2 showing, there is no page number, but in Figure 9
 3 is that there is evidence showing that --
 4 Figure 9A shows total denaturation of
 5 lactoglobulin shown by the fact that lactoglobulin
 6 disappears, the bands corresponding to
 7 lactoglobulin.

8 But the bands corresponding to
 9 alpha-lactalbumin in Figure 9A which is under
 10 non-reducing conditions and Figure 9B in the
 11 reducing conditions are still there, so even
 12 though these figures showing 9B that even though
 13 it seems that there is partial denaturation of
 14 alpha-lactalbumin, there is alpha-lactalbumin
 15 still in the milk in native form, non-denatured
 16 alpha-lactalbumin.

17 Q Okay. I would like to switch gears
 18 again, Dr. Harte. A couples times today
 19 Ms. Kaiser was talking to you about the
 20 clarification steps, I believe, it was called.

21 A Yes.

22 Q And do you recall that line of
 23 testimony?

24 A Yes.

25 Q And she specifically was asking you

1 questions about the 1.2 micron filtration step
2 that's described in Bertelsen.

3 Do you recall that?

4 A Yes.

5 Q And I believe you testified a couple
6 times that you don't view that as a clarification
7 step. Do you recall that?

8 A Yes.

9 Q What is the basis for that conclusion?

10 A Well, the fact that under those
11 conditions as I mentioned some of the whey
12 proteins would go into the retentate and some of
13 the whey proteins would go into the permeate of --
14 in this initial step.

15 Q Okay.

16 A Yeah. I -- I referred to clarification
17 as a process where only fines are removed, and in
18 Bertelsen's based on the -- on the type of
19 ultrafiltration -- sorry. I misspoke. Based on
20 the tangential flow filtration unit they are using
21 there are some of the whey proteins going to the
22 permeate and some of the whey proteins going to
23 the retentate.

24 Q Thank you, Dr. Harte.

25 There is one other question that was

1 asked of you and it's a long question and I wanted
2 to read it to you and I wanted to read your answer
3 and I wanted to ask if you understood that
4 question correctly with your answer, so please
5 just listen carefully to the question.

6 A Yep.

7 Q The question that was asked was:

8 So if after the filtering step you
9 included a concentrating step where you removed
10 water and then it was the concentrated cheese whey
11 that you did the reducing step to, in your opinion
12 would you be still reducing GMP in other cheese
13 whey retentate? And then I objected and you
14 answered. "I would call it a reduced GMP in a
15 concentrated cheese whey." And if you want me to
16 read that again I can.

17 A In a concentrated cheese permeate --
18 retentate, I mean. Sorry.

19 Q Okay. So did you miss -- would you like
20 to correct that answer?

21 A Yes.

22 MS. KAISER: Objection to form.

23 Q How would you like to clarify that
24 answer?

25 A I would say cheese whey retentate.

1 Q Okay. Thank you. I have no further
2 questions.

3 EXAMINATION

4 BY MS. KAISER:

5 Q I have some re-cross. So let's go back
6 to Exhibit 1001 and Example 1 which starts at
7 column 15. Our favorite example to talk about
8 today, the '860 patent.

9 A Let me get there. That's not it. Yes.

10 Q So thank you for the clarification that
11 WPC here is whey protein composition. So I
12 understood in redirect your testimony to be that
13 WPC here refers to the sweet whey of mozzarella
14 cheese, is that correct?

15 A Yes.

16 Q Okay.

17 And so when it talks about WPC that is
18 greater than 25 percent protein on a dry weight
19 basis from sweet whey of mozzarella cheesemaking,
20 you are saying that WPC is the sweet whey of
21 mozzarella cheesemaking that is the 25 protein.
22 Is that -- am I understanding your testimony
23 correctly?

24 A Yeah. What I read in this example is
25 that, yeah.

1 Q Okay.

2 And then the example goes on to say,
3 "The process begins with WPC retentate 80 percent
4 protein on dry basis that is concentrated using
5 ultrafiltration of pasteurized sweet whey
6 separated from cheese curd."

7 Do you see that?

8 A Yes.

9 Q And it's your testimony it sounds like
10 now that that WPC retentate which is the 80 -- I'm
11 sorry -- which is WPC80 is the cheese whey
12 retentate, right?

13 A That is -- yes. Sweet cheese -- sweet
14 -- sweet whey retentate or cheese whey retentate.

15 Q Okay. And then do you see that it says
16 the WPC or -- sorry. The 80 percent WPC (WPC80)
17 retentate is transferred to a temperature
18 controlled holding tank and kept cold at about
19 45 degrees C or less.

20 Do you see that?

21 A Yes.

22 Q And is it your testimony that once it's
23 in the tank and it's at 45 degrees F it remains
24 cheese whey retentate?

25 A The only thing that changed was the

1 temperature, right? So it's a cheese whey
2 retentate that --

3 Q So at this point it's been transferred
4 to a holding tank and cooled. Is it still a
5 cheese whey retentate? Dr. Harte, you had
6 30 minutes to go back and talk to your counsel
7 about this particular example.

8 A Yeah.

9 Q So I am wondering why it's a hard
10 question --

11 MR. KRIEGER: You don't have to
12 answer that.

13 Q -- to answer whether transferring it to
14 a tank and cooling it changes whether it's a
15 retentate or not.

16 MR. KRIEGER: Objection. You
17 don't have to answer that question,
18 Dr. Harte.

19 Q Well, let me ask my original question
20 again.

21 A Can I finish reading?

22 MR. KRIEGER: And for the record,
23 it was not 30 minutes.

24 A I would call it still a retentate after
25 cooling it down to 45 degrees C. I -- I wouldn't

1 change the name of what we have just based on --
2 well, if you are denaturing proteins maybe, but
3 the origin is a retentate of sweet whey.

4 Q Okay. And then do you see in column 15
5 again we are talking about Example 1 that in that
6 holding tank the WPC80 is mixed with water to make
7 a 14 percent protein solution.

8 Do you see that?

9 A Yes. Uh-huh.

10 Q And so after the WPC80 is mixed with
11 water in your view is it still a cheese whey
12 retentate as that term is used in claim 8?

13 A Well, if nothing -- if nothing changes,
14 it's just about moisture content, I would still
15 call it a cheese whey retentate.

16 Q Okay.

17 So are you correcting your testimony
18 from earlier today when you said it wasn't a
19 cheese whey retentate and you said it was a
20 diluted whey protein solution?

21 MR. KRIEGER: Objection, form,
22 mischaracterizes testimony.

23 Q It doesn't actually.

24 A Yeah. I would say a diluted cheese whey
25 retentate.

1 Q Okay.

2 A Yeah.

3 Q Is a diluted cheese whey retentate
4 different than a cheese whey retentate as that
5 term is used in claim 8?

6 A I would say no because only water is
7 changing so again my -- my big -- where I put the
8 boundary is whether anything in the composition is
9 changing in an important way, right? So that is
10 why clarification is something that I don't see as
11 changing the cheese whey.

12 Q Okay.

13 A In this case it is a diluted cheese whey
14 because -- a cheese whey retentate because water
15 is being added.

16 Q Okay.

17 So is it your testimony then that in
18 claim 8 the cheese whey retentate becomes not a
19 cheese whey retentate if it -- if it is changed in
20 an important way? I think that's what you just
21 said.

22 A Which is very general, right? Yeah.

23 Q I'm just asking what your opinion is.

24 A So within the context of what we are
25 talking in this patent in this case only water is

1 being added so the ratio of whatever we have in
2 there is not changing, so I am okay with calling
3 it diluted cheese whey retentate.

4 Q Okay.

5 A Yeah.

6 Q So you understand that if you go to
7 claim 8 because I think you testified in response
8 to your counsel's question that it's your opinion
9 that Example 1 practices claim 8. You
10 affirmatively testified to that.

11 Do you agree with that?

12 A Yes.

13 Q Okay. So I'm trying to understand the
14 basis for that answer. Okay?

15 A Yes.

16 Q So if you look at claim 8 it says first
17 filtering cheese whey from an enzymatically
18 coagulated milk into a cheese whey retentate and a
19 permeate. And then it goes on to say in a
20 reducing step, reducing native GMP in the cheese
21 whey retentate to form a reduced GMP cheese whey
22 retentate composition.

23 Do you remember we talked about that
24 previously?

25 A Yeah, but can you read that paragraph

1 again because I got lost.

2 Q Sure.

3 "Reducing native GMP in the cheese whey
4 retentate to form a reduced GMP cheese whey
5 retentate composition."

6 A Yes.

7 Q All right. So you would agree with me
8 that in claim 8 it's your opinion that you have to
9 reduce native GMP in the cheese whey retentate?

10 A Yes.

11 Q And so my question is -- because you
12 have a lot of opinions in your declaration about
13 what processing steps are not allowed for cheese
14 whey retentate to still be a cheese whey
15 retentate.

16 A Uh-huh.

17 Q I am trying to understand what
18 processing steps are allowed. Okay?

19 A Okay. Yep.

20 Q And so I understood your testimony
21 before you talked to your counsel to be that
22 concentration, for example, was not allowed.

23 Is that correct or not correct?

24 MR. KRIEGER: Objection, form.

25 A So I -- I do apologize for the

1 confusion. So what I am trying to say here is
2 that processing steps that do not change -- that
3 only remove fines and that respect the composition
4 of what we have in there would end up producing a
5 -- either a cheese whey retentate or a cheese whey
6 permeate and we would still call it a cheese whey.

7 Now, adding water is not changing
8 the composition of what we have in there. It's
9 just diluting. Now, when we are concentrating,
10 again, if we are using, let's say, reverse osmosis
11 where we are only removing water then again it
12 will be a concentrated cheese whey. Now, any
13 other process of concentration usually also
14 changes something else. It's very difficult to
15 concentrate by just removing water.

16 Q Okay.

17 A Hopefully it makes sense.

18 Q So if you remove cheese fines from a
19 cheese whey retentate it remains a cheese whey
20 retentate.

21 Am I understanding that correctly?

22 A If you --

23 MR. KRIEGER: Objection, form.

24 A If you remove fines from cheese whey it
25 remains a cheese whey.

1 Q And if you remove cheese fines from a
2 cheese whey retentate it remains a cheese whey
3 retentate, is that true?

4 MR. KRIEGER: Objection, form,
5 foundation.

6 A Removing cheese whey -- I'm sorry.
7 Removing fines -- so in this case this is a --
8 this is a cheese whey retentate where only fines
9 are being removed. I don't know why you would do
10 that, but yeah, I would call it following the
11 rationale that I am following for cheese whey I
12 would call it a cheese whey retentate.

13 Q Okay.

14 A Yeah.

15 Q And if you had a cheese whey retentate
16 and you removed only water from it, it would still
17 be a cheese whey retentate? Is that your
18 testimony?

19 MR. KRIEGER: Objection, form.

20 A If you would find a method where you
21 only remove water I would call it that, a cheese
22 whey retentate.

23 Q Okay.

24 A The issue is it is difficult to find
25 such a process where only water is being removed.

1 Q Okay. And so if you were say removing
2 water and lactose you would say that's --

3 MR. KRIEGER: I'm sorry. Doctor,
4 did you want to continue your answer?

5 A Yeah. I would add concentrated or
6 diluted too, right?

7 Q Okay. I'm going to get there.

8 A Yeah.

9 Q Okay.

10 So you said if you removed -- if you had
11 a process that removed only water from a cheese
12 whey retentate you would still have a cheese whey
13 retentate, is that right?

14 A Yes.

15 Q Okay.

16 And to your point if you had -- if you
17 dilute it so you only added water to your cheese
18 whey retentate you would still have a cheese whey
19 retentate? Is that your opinion?

20 A Yes.

21 Q Okay.

22 If you had a process that removed water
23 and fat, only those two things water and fat from
24 your cheese whey retentate, would it still be a
25 cheese whey retentate?

1 MR. KRIEGER: Objection, form.

2 A Well, that is a little bit tougher to
3 say because when we are removing fat -- so when we
4 are removing fines we are removing a little bit of
5 fat too there, but it's very little so -- but if
6 we are having a process that -- so what I am
7 trying to say here is that I don't think we have a
8 process where we only remove fat, right?

9 So the issue is that in many of
10 these processes whenever we are removing
11 something, we are removing something else, so it
12 is very difficult to come up with a process where
13 only fat is removed and everything remains the
14 same.

15 Q Is it your opinion that if no proteins
16 are removed in a process, so you perform a
17 process, it removes whatever it removes, but it
18 doesn't remove any proteins from the cheese whey
19 retentate does it remain a cheese whey retentate?

20 A Well, that is theoretical and I don't
21 think there is such a process that only does
22 something, and what you get would be very
23 different from cheese whey, so I wouldn't call it
24 a cheese whey retentate at that point because it's
25 -- the composition would be very different.

1 Q Okay.

2 What if you enzymatically hydrolyze BLG,
3 so once you do that is the cheese whey retentate
4 still a cheese whey retentate?

5 MR. KRIEGER: Objection, form,
6 beyond the scope.

7 Q Or I'm sorry. I think I said BLG, but I
8 meant GMP.

9 MR. KRIEGER: Objection, form,
10 beyond the scope.

11 A Well, in that case -- let me think.
12 Well, you are -- so this is a -- again, this is a
13 cheese whey retentate at which you are adding --

14 Q Enzyme.

15 A -- an enzyme. So this is a cheese whey
16 retentate composition at this point.

17 Q Okay.

18 A And the question is whether we --

19 Q Is it also a cheese whey retentate, no
20 composition?

21 MR. KRIEGER: Objection, form,
22 beyond the scope, asked and answered.

23 A I would say that at that point the
24 profile of proteins and peptides is changing from
25 what you have in cheese whey so it will be a

1 modified cheese whey retentate.

2 Q Okay. If you heated a cheese way --

3 THE COURT REPORTER: If you what?

4 Q -- heated a cheese whey retentate so
5 that some or all of the proteins denatured would
6 it still be a cheese whey retentate?

7 MR. KRIEGER: Objection, form,
8 beyond the scope.

9 A That would be a heated cheese whey
10 retentate.

11 Q Okay. But it wouldn't be a cheese whey
12 retentate?

13 MR. KRIEGER: Objection, form,
14 beyond the scope.

15 A I would call it a heated cheese whey
16 retentate.

17 Q Okay. If you spray-dried a cheese whey
18 retentate would it remain a cheese whey retentate?

19 MR. KRIEGER: Objection, form,
20 foundation, beyond the scope.

21 A I would call that a spray-dried cheese
22 whey retentate.

23 Q Okay. No further questions.

24 MR. KRIEGER: We have nothing
25 further.

1 MS. KAISER: Okay.

2 MR. KRIEGER: Thank you.

3 Thank you, Dr. Harte.

4 MS. KAISER: Thank you very much,
5 Dr. Harte.

6 THE WITNESS: Thank you.

7 THE VIDEOGRAPHER: Off the record
8 3:57.

9 THE COURT REPORTER: Ms. Kaiser,
10 would you like to order the transcript?

11 MS. KAISER: Yes, please.

12 THE COURT REPORTER: And the
13 video?

14 MS. KAISER: We will hold off on
15 the video.

16 THE COURT REPORTER: Okay. Hold
17 off on the video. And Attorney Krieger?

18 MR. KRIEGER: Yes, we will do the
19 same.

20 THE COURT REPORTER: Would you
21 like transcript and video?

22 MR. KRIEGER: Just transcript, no
23 video.

24 (Deposition concluded at 3:57 PM.)
25

1 I, FEDERICO HARTE, Ph.D., do
2 hereby certify that I have read the
3 foregoing transcript and that the same and
4 accompanying amendment sheets, if any,
5 constitute a true and complete record of my
6 testimony.

7
8
9
10 _____
Signature of Deponent

11
12 () No amendments
13 () Amendments attached

14 Acknowledged before me this
15 ____ day of _____ 2026.

16
17 Notary Public: _____

18 My Commission Expires _____

19 Seal:
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21
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25

1 STATE OF COLORADO)
2 COUNTY OF DENVER } ss. REPORTER CERTIFICATE

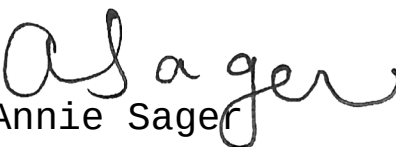
3 I, Annie Sager, certify that I am
4 a Court Reporter and Notary Public within
5 the State of Colorado; that previous to the
6 commencement of the examination the deponent
7 was duly sworn to testify to the truth.

8 I further certify that this
9 deposition was taken in shorthand by me at
10 the time and place herein set forth and was
11 thereafter reduced to typewritten form and
12 that the foregoing constitutes a true and
13 correct transcript.

14 I further certify that I am not
15 related to, employed by, nor of counsel for
16 any of the parties or attorneys herein, nor
17 otherwise interested in the result of the
18 action.

19 In witness whereof, I have affixed
20 my signature this 13th day of July, 2026.

21 My commission expires June 25, 2027.

22 
23 Annie Sager

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July 13, 2026

Federico Harte, Ph.D.
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1400 Wewatta, Suite 600
Denver, CO 80202

Re: Arla Foods Amba v. Leprino Foods Company
Date of Deposition: June 26, 2026

The transcript of your deposition taken in the above-entitled matter has been transcribed. The original transcript will be held for 30 days from the date of this letter before it is sealed and forwarded to the noticing attorney.

You have the right to review, sign and make corrections to your transcript within the 30-day period. Please call the above number, or e-mail to make an appointment for your review. It is our policy not to release the original transcript and complimentary copies are not provided.

If you are represented by an attorney, we advise that you contact your attorney to discuss this matter. If you are an independent witness and have questions, please contact the attorney who requested you to testify or this office for further instructions.

If you wish to waive signature, please sign and date below and return this letter to the above address. In the event you have not read, corrected, and signed your deposition within (30) days of receipt of this letter, it may be used with the full force and effect as though it had been read, corrected, and signed.

Cc: All counsel

DATE

Federico Harte, Ph.D.

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 < J >
 Jessica (3)
 jessica.kaiser@ashurst
 perkins.com (1)
 jkrieger@ktslaw.com (1)
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 Journal (1)
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 July (1)

June (5)
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msaia@ktslaw.com
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Okay (292)
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permeate (42)
permeates (1)
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Petitioner (3)
petitioner's (1)
pH (6)
Ph.D (11)
phase (3)
pick (1)
pilot (1)
pinpoint (2)
place (2)
placed (1)
places (1)

plaintiff's (1) plant (1) please (11) plus (1) PM (1) point (9) pointing (1) points (1) polyacrylamide (1) pore (11) portion (7) POSITA (3) position (6) possible (2) post-secondary (1) potential (1) powder (1) practical (1) practices (2) preceding (1) precise (1) precision (1) prefer (4) preferred (1) prefers (1) prepare (2) preparing (4) presence (6) PRESENT (6) preserves (1) pressure (2) pretty (3) previous (3) previously (2) primary (4) print-out (1) prior (7) privilege (2) probably (6) proceeding (4) process (79) processed (1) processes (7) processing (49) produced (1) producing (1) product (10) production (2) products (5)	professor (6) profile (18) projects (2) promote (5) prone (2) pronunciation (1) proper (1) properties (1) proportional (1) protease (5) protein (174) proteins (85) proteolysis (5) proteolytic (2) proteolyze (2) proteolyzed (1) proteolyzing (1) provide (1) provided (2) providing (1) Public (3) Publication (6) publications (3) pull (3) Pursuant (1) put (7) < Q > qualities (1) quaternary (2) question (74) questioning (2) questions (12) quick (1) quickly (1) quite (1) quote (1) < R > ran (2) range (14) rate (17) ratio (6) rationale (1) raw (1) reaction (1) reactions (1) reactive (5) read (26)	reading (2) reads (10) Ready (1) really (4) reason (4) recall (17) receive (3) recognize (3) record (26) recovery (2) re-cross (1) redirect (1) redline (2) reduce (17) reduced (55) reduced-GMP (1) reduces (4) reducing (27) refer (7) reference (6) referenced (1) references (1) referred (9) referring (6) refers (10) regard (5) regarding (6) regular (1) regularly (1) regulations (3) rejection (18) relate (1) related (3) relative (5) relatively (2) released (1) relevance (1) relevant (1) remain (8) remaining (1) remains (9) remember (8) removals (1) remove (24) removed (33) removes (3) removing (22) render (1) rennit (3)	repeat (10) repeats (1) reported (1) Reporter (21) represents (1) reproduced (3) require (1) required (2) research (9) residual (3) resolution (1) Resources (1) respect (3) respectively (1) respond (1) responds (2) response (1) restate (2) result (2) results (4) retain (2) retaining (2) retentate (250) retentates (1) reverse (5) review (4) reviewed (4) reviewing (3) rheology (2) right (118) rise (1) room (2) rotentate (1) roughly (8) rules (1) run (3) running (1) < S > Sager (4) Saia (2) sake (1) salt (1) salts (1) samples (2) sat (1) satisfy (1) save (1) saw (1)
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says (61)	sitting (1)	steps (20)	taken (10)
science (6)	Sixteenth (1)	stimulation (1)	takes (1)
scientist (3)	size (15)	STOCKTON (1)	talk (16)
scientists (2)	sizes (1)	store (1)	talked (19)
scope (20)	skill (1)	straight (2)	talking (26)
SDS (10)	skim (9)	strategy (1)	talks (3)
Seal (1)	slightly (3)	stream (1)	tangential (13)
second (8)	slow (1)	streams (3)	tank (7)
secondary (21)	slowly (1)	Street (3)	target (1)
seconds (1)	small (1)	strength (1)	taught (1)
section (2)	smaller (1)	strike (8)	teach (6)
see (103)	solid (1)	strong (1)	teaches (6)
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seeding (4)	solution (20)	structures (8)	technical (1)
seeds (3)	solutions (1)	struggle (4)	technology (2)
seen (8)	sorry (40)	students (1)	tell (7)
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selectively (6)	sounds (4)	Study (1)	temperature (21)
selectivity (2)	source (3)	subject (4)	temperatures (8)
sense (10)	speak (4)	subjected (3)	ten (3)
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sentence (20)	specifically (16)	subsequent (2)	Tennessee (3)
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separated (3)	speculating (1)	subtle (1)	terms (17)
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set (5)	springtime (1)	Suite (4)	text (2)
severely (1)	squares (2)	summary (1)	Thank (25)
shave (1)	ss (1)	summer (1)	theoretical (1)
sheets (1)	stabilization (2)	supersaturated (3)	thereof (1)
shelf-stable (1)	stained (1)	supersaturation (1)	thermal (3)
short (1)	stand (2)	sure (25)	thesis (3)
shorthand (1)	standard (4)	surface (1)	thicker (1)
showed (1)	stands (2)	sweet (101)	thing (11)
showing (9)	start (11)	switch (1)	things (11)
shown (9)	started (3)	sworn (2)	think (37)
shows (8)	Starting (9)	syllables (1)	thinking (1)
side (1)	starts (15)	synonym (1)	thinks (1)
Signature (2)	State (18)	system (2)	third (2)
significantly (1)	stated (2)	systems (2)	three (4)
signify (1)	statement (11)	< T >	threshold (1)
similar (4)	STATES (3)	table (10)	Thursday (4)
similarly (3)	State's (1)	tabs (7)	Time (32)
single (3)	stays (2)		times (6)

title (1)	U.S (5)	weight (31)
today (20)	UF (14)	Welcome (1)
told (2)	Uh-huh (43)	Well (65)
ton (1)	Uh-uh (1)	went (3)
tons (1)	ultimately (3)	we're (3)
tool (1)	ultra (1)	we've (1)
tools (1)	ultrafiltration (38)	Wewatta (3)
top (9)	understand (50)	When's (1)
topic (1)	understanding (44)	whereof (1)
topics (1)	understood (4)	whey (535)
total (10)	undesirable (1)	white (6)
tougher (1)	unhydrolyzed (3)	wide (3)
TOWNSEND (1)	unit (2)	widespread (1)
tracking (1)	UNITED (2)	widths (1)
TRADEMARK (2)	universities (1)	witness (8)
training (1)	University (10)	WO (1)
transcript (6)	unquote (1)	wondering (4)
transferred (3)	Uruguay (3)	Woodhouse (2)
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treatment (6)	utilizing (1)	working (2)
tremendously (1)	UTK (1)	WPC (41)
TRIAL (1)	< V >	WPC30 (3)
triangles (2)	varies (1)	WPC80 (11)
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twice (1)	want (29)	Yesterday (2)
two (19)	wanted (8)	yogurt (3)
two-thirds (1)	Washington (1)	Yuanfeng (2)
type (5)	water (39)	yuanfeng.gao@ashurst
types (5)	way (28)	perkins.com (1)
typewritten (1)	ways (2)	
typical (8)	website (3)	
typically (13)	Wednesday (4)	
typos (2)	week (1)	
< U >		