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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91194218
Party	Plaintiff Illumina, Inc.
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL APPEAL BOARD

ILLUMINA, INC.,)	Opposition No. 91194218
)	(parent) Ser. No. 77/768176
Opposer/Petitioner,)	
)	Opposition No. 91194219
vs.)	Ser No. 77/775316
)	
MERIDIAN BIOSCIENCE, INC.,)	Cancellation No.
)	92053479 Reg No. 3887164
Applicant/Registrant.)	Cancellation No.
)	92053479 Reg No. 386801

*** CONFIDENTIAL ***

*** TRADE SECRET, COMMERCIALY SENSITIVE ***

Deposition of Kenneth J. Kozak, a witness herein, called by the Opposer/Petitioner, for oral examination, pursuant to the Federal Rules of Civil Procedure, taken before George J. Staiduhar, Notary Public in and for the State of Ohio, pursuant to Notice, at the offices of Keating Muething & Klekamp, PLL, One East 4th Street, Suite 1400, Cincinnati, Ohio 45202 on Monday, March 9th, 2015, commencing at 9:45 a.m.

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I N D E X

WITNESS: Kenneth J. Kozak

EXAMINATION

PAGE

By Mr. Horne

4

E X H I B I T S

Kozak Deposition

PAGE

Exhibit 1 Declaration of
Kenneth J. Kozak in the
above-entitled matter

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1

KENNETH J. KOZAK

2

of lawful age, being first duly sworn, as hereinafter

3

certified, was examined and testified as follows:

4

EXAMINATION ON BEHALF OF COUNSEL FOR

5

OPPOSER/PETITIONER

6

BY MR. HORNE:

7

Q. Okay. Good morning.

8

A. Good morning.

9

Q. Have you been deposed before?

10

A. Yes, I have.

11

Q. How many times?

12

A. Once.

13

Q. When was that?

14

A. In the late '90s.

15

MR. HANKINSON: Let me just say,

16

Thomas Hankinson here on behalf of

17

Meridian and also in the room Michael

18

Hurst, also on behalf of Meridian.

19

MR. HORNE: And I am Brian Horne,

20

and I am here on behalf of Illumina

21

along with William Noon from Illumina.

22

BY MR. HORNE:

1 Q. So late 1990s?

2 A. Yes.

3 Q. What was the nature of the case?

4 A. It was theft of trade secrets.

5 Q. Who were the parties?

6 A. Meridian Bioscience and Dr. Arthur Yi, spelled
7 Y-i.

8 Q. Meridian was the Plaintiff?

9 A. Yes.

10 Q. What was your -- what was your role in the case?
11 Why were you deposed?

12 A. I was deposed because of my knowledge on the
13 product that was at question. We developed a
14 product for Helicobacter pylori detection, and
15 the individual who stole the trade secrets
16 after he left Meridian developed it the same
17 product.

18 Q. All right. Other than that, no other
19 depositions?

20 A. No, sir.

21 Q. So why don't we go over some of the ground
22 rules. I am assuming your counsel went over

1 these in preparation. First of all, you
2 understand that your testimony here today is
3 sworn testimony under the penalty of perjury
4 just as if you were testifying in Court?

5 I will be asking you a series of
6 questions, and it is your job to answer those
7 questions to the best of your ability. If you
8 don't understand, would you please ask for
9 clarification?

10 A. I will.

11 Q. If you don't ask for clarification, we will go
12 along with the assumption that you understood
13 the question.

14 A. I understand.

15 Q. We will be going -- hopefully, we won't be going
16 terribly long but long enough to take breaks. I
17 try to take a break every hour, hour-and-a-half,
18 hour and 15 minutes. If for some reason you
19 need a break a little bit sooner, use the
20 restroom, stretch your legs, stretch your
21 back, or anything like that, would you let me
22 know?

1 A. I appreciate that.

2 Q. Only thing we ask, that you don't ask for a
3 break if there is a question pending. Is that
4 all right with you?

5 A. I understand.

6 Q. Counsel may object from time to time to my
7 questions. Those objections for the most part
8 are for the record unless he specifically
9 instructs you not to answer the question.

10 MR. KOZAK: Objection just for the
11 record.

12 Q. Do you understand that?

13 A. I understand.

14 Q. Good. And you still answered.

15 Because we are in a deposition, it
16 is a little bit of a formal process. It is
17 important to give verbal answers to the
18 questions. Sometimes you want to shake your
19 head uh-huh or uh-uh and doesn't transcribe, so
20 if you can say yes or no?

21 A. I will.

22 Q. The other thing, we are trying to create a

1 record. There are two important things to
2 remember there:

3 First of all, let me finish my
4 question before you answer.

5 A. I understand.

6 Q. Okay. Great. We will have a tendency to jump
7 in, and sometimes you know what I am going to
8 ask. So first of all, we can't talk over each
9 other, and second of all, sometimes you will
10 know what I am going to ask, and you are going
11 to want to jump in and give the answer because
12 that's the way normal people would talk.

13 But because we are trying to create
14 a record, it is important you let me get the
15 whole question on the record first, then you can
16 answer that question.

17 A. I understand.

18 Q. Great. Did you do anything to prepare for your
19 deposition today?

20 A. We met with our legal counsel.

21 Q. Okay. Who is "we"?

22 A. Myself, and then we had a meeting with

1 Dr. Arthur Yi, who you will -- I'm sorry
2 -- Dr. Slav Elagin, who you will meet
3 tomorrow.

4 Q. When did you meet by yourself with counsel?

5 A. We met on Friday.

6 Q. For how long?

7 A. Roughly three and-a-half to four hours.

8 Q. And that was a meeting by yourself, with
9 counsel?

10 A. With Slav Elagin.

11 Q. Okay.

12 A. The four of us.

13 Q. I thought I was hearing two meetings. So there
14 was one meeting on Friday?

15 A. I apologize for that.

16 Q. All right. No problem. Anybody else call into
17 the meeting or just the four of you?

18 A. Just the four of us.

19 Q. Did you read any documents at that meeting?

20 A. Yes, we did.

21 Q. Can you give me an idea of the volume of
22 documents you reviewed?

1 A. What do you mean by volume?

2 Q. Size, in other words, was it 10 boxes? Was it a
3 file folder?

4 A. It was 10, 15 pages.

5 Q. Any of those documents refresh your recollection
6 as to what you expected to testify about today?

7 A. No.

8 Q. Other than your meeting with counsel on Friday,
9 did you do anything else to prepare for your
10 deposition today?

11 A. I reviewed the deposition that I gave yesterday.

12 Q. Yesterday you reviewed the deposition you gave
13 in the trade secret case or --

14 A. I'm sorry. I apologize; declaration.

15 Q. No problem.

16 A. I read it yesterday.

17 Q. Other than reading your declaration yesterday
18 and meeting with your counsel Friday, did you
19 do anything else to prepare for today's
20 deposition?

21 A. Not to my knowledge, not that I can recall.

22 Q. Okay. If I recall from your declaration --

1 A. May I ask you a question on that?

2 Q. Sure.

3 A. Are you talking specifically about today's
4 meeting?

5 Q. As opposed to -- what else would you have in
6 mind?

7 A. If I had e-mails from let's say Mike Hurst
8 throughout the last four years.

9 Q. Yeah, I mean preparing to be deposed today.

10 A. Preparing to be deposed.

11 Q. Yeah. So I am not talking about work history
12 at --

13 A. So you are talking about specifically the
14 preparation for this meeting.

15 Q. Yes.

16 A. Okay.

17 Q. I remember from your declaration you the
18 graduated college in 1976?

19 A. That is correct.

20 Q. Could you remind me what your degree was?

21 A. Microbiology.

22 Q. Did you get any advanced education?

1 A. I did not.

2 Q. Any formal training after your undergrad degree?

3 A. No.

4 Q. Your declaration said you started at Meridian in
5 1987. Is that correct?

6 A. That's correct.

7 Q. What did you do between graduating and coming to
8 Meridian?

9 A. I worked at the University of Cincinnati. I
10 worked in the Department of Surgery, Kidney
11 Transplant Division, looking at host graft
12 rejection and reasons for rejection. I did that
13 for six years. Then I moved to the Department
14 of Microbiology and Molecular Genetics where I
15 worked on bacterial toxins and their
16 interactions with host cells.

17 Q. Did you do that from 1982 to 1987?

18 A. That is correct.

19 Q. And then in 1987, you went to Meridian?

20 A. That is correct.

21 Q. And you started as a senior research associate
22 there?

1 A. Correct.

2 Q. Briefly what were your responsibilities as a
3 senior research associate at Meridian?

4 A. To build new products in research and
5 development to bring to the marketplace.

6 Q. What type of products did you work on?

7 A. I worked on latex agglutination assays. I
8 worked on Elisa Technology.

9 Q. Can you spell that?

10 A. E-l-i-s-a, and I worked on rapid flow assays in
11 a card system.

12 Q. Anything else?

13 A. Not that I can recall today.

14 Q. And your responsibility was to build new
15 products I think you said?

16 A. My responsibility was to understand the
17 clinical lab setting, understand the
18 competitors, and build products to meet both our
19 customer's needs as well as outperform competing
20 products.

21 Q. What did you do to understand the clinical lab
22 setting?

1 A. We visited clinical labs.

2 Q. How many clinical labs would you say you
3 visited?

4 A. I can't recall at this point.

5 Q. Was it five or a hundred?

6 A. Over the course of my career, it has probably
7 been more than 50.

8 Q. So more than 50 since 1987 to today?

9 A. Correct.

10 Q. And I guess we are going to ask the question
11 generally:

12 What did you do when you visited
13 the clinical labs to understand the clinical lab
14 setting?

15 A. We meet with the director of the lab. We meet
16 with the lab technicians. We look at their
17 sample work flow.

18 Q. Can you -- what do you -- what does sample work
19 flow mean?

20 MR. KOZAK: Objection. It sounded
21 like the witness' answer was incomplete.

22 Q. Yeah. I am going to pickup and go. I want to

1 stop you there.

2 You said you looked at sample work
3 flow?

4 MR. HANKINSON: Same objection.

5 A. We look at sample work flow to understand how a
6 sample is collected from a patient and how it is
7 brought into the clinical lab, how it is
8 processed within that clinical lab, how it
9 is tested, and how that data is reported back
10 out.

11 Q. I apologize for jumping in too soon. Thanks.

12 A. Apology accepted.

13 Q. I should have listened to the objection.
14 Anything else you would do?

15 A. There is a myriad of things we look at of which
16 I can't remember them all today, but if you are
17 bringing in a piece of instrumentation, what is
18 its size, where can it fit, what are the power
19 requirements that are necessary to put that
20 piece of equipment in?

21 How many steps does the assay take?

22 If the steps are cumbersome, we get feedback

1 trying to make that process easier for the
2 technician so there is less chance of producing
3 an error and an improper end result, which would
4 result in improper diagnosis of a clinical
5 patient.

6 Q. When you became vice president of R & D was in
7 1999?

8 A. That's correct.

9 Q. What were your responsibilities as vice
10 president of R & D?

11 A. I managed all the undertakings of the product
12 development group to bring products to market,
13 the research teams who were generating new ideas
14 for products, bringing in new technology so we
15 could expand and keep on the forefront of
16 diagnostics. I was involved in all budget
17 generation. I was involved with understanding
18 of our interworkings with the outside field. I
19 was responsible for all clinical trials. I was
20 responsible for all intellectual property of
21 Meridian's products to name a few of the things
22 we did.

1 Q. You say all intellectual property. Does that
2 include trademarks?

3 A. Trademarks at that time were handled by our
4 marketing department.

5 Q. Now, during your time as vice president of R &
6 D, what types of interactions did you have with
7 customers?

8 A. Same as I had before. It was very important
9 that we went out from meeting customers, going
10 on sales calls, meeting with clinical trial
11 sites, going to meetings to make sure that we
12 had a presence at meetings, we could meet
13 customers.

14 In our interfacing with our
15 marketing department, it was critical that
16 marketing and R & D were always aligned in our
17 marketing process.

18 Q. Can you describe the types of customers -- let's
19 talk about in the period from '99 to 2007, who
20 were these customers?

21 A. Our customers were purchasers of IVD
22 manufactured products in the microbiology,

1 primarily in the microbiology areas, and
2 their responsibility was to aid in the
3 process of diagnosing patients, which results,
4 then, would help patient management to the
5 physicians.

6 Q. And my question was a little bit more directed
7 to, can you describe what these entities were?
8 You mentioned the clinical lab setting. That's
9 kind of what I am gearing at.

10 Were they clinical labs? Were they
11 hospitals? What types of entities were these?

12 A. I need to understand a little better of how you
13 are defining labs. I want to define that in my
14 language.

15 Q. Please do, and just tell me how you are defining
16 that.

17 A. Clinical lab, as I define it, is for our area --

18 Q. "Our," you mean Meridian's?

19 A. Meridian's, hospital, microbiology, clinical
20 lab, who is buying FDA cleared products
21 diagnosing infectious diseases. I also dealt
22 with what we would call reference labs, and that

1 name means a lab like Quest or Lab Corp., who
2 also then within their structure had a specific
3 clinical lab purchasing FDA cleared products
4 for, again, diagnosing patients, reporting data
5 out to help patient management.

6 Part of my role also was to
7 conduct clinical trials of all new products
8 shall and those trials designed to assure
9 that our products are safe and effective. That
10 data would be submitted to the FDA for
11 clearance. Typically, we would have, at least,
12 three sites geographically distributed
13 throughout the United States to conduct these
14 trials.

15 Q. So when you were defining -- you defined
16 clinical lab and also talked about reference
17 labs, Quest and Lab Corp. being an example,
18 can you give me an example of some of the
19 entities that you were characterizing as
20 clinical labs?

21 A. Are you talking a specific name?

22 Q. Yeah. Just so I can --

1 A. I am talking about the microbiology department
2 at Children's Hospital, Cincinnati, Ohio, headed
3 by Joel Morteson. I am talking about Bethesda
4 Hospital clinical lab system for infectious
5 diseases at the time headed by Larry Gray.

6 Q. Can you give me one more?

7 A. I am talking about Children's Hospital,
8 Wisconsin clinical lab infectious diseases
9 headed by Sue Kehl.

10 Q. In this period of '99 to 2007, how many
11 customers would you say you interacted
12 with?

13 A. As I sit here today, it is almost impossible to
14 know, but it is hundreds.

15 Q. I thought earlier when we talked, I thought you
16 said you had interacted over the time from '87
17 to now about over 50?

18 MR. HANKINSON: Objection. Go
19 ahead.

20 A. For clarity, what I said was 50 labs.

21 Q. Okay.

22 A. When you go to a laboratory, as I said earlier,

1 there are multiple people we interface with in
2 each lab. So when you ask me how many customers
3 there are, there are hundreds within those 50
4 lab settings.

5 Q. Okay. Thanks for the clarification.

6 So you are talking about hundreds
7 of people, not hundreds of labs?

8 A. I originally said, as I sit here today, I said
9 at least 50 labs.

10 Q. Okay.

11 A. Therefore, there are hundreds of people we
12 interface with.

13 Q. Was it also your responsibility as vice
14 president of R & D to keep track of
15 competitors?

16 A. Yes.

17 Q. How would you do that?

18 A. At Meridian, we have a process whereby we
19 determine potential areas to develop new
20 products. We develop what we call a "term
21 sheet." Within that term sheet are specific
22 characteristics that a product must have.

1 That term sheet is developed by
2 R & D and marketing. Within that context, we
3 identify specific performance characteristics,
4 specific targets for price, specific intended
5 uses, and potential for areas of which we have
6 to compete with competitors so that we know that
7 our designs are appropriate.

8 Q. Is that your complete answer?

9 A. As I sit here today, that's the main thrust of
10 that document.

11 Q. Okay. Maybe there was a miscommunication.

12 How do you -- how does Meridian go
13 about -- or how do you go about keeping track of
14 you're competitors?

15 MR. HANKINSON: Objection to form,
16 including an objection that the question
17 is compound.

18 A. Could you repeat that question for me, please?

19 Q. Let me rephrase it.

20 How did you keep track of your
21 customers as vice president of R & D from 1999
22 to 2007?

1 A. How did I personally?

2 Q. Yes.

3 MR. HANKINSON: Objection to
4 form. You said customers, and you may
5 have meant competitors, and I don't want
6 to --

7 MR. HORNE: No. I appreciate that.
8 I thought I said competitors. Let me
9 ask that question again.

10 BY MR. HORNE:

11 Q. How did you personally as vice president of
12 R & D keep track of your competitors?

13 A. Again, as I said earlier, we are in specific
14 areas of diagnostics. So for instance, we are
15 the leader in the C. difficle detection. We
16 keep track of every competitor in that
17 marketplace.

18 Every new product that we develop
19 has a team of R & D researchers and marketing
20 researchers who come together and champion that
21 product, and as I said before, we identify
22 specific performance characteristics those

1 products must meet to be successful in the IVD
2 marketplace. Within that is an analysis of our
3 competitive market.

4 Q. How do you become aware of who the competitors
5 are?

6 A. There are two mech -- there are multiple
7 mechanisms by which this happens. I am part of
8 all transfer teams.

9 Q. All transfer teams?

10 A. Yes, of which this is part of that process. At
11 that time, as an executive, I am on the design
12 review board who signs off on all these
13 enterprises. In addition to research brought to
14 me by that process, we attend meetings. We do
15 literature searches. I personally have done
16 those. We look at what's out there. I
17 constantly doing literature searches. I am
18 constantly going to meetings to make sure if we
19 see something new on the horizon that is either
20 a threat to our business or an opportunity for
21 our business, that we can be poised and ready to
22 go into that area.

1 Q. You said you attended meetings. What type of
2 meetings would you attend?

3 A. I would attend scientific meetings, ASM, AACC,
4 CVS, to name a few, Medica.

5 Q. Would you attend trade shows?

6 A. To me, a trade show and scientific meeting are
7 very similar if not the same. A marketing
8 individual might say trade show like AACC. They
9 may call it a trade show. I still call it a
10 scientific meeting.

11 Q. Let's stick with '99 to 2007. Did you have any
12 interactions with Illumina during that time
13 period?

14 A. No.

15 Q. Did you know anything about Illumina from '99 to
16 2007?

17 A. No. They weren't a competitor.

18 Q. During your time as vice president from 1999 to
19 2007, did you participate at all in the sales or
20 contracting process?

21 A. Contracting process, not directly. I was aware
22 of contracts. I was aware of pricing as a

1 result of those contracts. I did not directly
2 interface with a purchasing agent go per se
3 unless I was on a sales call, and they asked me
4 to go talk with the purchasing agent. And there
5 was another half to that question I missed.

6 (Question read.)

7 A. (Continuing) Relative to sales, we often went
8 into the field with our sales reps and went on
9 sales calls.

10 Q. What do you mean my "sales call"?

11 A. Sales rep would go into the clinical lab that
12 was purchasing IVD products. We would accompany
13 them to meet with the lab directors, to meet
14 with the decisionmakers, to meet with the lab
15 technicians.

16 Q. These were current customers?

17 A. At that time, yes.

18 Q. During your time as VP of R & D, did you
19 participate at all in the process to, for lack
20 of a better phrase, get a new customer?

21 A. Absolutely.

22 Q. Okay. What did you do? How did you do that?

1 A. We would go on sales calls. We would work with
2 our clinical trial sites who would then be on
3 the forefront of looking at a new product and
4 working with them to bring that product online
5 once it received FDA clearance.

6 Q. And so what would you do to work with the
7 clinical trial sites?

8 A. I managed the clinical trial sites. My team was
9 responsible for clinical trial management.

10 So we would select trial sites that
11 could perform the appropriate research according
12 to the FDA specifications and our clinical trial
13 specifications to generate the appropriate data,
14 comparing our product to the gold standard,
15 often then looking at a predicate device within
16 that study, and then, because of that
17 relationship, converting them to a purchaser of
18 Meridian's product once it is FDA cleared and
19 only once it is FDA cleared.

20 Q. Other than -- and we will stick within the '99
21 to 2007 time frame -- other than attempts to
22 convert a clinical trial into a customer, did

1 you do any other work to gain customers for
2 Meridian's products?

3 MR. HANKINSON: Objection to form.

4 A. I thought I answered that already, but we and I
5 often went on sales calls to meet with customers
6 with our sales representative to bring in the
7 research R & D perspective while they bring in
8 the sales perspective, to hopefully be
9 successful and convert that customer to a
10 Meridian buyer of our product.

11 Q. Were those current customers or --

12 A. I don't understand what you mean by "current
13 customers." We are talking about 1999 to
14 2007.

15 Q. Uh-huh. Were they customers at the time you
16 were meeting with them?

17 A. Those are -- yes; current customers and
18 potential new customers.

19 Q. That's what my question was: Did you meet with
20 potential new customers during this time of 1999
21 to 2007?

22 A. I need clarity on that question.

1 Q. Sure.

2 A. Is it a customer who has never heard of
3 Meridian, never purchased anything from Meridian
4 before?

5 Q. Who wasn't currently purchasing products from
6 Meridian.

7 MR. HANKINSON: Objection to form.

8 A. Currently purchase -- I don't understand your --
9 I don't mean to be difficult, but I don't
10 understand.

11 Q. I understand. I want to distinguish between --
12 let me take a step back.

13 My understanding, generally medical
14 device sales is sales reps go and meet with
15 customers on some type of periodic basis. They
16 call on customers that are currently buying
17 their product to check in on them. And I want
18 to distinguish between that type of sales call
19 where you ride along with the sales rep to see
20 how customers are doing versus going and trying
21 to sell a new customer to buy Meridian's
22 products.

1 A. We usually were brought in because we had a
2 customer not purchasing our product, and we were
3 brought in to, hopefully, close that deal, to
4 help close that deal.

5 But on those calls, we would also
6 visit customers they have currently as a
7 courtesy because we went to the field; we just
8 didn't just go to see one customer. It was not
9 cost effective. We would see a series of them
10 on that day or two days or a week.

11 Q. So you would go with a sales rep on sales calls,
12 but you were not participating directly in the
13 contracting process?

14 A. At that point, no.

15 Q. Let's talk about your responsibilities when you
16 became chief technical officer in 2007?

17 A. Chief technical officer.

18 Q. And you have been CTO since 2007?

19 A. Correct.

20 Q. What have your responsibilities been as CTO for
21 Meridian?

22 A. I am in charge of all clinical trials, the

1 verification, and product support team. I am
2 responsible for new technology discovery. I am
3 responsible for all IP as it relates to patents,
4 both FTO and new patents generation.

5 Q. Is that it?

6 A. I could add: And all other duties deemed
7 necessary by management. It is never that is
8 all it is.

9 Q. Understood.

10 A. Okay. Excuse me. My throat is getting dry.
11 Can I get a little coffee?

12 MR. HORNE: Sure. Let's get go off
13 the record.

14 (Discussion held off the record.)

15 A. Thank you.

16 Q. No problem.

17 A. Could I add one point of clarification to my
18 duties as CTO?

19 Q. Please do.

20 A. I am also a team member on the design control
21 process for every new product that comes through
22 Meridian's research and marketing development

1 teams.

2 Q. I am going to ask now for your time as a CTO
3 from 2007, so the same questions I asked about
4 your responsibilities from '99 to 2007. And if
5 the answer is nothing has changed or is the
6 same, that may short cut things.

7 But --

8 MR. HANKINSON: Objection to form.

9 Q. -- did you interact with customers during your
10 time -- do you interact with customers in your
11 time at CTO.

12 A. Yes.

13 Q. How so?

14 A. From the point of setting up and designing
15 clinical trials, from interfacing with our
16 customers at meetings, interfacing with
17 customers as we bring them into Meridian as
18 subject matter experts to discuss the IVD
19 marketplace and trends within the IVD
20 marketplace to name a few.

21 Q. And you say interface with customers at
22 meetings. What do you mean by that?

1 discuss future trends that they are seeing and
2 how we can look at our technology so that we
3 continue to meet their needs as we move into the
4 future.

5 Q. Do you visit customers in your role as CTO?

6 A. Yes.

7 Q. Other than clinical trials?

8 A. Yes.

9 Q. How often would you say you visit customers
10 since you have been CTO, since 2007?

11 A. Are you looking for a frequency per time unit?

12 Q. Sure. Let's start there.

13 MR. HANKINSON: Objection. Too
14 awesome.

15 A. I don't keep track of the data that way. We try
16 to get out -- or I try to get out every other
17 month. I can't pinpoint that exactly. There
18 may be some months I do a lot and other periods
19 of time not much. I have a staff who reports to
20 me, who do go out more frequently than I do at
21 this point. I am often on phone calls with
22 them.

1 Q. "Them" you mean --

2 A. The clinical trial sites or even potential
3 clinical trial sites.

4 Q. And I want to ask, other than clinical trial
5 sites, do you visit customers and interact with
6 customers besides at the scientific meetings,
7 besides bringing them into Meridian to look the
8 at trends?

9 A. Yes. Not as frequently as I did before, but
10 there are occasions when I do that.

11 Q. And just for clarification, how frequently do
12 you do it now, visit customers?

13 A. Over the last year, I may have only done one.
14 Prior to that, there were multiple trips.

15 Q. When you say prior to that multiple trips, you
16 mean multiple trips per year?

17 A. Multiple trips per year.

18 Q. How many would you say?

19 A. Minimum of three.

20 Q. How many customers do you think you would visit
21 on those three, in those three trips?

22 A. We typically will visit five per day, and these

1 are rough estimate in my memory. I don't keep
2 track of those demographics.

3 Q. Okay.

4 A. But it is more than one.

5 Q. So how long would be a trip be. And you said
6 five per day and three trips per year. How many
7 days would a trip --

8 A. It all depends. When I went to LA, it was three
9 days.

10 Q. Is it normally a day or two or normally two
11 weeks?

12 A. No, no. It is never weeks. It is days.

13 Q. So a trip would be a couple days?

14 A. Couple days.

15 Q. And you would visit maybe five customers per day
16 over a couple day period?

17 A. Sure, I believe.

18 Q. As CTO, have you been involved since 2007 with
19 the contracting process, with the customer?

20 A. I am not involved in direct contracting
21 processes. As CTO, I have knowledge of
22 contracts. We often discuss the contracting

1 process internally because of sales dollars and
2 how we are positioning our products relative to
3 cost. So it is very important that we all
4 understand how our products are positioned
5 relative to costing.

6 Q. And since you have been CTO in 2007, do you keep
7 track of your competitors?

8 A. Yes. And I will answer that that process hasn't
9 really changed, except it has gotten more
10 defined and evolved, and we have incorporated
11 more design control processes.

12 Q. How has the process become more defined and
13 evolved?

14 A. We are much better now at tracking through
15 documentation to meet the QSR regulations of the
16 FDA through the design control process.

17 Q. How does tracking documents through QSR for the
18 FDA process allow you to keep track of your
19 competitors?

20 A. Part of that documentation process is a listing
21 of competitors so that we know we have products
22 that can compete in that marketplace. The

1 design control process is from ideation all the
2 way through customer launch or product launch
3 and then monitoring it after that.

4 So we must maintain documentation
5 throughout that process to make sure that our
6 product is meeting customer needs and
7 expectations as part of the QSR regulations.

8 Q. In your time as CTO from 2007 to now, have you
9 had any interaction with Illumina?

10 A. No.

11 Q. Have you done anything to keep track of Illumina
12 and how it operates its business from 2007?

13 A. No, outside of what I have gained from this
14 proceeding.

15 Q. What have you gained from this proceeding?

16 A. Just the knowledge that I have that Illumina is
17 questioning our use of the trade mark ILLUMIGENE
18 and ILLUMIPRO.

19 Q. So other than this proceeding, you don't know
20 anything about Illumina, how they do their
21 business, who their customers are?

22 A. I want to make sure I understand what you are

1 asking.

2 Do I know that Illumina is a
3 company that makes sequencing and parts, if you
4 will, for diagnostic other companies? That I
5 know.

6 Q. Okay.

7 A. But as far as what their business plans are, I
8 am not fully aware of that. But I know they
9 make sequencing machines and equipment that is
10 highly, highly expensive. They make enabling
11 components for others to build products, and to
12 my knowledge, they don't have any IVD products
13 in the infectious disease arena of which we
14 compete. So if that limits my knowledge of
15 Illumina.

16 Q. How did you gain this knowledge of Illumina you
17 just told me?

18 A. Trade shows. When you go to the scientific
19 meetings and trade shows, there are multiple
20 booths with multiple different kind of companies
21 within those showing off their products.
22 Illumina is present. Meridian is present. We

1 function differently.

2 But will I stick my head in the
3 Illumina booth to see what they have? Sure. Do
4 I spend a lot of time there? No.

5 Q. Other than seeing Illumina at trade shows, have
6 you come across -- and this proceeding -- have
7 you come across Illumina in any way?

8 A. No. I have never seen them in labs we
9 frequented. I have never seen them as a direct
10 competitor, and from my knowledge, I have never
11 seen Illumina come up as a competitor to one of
12 the products that we are generating through our
13 process.

14 Q. I want to switch gears a little bit and talk
15 about Meridian's trademark products, and by that
16 I mean the ILLUMIGENE and the ILLUMIPRO
17 products.

18 A. Uh-huh.

19 Q. Let's start with ILLUMIGENE. Can you just first
20 describe what the ILLUMIGENE product is?

21 A. The ILLUMIGENE product is the molecular-based
22 detection using isothermal amplification based

1 on LAMP technology that I licensed from a
2 company called Eiken, E-i-k-e-n, Chemical
3 Company from Japan in 2006.

4 The design of the product is to be
5 user friendly, simple to operate, simple to run,
6 and in conjunction with the ILLUMIPRO data can
7 be interpreted by the instrument to determine if
8 a patient is positive or negative for a specific
9 target. That's the 50,000 foot view.

10 Q. Thank you. Let's talk specifically about
11 ILLUMIGENE, and then we will get into a little
12 more detail of ILLUMIPRO. Just a little bit
13 more basic: What physically is ILLUMIGENE? Is
14 it a kit?

15 MR. HANKINSON: Object.

16 Q. If I buy a ILLUMIGENE product, what am I
17 getting?

18 MR. HANKINSON: Objection to form.

19 A. If you buy an ILLUMIGENE product, you will get a
20 complete diagnostic kit that has been cleared by
21 the FDA for use, for its specific intended use
22 to aid and assist the diagnoses of patients with

1 a specific disease state. The ILLUMIGENE kit by
2 itself needs the ILLUMIPRO to interpret that.

3 Q. Okay. And can you describe a little bit more
4 physically, what physically is the -- is it a
5 kit?

6 A. It is a diagnostic kit IVD cleared.

7 Q. Okay. So what physically specifically is it?

8 A. I am having trouble understanding.

9 Q. I mean, does it come with a couple cotton swabs?
10 What am I getting?

11 A. So you want the kit components?

12 Q. Perfect. Thank you.

13 A. Comes with a box labeling "cleared by the FDA,"
14 and you open up the box, and depending on the
15 kit, there are different configurations. But
16 you will have individual little plastic devices
17 that we have learned how to dry within that
18 device control beads and detection beads or a
19 single bead in each.

20 In addition to that, there will be
21 a sampling device for C. difficle. You will
22 take your stool sample, will be collected on a

1 brush, placed into this device. The device has
2 a specific buffer that we have designed and
3 developed. The device has a filter. You
4 squeeze it, drops come out the bottom. You then
5 transfer that to reaction, you heat treat it,
6 and then add it to the Illumina, a little
7 plastic device that has our beads.

8 Group A strip, very similar.
9 Doctors collect the swabs. Swab goes into the
10 sampling device. Sampling device gets filtered
11 through the filtration system, manually, very
12 simply done. You do a 95 degree heat step, add
13 that sample to the Illumina device, put it in
14 the reader and read the results four minutes
15 later.

16 Q. When you say put it in the reader, you are
17 referring to the ILLUMIPRO?

18 A. Yes. It is a closed system, so we can only use
19 our reader for kits that Meridian has designed
20 and developed. You can't use it for any type of
21 research.

22 Q. And you can't use any other competitor's kit

1 with the ILLUMIPRO?

2 A. No.

3 Q. And can the ILLUMIGENE kit be used with any
4 other company's reader or product?

5 A. No.

6 Q. So ILLUMIGENE only works with ILLUMIPRO and visa
7 versa?

8 A. It is cleared to be used together. It is a
9 closed system, so it can't -- a customer cannot
10 get into the system and change the software. So
11 every product has its own set of software
12 requirements so that the parameters are
13 appropriate for that kit.

14 So when we develop a new kit, we
15 have to upgrade every reader with that software.
16 So it is not a research tool. It is only used
17 for clinical diagnoses and FDA cleared products
18 that marry up to it.

19 Q. And besides that, even if there are other
20 FDA cleared products, Meridian's
21 ILLUMIGEN-ILLUMIPRO aren't interchangeable so to
22 speak with any competitor's products. Is that

1 correct?

2 A. We could not put our device on their reader.
3 They could not take theirs and put it on our
4 reader.

5 Q. Can you list for me the different -- I don't
6 know if disease is the right word, and feel free
7 to use a better word -- but different diseases
8 viruses that the ILLUMIGENE can test for or the
9 ILLUMIGENE ILLUMIPRO can test for?

10 A. That we have currently cleared or what its
11 capabilities are in the whole diagnostic
12 area?

13 Q. Why don't we start with currently cleared, and
14 then we can answer the next question.

15 A. Hopefully, I can remember them all but we have
16 kits for C. difficle, Group A strip, Group B
17 strip, mycoplasma, pertussis. We recently
18 launched a CT/NG.

19 Q. Slow down just a second.

20 A. Sorry.

21 Q. That's okay. Keep going.

22 A. I'm trying to think. That's all I can remember

1 right now.

2 Q. What is myco --

3 A. Mycoplasma.

4 Q. What is that?

5 A. It is an upper respiratory disease sometimes
6 referred to as walking pneumonia; treatable.

7 Q. And what is pertusis?

8 A. Bordetella pertusis is whooping cough. So there
9 is outbreaks of that recently because of the
10 lack of effective vaccines or people not getting
11 vaccines.

12 Q. Those darn Californians.

13 A. I won't go there.

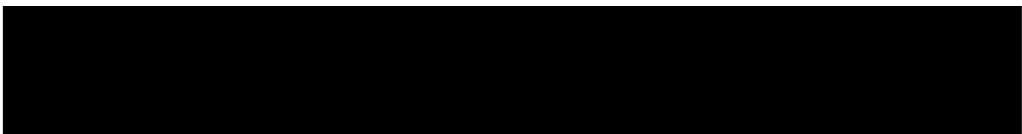
14 MR. HANKINSON: No objection.

15 (Laughter.)

16 Q. And you mentioned a CT/NG?

17 A. CT chlamydia NG gonorrhea, recently launched in
18 Europe.

19 Q. What about staph? Is it staphylococcus or staph
20 infection, does ILLUMIGENE test for that?

21 A. 

22

1

2

3 Q.

4 A.

5

6

7 Q.

8 A.

9 Q. Why not have staph for ILLUMIGENE?

10 A. There are multiple reasons for that because in
11 addition to detecting staph and MRSA directly,
12 customers also want to know are there other
13 mechanisms by which you can be resistant to
14 oxacillin? The Meridian platform does not lend
15 itself well to multiple analytes. So we would
16 have multiple tubes or little devices that we
17 would have to design.

18 So at this point, we have opted not
19 to go down that path. It doesn't mean we won't;
20 it just means there are other targets we can be
21 more effective with.

22 In addition, there are a lot of

1 mutations for MRSA, which have caused some
2 difficulties to other companies who have
3 actually had the products on the market.

4 MR. HANKINSON: Meridian
5 provisionally designates this -- the
6 transcript of this deposition as
7 commercially sensitive trade secret
8 material and confidential. Under the
9 protective order, we will review the
10 transcript and potentially dedesignate
11 or reduce the designation level of
12 certain portions.

13 A. And then, lastly, with respect to the MRSA
14 product, testing for MRSA is on the decline.

15 Q. If I understood your testimony correctly, the
16 ILLUMIGENE system is capable of testing for
17 multiple analytes?

18 MR. HANKINSON: Objection to form.

19 A. The test system is designed in such a way that
20 multiple analytes could be detected, but it
21 would require multiple devices if you want a
22 separate answer.

1 Q. When I asked you the types of products that the
2 ILLUMIGENE system is designed for, did you
3 distinguish between currently and potentially.
4 Did I understand that correctly?

5 A. Correct.

6 Q. What potentially could ILLUMIGENE be designed
7 for?

8 MR. HANKINSON: Objection to form.

9 A. It could be designed for any infectious disease
10 product with minimal steps, especially as
11 relates to DNA-based targets such as malaria
12 from whole blood.

13 Q. Can you give me some other examples?

14 A. We could detect flu A, we could detect flu B,
15 even those are RNA viruses with some steps
16 preceding that to make sure that we change RNA
17 to DNA, which most products have to do. The
18 BCO, there are hundreds of targets that we have
19 looked at. It is what is most relevant in the
20 marketplace to generate sales dollars. It is
21 capable of detecting anything very simply that
22 has a DNA base.

1 Q. So the ILLUMIGENE system is capable of detecting
2 any infectious disease that has a DNA base?

3 MR. HANKINSON: Objection to form.

4 A. It can also detect things with RNA as long as it
5 is converted to DNA first, but those are
6 multiple steps involved in that process.

7 Q. But it is capable of that?

8 MR. HANKINSON: Objection to form.

9 A. Technically, any molecular method could detect
10 anything. It is a very generic question. I am
11 having trouble pinpointing what you may be
12 specifically looking for there.

13 Q. Could the ILLUMIGENE system be configured to
14 detect HIV?

15 A. While it may have that capability, blood borne
16 infectious diseases is not a target of Meridian
17 nor has it ever been a target of Meridian.

18 Q. Why is that?

19 A. There are already multiple competitors in that
20 marketplace.

21 Secondly, for HIV, it is very
22 important that you get a viral load, i.e., how

1 much virus is there per unit? ILLUMIGENE is
2 more for saying is it there or is it not? It is
3 not specifically designed to say how much of it
4 is there.

5 Q. You mentioned that the ILLUMIGENE system uses
6 LAMP technology?

7 A. Uh-huh.

8 Q. Is that -- how does LAMP technology relate to
9 PCR?

10 A. PCR is a technology that relies on an enzyme and
11 a cycling process whereby you heat the sample,
12 let it cool, heat the sample and let it cool,
13 generating basically replicates of the target.
14 So they call it thermal cycling is the key
15 component there.

16 Isothermal application does not do
17 that at all. It relies on an enzyme operating
18 at a single temperature to generate enough
19 target to allow reactions to happen to detect
20 that target amplification.

21 Q. And Meridian, if I remember correctly, licensed
22 the LAMP technology in about 2006?

1 A. Yes.

2 Q. Do you know when LAMP technology was developed?

3 A. Invented?

4 Q. Sure.

5 A. I don't recall the date of the original patent.

6 I have them, but I don't recall the dates.

7 Q. Can you give me --

8 A. I think the life of the patent has, at least,
9 still a decade. Don't hold me to that number.

10 I just can't recall those patents off the top of
11 my head.

12 Q. Other than the ILLUMIGENE system, do you know
13 whether LAMP technology is used in any other
14 form?

15 MR. HANKINSON: Objection to form.

16 A. To my knowledge, Eiken technology has the -- has
17 used the technology in Japan for some commercial
18 applications. To my knowledge, Meridian is the
19 only company who has an FDA cleared product
20 using the Eiken technology used in infectious
21 diseases.

22 Q. And when you say "Meridian is the only one to

1 use the Eiken technology," do you mean

2 Meridian is the only one to use the LAMP

3 technology?

4 A. Eiken and lamp in my opinion are the same
5 technology. Apologize for lack of clarity.

6 Q. And let me ask the question broader:

7 I asked whether you have anyone
8 else using LAMP technology in the product. Do
9 you know anyone, other than the ILLUMIGENE
10 system and the Eiken product in Japan, if the
11 LAMP technology is being used for any other
12 purpose?

13 MR. HANKINSON: Objection to form.

14 A. I don't know what you mean by "any other
15 purpose."

16 Q. Other than a commercial product, is it maybe
17 used for research? I just want to make sure my
18 question wasn't too limiting when I asked about
19 a product.

20 MR. HANKINSON: Objection to form.

21 A. I have read papers that use LAMP technology. So
22 in the research setting, it appears there are

1 people using that technology.

2 Q. Do you know whether LAMP technologies was used
3 in a research setting before it became used in
4 the commercial setting?

5 MR. HANKINSON: Objection to form.

6 A. There were papers, and it goes back relating to
7 the patents that Eiken generated.

8 Q. What do you mean when you say it goes back to
9 patents Eiken generated?

10 A. Eiken generated patents, that's public
11 information, and within that context, then,
12 after that, there are papers that I have seen
13 that have been generated.

14 Q. And do you remember anything about those papers,
15 how they describe LAMP being used?

16 A. Not specifically outside of the basic premise of
17 it.

18 MR. HANKINSON: Shall we take a
19 break?

20 THE WITNESS: I could use a break.

21 Is now a good time?

22 MR. HORNE: Yeah, that's fine.

1 (Recess had.)

2 BY MR. HORNE:

3 Q. Are you familiar with a technology called PCR?

4 A. Yes.

5 Q. Do you know when PCR was developed?

6 A. I want to say it was somewhere circa 1955.

7 Q. Do you know when PCR was first used in an IVD
8 product?

9 A. I do not.

10 Q. Do you have an idea how long after a PCR
11 was developed that it was used in an IVD
12 product?

13 A. I do not.

14 Q. Do you know whether it was used in the research
15 arena for a period of time before it was used in
16 an IVD product?

17 A. Research arena as in academic research?

18 Q. Any type of research.

19 A. It was.

20 Q. For how long was it used -- what type
21 of research are you aware PCR being used
22 for?

1 A. It was used for detection of DNA.

2 Q. In a research setting?

3 A. Originally.

4 Q. Do you know how long PCR was used for detection
5 of DNA in a research setting before it was used
6 in a commercial product?

7 A. I do not know.

8 Q. So I want to get in a little more specifics on
9 something you touched on before. The field of
10 use for the ILLUMIGENE products -- and I am
11 using as ILLUMIGENE and ILLUMIPRO. Is that the
12 way you have been using the term?

13 A. Yes.

14 Q. What field of use did the ILLUMIGENE and
15 ILLUMIPRO products operate in?

16 A. They operate in infectious diseases as it
17 relates to gastroenterology, upper respiratory,
18 respiratory. That's what I can think of right
19 now off the top of my head.

20 Q. And earlier you referred to operating in the
21 infectious disease space. I think you mentioned
22 the microbiology space?

1 MR. HANKINSON: Objection to form.

2 Q. How do those relate to each other?

3 A. How does what relate to what?

4 Q. Is microbiology a subset of infectious disease?

5 A. Microbiology, in my opinion, is the subset of
6 molecular diseases. As you define a molecular
7 disease can be anything from having a genetic
8 deficiency, which causes sickle cell anemia, to
9 detecting a target in a stool sample that is a
10 bacteria that shouldn't be there.

11 Q. And can you describe what subset of molecular
12 disease microbiology is, occupies?

13 MR. HANKINSON: Objection to form.

14 A. Subset?

15 Q. Did I understand you to say that microbiology is
16 a subset of molecular disease?

17 A. Well, if you define molecular disease as
18 anything that is aberrant with the genome, that
19 would include human genetic deficiencies where
20 we don't work there, target there. We target
21 specifically on infectious disease analytes such
22 as bacteria and viruses that cause human

1 disease.

2 Q. And when you say infectious disease analytes, is
3 that --

4 A. Targets. It is bacteria or viral targets.

5 Q. Is that -- would you consider that to be a
6 subset of the microbiology space, or is that a
7 subset of microbiology?

8 A. Is that a subset -- that is part of
9 microbiology. Please remember microbiology is a
10 very broad subject because there is infectious
11 diseases, there is microbiology of water
12 purification of which this does not cover.
13 There is fermentation of beer and wine that
14 require microbes that is not covered by my
15 definition.

16 (Kozak Exhibit 1 was marked for
17 identification.)

18 BY MR. HORNE:

19 Q. Turn to your declaration, which I have marked as
20 Exhibit 1. It is right there in front of you.

21 A. I see it, yes.

22 Q. Can you turn to paragraph 6?

1 In there you say "within the
2 broader category of infectious disease,
3 Meridian's clinical diagnostic products are
4 focused in the microbiology space."

5 So are you saying there that
6 microbiology is a subset of infectious
7 disease?

8 A. Within the broader -- what I am saying is within
9 infectious disease, we are focused on
10 microbiology space. I define microbiology space
11 as microbes and viruses that cause human
12 infectious diseases.

13 Q. What other parts or categories would there be an
14 infectious disease?

15 A. What other parts of --

16 Q. Within the broader category of infectious
17 disease, Meridian's microbiology space,
18 what other subsets of disease are you aware
19 of?

20 A. I am having a little trouble understanding that
21 question. I just need to think for a minute and
22 make sure I am answering your question

1 correctly.

2 Q. As I -- go ahead.

3 A. No, please.

4 Q. As I read the sentence -- and maybe I am reading
5 it incorrectly -- you say "within the broader
6 category of infectious disease, Meridian's
7 clinical diagnostic products are focused in the
8 microbiology space."

9 I read that to mean that there
10 could be a lot under infectious disease and
11 microbiology spaces but one specific area within
12 the broader category of infectious disease. So
13 I am wondering what you are distinguishing it,
14 if anything, from.

15 A. Maybe it is like we don't focus on blood borne
16 pathogens, is in the broader space such as HIV
17 or the HCVs. We don't work in that area, for an
18 example.

19 Q. Are there any other areas of infectious disease
20 that you are distinguishing by saying that
21 Meridian is in the microbiology space?

22 A. As I sit here today, I can't recall.

1 Q. In the next sentence, you say "Meridian's
2 'molecular diagnostic' products test for and
3 identify the microbial invader. Meridian's
4 products do not focus on or have any
5 relationship with the genetics of the human
6 patient" and "human" is italicized. The term
7 "molecular diagnostic" is in quotes. Is there a
8 reason you put the term "molecular diagnostic"
9 in quotes?

10 A. No, not specifically. But when I say "molecular
11 diagnostic products," I am referring to the
12 ILLUMIGENE product line, and they do
13 qualitatively detect the microbial invaders that
14 we have targeted. The last half of that is, we
15 do not look at any targets within the human
16 patient itself that have abnormalities along
17 with their human genome.

18 Q. And that was my in next question: You
19 italicized "human." So are you looking at the
20 genetics of anything else?

21 A. No.

22 Q. Why did you italicize "human" there?

1 A. I just think we want to make it very clear we
2 are only testing humans.

3 Our products are cleared to test a
4 very specific set of patients who have very
5 specific requirements as stipulated by the FDA
6 in our intended use. While we are testing
7 samples from a human patient under specifics, we
8 are not testing the human patient itself and
9 their genome.

10 Q. I want to switch gears a little bit and talk
11 about Meridian's customers for the ILLUMIGENE
12 product?

13 A. Yes, okay.

14 Q. And is there -- can you describe the typical
15 customer for the ILLUMIGENE products?

16 A. A typical customer?

17 Q. Uh-huh.

18 A. I believe they are all atypical but Meridian's
19 customers are at multiple levels within the
20 infectious disease lab. So we have a director
21 highly educated, highly conscientious about the
22 data they generate, individual who manages the

1 laboratory.

2 Q. Okay. So I want -- I do want to get into that
3 detail, but before we go there, I am talking a
4 little bit at a higher level --

5 A. Sorry.

6 Q. Don't be sorry. You mentioned reference labs,
7 clinical labs such as at the Children's
8 hospitals. I want to, at that level, understand
9 who the customers are, who the entities are, and
10 then I would like to get into the specifics of
11 those.

12 A. Are you --

13 MR. HANKINSON: Hold on. Is your
14 question complete?

15 MR. HORNE: Yeah.

16 MR. HANKINSON: Objection to form.

17 Counsel has cut off the witness'
18 prior answer and attempting to ask a new
19 question. Now you can answer.

20 A. Can you repeat the question now?

21 Q. Sure. I am going to get into the details of the
22 structure and lab directors and personnel in a

1 little bit. I want to talk first, the bigger
2 picture of the entities for lack of a better
3 word.

4 Earlier you mentioned reference
5 labs and clinical labs. That type of
6 description is what I am looking for now, and
7 then we can get into the specifics of who
8 Meridian deals with at those entities?

9 MR. HANKINSON: Objection to form.
10 Counsel is essentially scripting the
11 type of answer to the question that he
12 wants. I request that you ask a
13 question.

14 Q. What is the question you can answer?

15 MR. HANKINSON: Is this Jeopardy?
16 (Laughter.)

17 A. Would you rephrase it?

18 Q. Can you describe the type of entities to which
19 Meridian sells its ILLUMIGENE products?

20 A. The type of entities we sell our products into
21 are infectious disease testing laboratories
22 found within hospitals, found within reference

1 laboratories such as Quest or Lab Corp. That is
2 the 50,000 foot view.

3 There are a myriad of laboratories
4 found within the hospital setting that we don't
5 target; we just specifically target the
6 infectious disease microbiology area.

7 Q. You said there was a myriad of labs in the
8 hospital you don't target. What labs are you
9 referring to that you don't --

10 A. Hematology, clinical chemistry, X-ray, I mean,
11 there is lab after lab within the hospital
12 setting that all have unique functions to help
13 patient management. We target a specific area
14 with our FDA cleared products.

15 Q. I have heard the term -- and I believe you used
16 it in your declaration of clinical diagnostic
17 lab. What do you mean when you refer to a
18 clinical diagnostic lab?

19 A. In my vernacular, clinical diagnostic lab would
20 be narrowed to the specific
21 microbiology/infectious disease laboratory.
22 Clinical diagnostic laboratories encompass, by

1 definition, every laboratory found within a
2 hospital or a reference lab that can manage
3 patient care. Hematology is a clinical
4 diagnostics laboratory. We do not go there.

5 Q. Do you have an idea for the ILLUMIGENE products
6 of the relative volume of business between
7 reference labs and labs within hospitals?

8 A. Off the top of my head today, I don't know.

9 Q. Is it 50-50 or --

10 A. No. It is not at that level. I want to say
11 maybe 70-30 where the majority is hospital
12 laboratories. There is a process called
13 decentralization, which is happening, so the
14 reference labs are losing ground.

15 Q. What does "decentralization" mean?

16 A. That's where samples would be collected from
17 multiple centers and sent to a single center.
18 So Lab Corp.'s business is we will collect
19 samples from patients throughout an area and
20 have those hospitals send the samples to us, and
21 we will test them per the order.

22 What is happening now is the

1 clinical labs are keeping those samples and
2 looking for technologies to keep their sample
3 population within their setting to manage
4 patient care better.

5 Q. You say the clinical labs are keeping --

6 A. The hospital clinical labs. The hospital
7 infectious disease labs -- and remember this is
8 throughout the whole hospital system and
9 different types of laboratories. The infectious
10 disease, they are trying to maintain a
11 centralization at their hospital to manage
12 patient outcomes faster and better.

13 Q. So is that akin to just bringing the work
14 in-house?

15 A. Exactly. Maybe I should have said that first.

16 Q. Now, I would like to talk a little bit more
17 about the organizational structure within each
18 of these types of entities.

19 A. Uh-huh.

20 Q. I will start with the reference labs. Can you
21 explain or do you know how the reference labs
22 are organized from an organizational structure

1 standpoint?

2 A. I don't know how they are fully organized for
3 every complete detection system that they
4 employ. But we have worked, let's say, with
5 Lab Corp., specifically with Barbara Bode, who
6 is in charge of bringing in diagnostic
7 applications in the infectious disease areas,
8 and we work with her staffs directly.

9 Q. And what is her title?

10 A. I do not recall off the top of my head, but she
11 is a senior -- she is a senior level person at
12 Lab Corp.

13 Q. Do you have any understanding what other
14 responsibilities are?

15 A. She is responsible for saying yea or nay to any
16 diagnostic application brought into the
17 Lab Corp. system in infectious diseases.

18 Q. Is she limited to just with infectious diseases?

19 A. Yes, to my knowledge today. Her job title may
20 have changed, but as I sit here today, my
21 interface with her has been in that arena.

22 Q. Okay. Other than Lab Corp., can you speak

1 generally how reference labs are organized?

2 MR. HANKINSON: Objection to form.

3 A. I cannot specifically talk about how all their
4 interworkings within their systems work.

5 Q. What can you tell me about their organizational
6 structure?

7 A. We work at Lab Corp. with their head of the
8 clinical laboratory, who is interested in a
9 disease product that we manufacture or that we
10 are selling into to get them interested in a
11 product that we manufacture.

12 We work with them on feasibility
13 studies. We work with them on helping validate.
14 If they are successful, they will bring our
15 products on line. They will conduct their own
16 clinical evaluation of our product, and they
17 would have no reluctance to let us know if it is
18 not working appropriately in their setting or if
19 it is working appropriately.

20 Q. And when you say you work with the head of the
21 clinical lab --

22 A. Uh-huh.

1 Q. -- is that the head of -- is that person limited
2 to infectious disease?

3 A. That's in their infectious disease area, and I
4 apologize for using the word "clinical lab"
5 broadly, so I am only focused on infectious
6 disease laboratories that use our FDA cleared
7 products.

8 Q. Okay. Outside of the hospital setting, can you
9 describe, other than Lab Corp., can you describe
10 the type of entity that may have an infectious
11 disease to whom Meridian is selling their
12 products?

13 A. Outside of Lab Corp.?

14 Q. Yes.

15 A. You mean like Quest or Kaiser Permanente, which
16 is similar.

17 Q. Maybe we will walk through your declaration a
18 little bit, but in your declaration, you are
19 referring to clinical diagnostic labs and a
20 reference side and a clinical side and a
21 clinical director. I want to -- and different
22 divisions within the clinical lab. That's kind

1 of what I want to flush out here.

2 A. Okay. So there is the clinical lab using
3 specific FDA cleared tests?

4 Q. Uh-huh.

5 A. There is also these labs within the hospital
6 using non FDA cleared tests.

7 Q. So we are talking about hospitals now?

8 A. Hospitals. It is also true for reference labs
9 as I define Lab Corp. or Quest or Kaiser
10 Permanente.

11 Q. So Lab Corp., Quest, Kaiser, and hospital, this
12 structure would apply to all --

13 A. Uh-huh. They are very, very similar because
14 they are under the same guidelines as a hospital
15 is.

16 Q. Okay.

17 A. They must use FDA cleared products. If they do
18 not use an FDA cleared product, then they must
19 have appropriate validation to use that, to
20 manage any kind of patient.

21 Q. Okay. So if you are comfortable talking about
22 the hospital and reference labs together, then I

1 think it would make it simpler?

2 A. I think it would make it simpler if we said
3 where they get their samples are a little
4 different. Their overall structures are the
5 same, and I think we can probably streamline
6 that a little bit.

7 Q. Streamline is always good as long as we are
8 staying accurate. Okay.

9 A. I will do my best to always stay accurate.

10 Q. With that, can you describe a little bit of the
11 structure of these labs?

12 A. Let's just go to a basic lab. You have a
13 director of sorts.

14 Q. Let's take another step back. I apologize.

15 You mention in your declaration, I
16 thought you said something about a reference
17 side and clinical side. Can you explain that
18 first?

19 MR. HANKINSON: Objection to form.

20 Every time the witness is answering,
21 your question with respect to the
22 structure of the lab with specifics, you

1 cut him off, and you direct him to a
2 more generalized topic. That's my
3 objection, but please go ahead.

4 MR. HORNE: I disagree.

5 BY MR. HORNE:

6 Q. But go ahead.

7 A. We sell into the clinical lab for infectious
8 diseases that is using FDA cleared products. At
9 large institutions or other institutions, some
10 of these laboratories have a research side. It
11 may be found -- usually not found within the lab
12 but found elsewhere within the hospital. We do
13 not sell products into that area.

14 Q. Okay. So from top down, we have got clinical
15 lab side and a research side.

16 A. Yes.

17 Q. And Meridian is completely separate from the
18 research side.

19 A. Meridian -- the group that has infectious
20 diseases does not sell into that arena.

21 Q. And that's the group that includes the
22 ILLUMIGENE products?

1 MR. HANKINSON: Objection.

2 A. I'm sorry. You just lost me. I thought we were
3 talking about the clinical lab using IVD
4 products. That's where we sell our product. We
5 do not sell into the research side with our IVD
6 products.

7 Q. Correct.

8 A. Okay. So we are on the same page.

9 Q. Yes.

10 A. I apologize.

11 Q. Research put aside, now the clinical lab side, I
12 want to make sure I understand the structure
13 there. You said that that Meridian is in the
14 infectious disease part of the clinical lab?

15 A. The clinical labs that run infectious diseases,
16 they use IVD FDA cleared products is where we
17 sell our products into.

18 Q. And I understand that that's the part of the lab
19 that, the clinical lab that Meridian is in. I
20 want to make sure I understand kind of the
21 overall structure of that clinical lab. So we
22 put reference labs aside.

1 Now, in the clinical lab, can we
2 start at the top and then kind of work down to
3 where the clinical lab that runs infectious
4 diseases is for lack of a better word --

5 MR. HANKINSON: Objection to form.
6 Mischaracterizes the prior line of
7 questioning.

8 A. I am a little bit lost what you mean now by the
9 clinical lab. Are we talking about clinical
10 labs within the hospital or the clinical lab
11 just focused on infectious diseases?

12 Q. That's what I am trying to find out. Your
13 declaration mentioned some -- I think in
14 paragraph 7 of your declaration you say "several
15 specializations within a clinical diagnostics
16 lab.

17 A. The clinical diagnostic group within a hospital
18 is composed of multiple entities to manage
19 patients, everything from microbiology,
20 chemistry, hematology, lipid tests, all those
21 kind of tests are managed within the hospital
22 setting.

1 We do not sell into the clinical
2 chemistries. We do not sell into the
3 hematologies. We do not sell into any research
4 lab found within those entities, within that
5 major hospital. We sell into the clinical
6 diagnostic lab focused on infectious disease
7 microbiology.

8 Q. So do all of these labs runs as completely
9 separate entities?

10 A. I can't tell you how they run. I can tell you
11 how the infectious disease lab runs because
12 doctors will order tests on a patient. Samples
13 are collected for that specific order. Samples
14 then go through the system, through the
15 appropriate areas for the appropriate testing.

16 If they collect a stool sample for
17 C. diff, it will end up in the microbiology area
18 to be tested for C. diff. If I am getting a
19 bilirubin done, it is going to go to clinical
20 chemistry for kidney failure.

21 Q. Okay. And the same holds true for reference lab
22 like Quest or Lab Corp.?

1 A. Reference labs have a very similar setup.
2 They test multiple things in multiple different
3 labs.

4 Q. Okay. So for the microbiology or infectious
5 disease lab in a hospital, can we go top down,
6 talking about the organizational structure
7 there?

8 A. Okay.

9 Q. Okay.

10 A. That's a question?

11 Q. Yeah, yeah. Would you please describe the
12 organizational structure of a clinical lab from
13 top down?

14 A. Clinical lab is usually headed by --

15 MR. HANKINSON: Objection to form.

16 Q. -- infectious disease clinical lab.

17 A. It is headed by usually a director, highly
18 educated individual. In fact, when I say that,
19 every person within a clinical lab setting is
20 highly educated. We will have an individual who
21 is making sure, making a lot of the decisions
22 relative to what products are being brought in,

1 what technologies are being brought in to best
2 manage their patient population.

3 Q. And that's the director?

4 A. Usually, the director. Below that individual is
5 usually a manager type, and I don't want to get
6 hung up on all the different titles because
7 every organization has their own titles.

8 Q. Uh-huh.

9 A. But they have a manager, a lab manager, who is
10 usually managing all the day-to-day activities
11 of all the research staff -- hang on, I don't
12 want to use the word "research" -- of all the
13 clinical staff who are performing daily tasks,
14 and they make sure the workloads are right, they
15 have the proper inventory, the patients are
16 being managed appropriately.

17 Usually, depending on the
18 laboratory, at least once a week, if not daily,
19 there is a meeting between all staff members. I
20 have been at these meetings where they talk
21 about patient management, who is doing what,
22 what patient has what, what are they being

1 diagnosed for?

2 Doc wanted MRSA. Was MRSA negative
3 but something else? How do we manage that
4 patient? What tools do we have?

5 Then, obviously, you have the
6 laboratory technicians who perform specific
7 tasks and specific assays within that overall
8 lab. And those people usually have a med tech
9 degree or higher. So moving down, it is M.D.,
10 Ph.D., and then somebody with some kind of
11 senior level --

12 Q. When you say moving down --

13 A. From that director side, moving down to the lab
14 techs that usually have a microbiology degree or
15 lab tech degree, and they are specifically
16 trained to work on the assays that they are
17 responsible for.

18 Q. So you go from director down to lab manager down
19 to technicians?

20 A. Yes.

21 Q. Generally speaking?

22 A. Generally speaking, that's the structure.

1 Q. And that's the same at a reference lab?

2 A. Reference labs are very similar.

3 MR. HANKINSON: Objection to form.

4 A. Reference labs within infectious disease area
5 are very similar.

6 Q. To a hospital?

7 A. To a hospital setting.

8 Q. Do you know who the director reports to?

9 MR. HANKINSON: Objection to form.

10 Vague.

11 A. I don't know.

12 Q. And do you know how, if at all, the infectious
13 disease clinical lab would interact with the
14 chemistry or the hematology or any of the other
15 clinical labs within a hospital?

16 A. No. I only know the infectious disease lab. I
17 don't know how they are all intertwined.

18 Q. Do you know to what extent they are or are not
19 siloed from each other?

20 A. I know by function they are siloed, but data
21 management, I don't know.

22 Q. What do you mean by "function they are siloed"?

1 A. Because you have a specific lab doing a specific
2 function. So the clinical diagnostic infectious
3 disease lab is doing that. They are siloed.
4 How the data reports off on the patient and the
5 whole LIS system or how it's managed in the
6 hospital, I do not know.

7 Q. Do you know where they are physically with
8 respect to -- "they," I shouldn't use so many
9 pronouns -- do you know where physically the
10 infectious disease lab personnel operate
11 relative to, let's say, the other clinical labs
12 within a hospital or Lab Corp.?

13 MR. HANKINSON: Objection to form.

14 A. No. Every hospital is different. Every
15 hospital is multiple floors. Every hospital
16 is has multiple areas. I know how to get from
17 the elevator up to the infectious disease lab
18 at Children's Hospital. Outside of that, I
19 don't know, and secondly, we are usually
20 escorted.

21 Q. Do you know whether all reference labs are --
22 strike that.

1 Do you know whether all reference
2 labs have separate infectious disease divisions
3 as compared to a chemistry or hematology
4 division?

5 A. I know the ones that I have worked with, they
6 have been separate.

7 Q. So I would like to talk a little bit about the
8 manner in which the ILLUMIGENE products are
9 purchased by a customer. Can you explain
10 that?

11 MR. HANKINSON: Objection to form.
12 Vague.

13 A. Okay. From my personal knowledge, interfacing
14 with some labs that I have worked with, we
15 initially target the clinical lab that does the
16 infectious disease testing with our product. We
17 have to ensure that our product meets their
18 needs relative to sample type, sensitivity,
19 specificity, work flow, timing, cost, things
20 like that.

21 So we will talk through that
22 process with them because we go into some

1 places, and they are using an ESOP system. We
2 are not cleared for an ESOP system. We can't
3 sell it to them, we can't sell it. It is not a
4 suitable sample type.

5 Assuming that we have met those
6 requirements and that they have -- usually, they
7 will do some type of testing on their own to
8 assure that it does meet their work flows, and
9 is it appropriate or a better replacement for
10 their standard of care; then they usually make
11 the recommendation to the purchasing people to
12 say we want to buy this.

13 In addition, our sales force goes
14 into -- at that point goes into the purchasing
15 department and the purchasing agents and
16 discusses the cost savings of using our product
17 with them. So there is two pieces to the
18 equation.

19 It is how much? Is it cost
20 effective? And how does it relate to patient
21 management? So both of those sales processes go
22 on together now. We are fortunate with our

1 ILLUMIGENE product that we do not have capital
2 expenditures. Our readers are free. Our little
3 instrumentation is free, which makes our process
4 a little bit simpler than a lot of people who
5 are selling extremely expensive pieces of
6 equipment. So that's how that goes?

7 And then, there is a specific
8 process within Meridian of which the sales reps
9 must have all purchase prices or sales per test
10 approved by Meridian corporate.

11 Q. Supposed to have what approved?

12 A. The cost per test. So the sales rep obviously
13 wants to make a sale. Obviously, the
14 institution itself wants to have the most
15 inexpensive cost possible, and then, usually
16 internally within Meridian, we will approve or
17 make recommendations relative to that costing
18 process and how much we are willing to let a
19 customer buy our product for on a per test
20 basis.

21 And it has to do everything with
22 sample throughput, how many kits are they going

1 to buy a year? Are they going to buy other
2 products, things like that.

3 Q. You mentioned the purchasing department.

4 A. At an institution, uh-huh.

5 Q. Yeah. Are there separate purchasing
6 departments?

7 A. For what?

8 Q. Well, you mentioned there is a clinical --
9 infectious disease clinical diagnostics lab, and
10 there may be other diagnostics labs at a
11 hospital.

12 A. I can't answer if there is a multiple purchasing
13 department for a hospital. I do know that we
14 have worked with individuals within the
15 purchasing department responsible for that
16 department. If they have 12 purchasing
17 departments, I can't answer that. To my
18 knowledge, we only work -- we usually work with
19 certain entities.

20 Q. What do you mean by entities?

21 A. A certain group within the hospital who then
22 says we want to have Meridian -- we want to buy

1 the product from Meridian at this price, and
2 then a contract is generated.

3 Q. Do you know where the purchasing people that
4 Meridian deals with deal with the purchasing of
5 products other than infectious disease?

6 A. I can't answer that. I am only focused on the
7 Meridian products and what they are purchasing.

8 Q. Meridian wants to sell its products, let's say
9 the ILLUMIGENE products to a new entity that is
10 not currently buying Meridian products, what
11 would be the first point of contact for Meridian
12 of that entity?

13 A. We would go -- our sales rep would go to the
14 director level individual, talking about, let's
15 say, a new product we have.

16 Q. Okay. When you say the director level
17 individual, what do you mean by the director
18 level?

19 A. As I mentioned earlier, the head of the lab, the
20 head of the laboratory.

21 Q. When you say head of the lab, you mean of all
22 clinical diagnostics?

1 A. No. When I say head of the lab, I am only
2 referring to clinical diagnostic lab, infectious
3 disease area. I apologize for my lack of
4 clarity. So our point of contact is usually
5 always that individual who is managing that
6 group of individuals.

7 Q. Do you know whether the first point of contact
8 the individual managing in the infectious
9 disease lab, does that person have
10 responsibilities for other diagnostic labs
11 within the hospital, within Lab Corp.?

12 MR. HANKINSON: Objection. Vague.

13 A. I can't answer that question. All I know is the
14 individual that we are contacting is the
15 responsible individual who can buy our product
16 or make recommendations to purchasing our
17 product.

18 Q. And you don't know whether that person is
19 responsible for purchasing other types of
20 diagnostic products besides the infectious
21 disease products that Meridian sells?

22 MR. HANKINSON: Objection. Vague

1 as to that person.

2 (Record read.)

3 A. As I said, I really can't answer that question.
4 I don't have any knowledge of them buying other
5 things. I do know they have knowledge. I do
6 know personally they have knowledge. I have
7 knowledge that they have purchased a Meridian
8 product or a competitor product. They will tell
9 me that point blank, but whether or not they are
10 buying something for hematology, in my personal
11 opinion, I never ever heard a diagnostic
12 director in that area saying "oh, I buy
13 hematology products." That has never come up in
14 a conversation I have had with them.

15 But do they do it? I don't have
16 knowledge of that.

17 MR. HORNE: Why don't we take a
18 quick break.

19 (Discussion held off the record.)

20 (Recess had.)

21 BY MR. HORNE:

22 Q. Could you turn to paragraph 12 of your

1 or department use an RUO product for a lab
2 developed product?

3 A. An RUO product for a lab developed test?

4 Q. Uh-huh.

5 A. By definition, "RUO" means "research use only."
6 With that said, it is only for research
7 purposes.

8 Q. Okay. Can a lab, can the diagnostics lab use a
9 product that is designated research use only in
10 a lab developed test that that clinical lab
11 develops?

12 MR. HANKINSON: Objection. Vague
13 and ambiguous as to clinical lab.

14 A. I am more concerned about RUO. How are you
15 defining RUO product? Are you talking about an
16 enzyme within a product they manufacture? What
17 are you -- I need --

18 Q. Okay.

19 A. I just need some specifics to help me answer.

20 Q. How about a product not cleared by the FDA?

21 A. A product that is not cleared by the FDA?

22 Q. Let me take another step.

1 Are you familiar with the term "lab
2 developed test"?

3 A. Yes.

4 Q. Or LDT?

5 A. Uh-huh.

6 Q. What does that mean to you?

7 A. Laboratory developed test of which it must meet
8 specific requirements before it is able to be
9 used for patient diagnoses. It must be
10 validated by the lab and properly controlled by
11 the lab under FDA guidance and guidelines.

12 Q. What do you mean by FDA guidance and guidelines?

13 A. FDA has guidelines relative to the management,
14 development, and use of LDTs in patient
15 diagnosis. Laboratories must conform to those
16 guidelines.

17 Q. So do LDTs have to use FDA cleared products?

18 A. Laboratory developed test is a test.

19 Q. Uh-huh.

20 A. It is not a -- let me go back. Repeat that
21 question, please.

22 MR. HANKINSON: No, no. You should

1 ask him whether he wants to reread it,
2 rephrase it.

3 MR. HORNE: If he wants it read
4 back, if you want a question read back
5 ever, feel free to ask the court
6 reporter.

7 A. Could you read back the question?

8 (Question read.)

9 A. See, I don't know what that means because an LDT
10 is a test unto itself. An FDA cleared product
11 is a test unto itself. So an LDT and an FDA
12 cleared product are two different entities. An
13 LDT, if it is manufactured and used in a
14 specific lab, and it can only be used for
15 that lab. It has to meet certain FDA
16 requirements before the lab can report patient
17 data on it.

18 If not, it is an RUO, and it is not
19 used for patient management whatsoever. The FDA
20 has very strict requirements about labeling of
21 products on their intended uses.

22 Q. Does the equipment used in LDT have to be FDA

1 cleared in order to use in an LDT?

2 A. The equipment used in the LDT has to conform to
3 FDA guidelines relative to calibration
4 reproducibility. There are a lot of strict
5 requirements on how that instrument is used. An
6 instrument is usually cleared specifically with
7 an IVD product for clearance and is only
8 intended to be used for that clearance.

9 So if you have an IVD instrument
10 cleared and I can use one of yours, for example,
11 if you are using the product instrument for
12 Factor V, it is only cleared for that.

13 Q. Right.

14 A. It is not cleared for other stuff.

15 Q. Okay.

16 A. So to use that in the lab for something else, it
17 has to be validated by that lab for that
18 specific use.

19 Q. So an infectious disease clinical diagnostics
20 lab could use an instrument that is not FDA
21 cleared as long as that instrument is used in a
22 validated LDT, couldn't it?

1 MR. HANKINSON: Objection.

2 Mischaracterizes the prior testimony.

3 A. Repeat the question please.

4 (Question read.)

5 A. First of all, this is getting very complicated
6 because normally those labs are on the research
7 side. But assay, if it is validated by the lab
8 and the equipment used by that lab is also
9 validated for that intended use only, there is
10 the potential that it could be, but in the area
11 that we sell into, they are running IVDs, which
12 are already cleared.

13 The LDT products are usually
14 managed by a separate person in a separate
15 setting because they are exactly that, they are
16 RUO LDT.

17 Q. Who is a separate person, separate setting?

18 What is a separate setting?

19 A. Usually, it is a separate lab. Usually, it is
20 under a separate manager/director.

21 Q. So are you saying that infectious disease
22 clinical labs never run LDTs?

1 A. That is not what I am saying; what I am saying,
2 the infectious labs responsible for running FDA
3 cleared run those. Usually, there is a separate
4 lab entity that runs LDTs or RUOs separately.

5 Q. What is that separate entity?

6 A. It is usually the research portion, there is
7 usually a research lab that does that, usually
8 managed by a separate research director.

9 Q. So do infectious disease clinical labs ever run
10 LDTs?

11 A. To me, that question is very vague.

12 Q. What's vague about the question?

13 A. Because you are saying, does any clinical lab
14 that does infectious disease run LDTs? To me,
15 those are two separate labs that I have seen in
16 my interaction with the labs.

17 Is there a research group running
18 LDTs reporting out data? Yes.

19 Is there a group running IVDs
20 cleared by the FDA? Yes. You keep wanting to
21 bundle them together.

22 Q. I just want to know if they ever are bundle

1 bundled together, and I want to know if your
2 testimony is whether they are always completely
3 separate. I just want to know.

4 A. They are not always completely separate. For
5 most of my interactions, I have seen them as
6 separate.

7 Q. Are they ever together?

8 MR. HANKINSON: Objection. Asked
9 and answered.

10 A. I thought I just said -- I said most. So in my
11 interactions, I may have only seen one that had
12 been incorporated or two. Does that answer your
13 question?

14 Q. If you go to paragraph 13, the first two
15 sentences, the first sentence says "the clinical
16 director is typically one of two director-type
17 positions within the larger laboratory setting
18 of a hospital or reference lab environment. The
19 other director at this level is the research
20 director."

21 In the first sentence, who are you
22 referring to when you say "the clinical

1 director"?

2 A. We already discussed thoroughly the clinical
3 director running the IVDs. This is an
4 individual usually who is running the research
5 lab portion. It is usually separate, and those
6 are the ones that are, let's say, responsible
7 for developing an LDT.

8 Q. We may have spoken past each other.

9 The first two sentences of
10 paragraph 13 refer to a clinical director being
11 one of two.

12 A. They will have usually a title of clinical
13 director, but it is for research versus clinical
14 director IVD or patient management.

15 Q. Okay. Then, who is the other director that is
16 called the research director?

17 A. That's what I meant. That is the research
18 director. So there is a clinical research
19 director/clinical director. I apologize if my
20 language is misleading.

21 Q. Okay. And I apologize if --

22 A. There are two types: There is the clinical

1 director; research director.

2 Q. Okay.

3 A. I apologize.

4 Q. Right. So paragraph 13, you refer to a clinical
5 director as one of two director types. The
6 other is the research director.

7 A. Uh-huh.

8 Q. Who are you referring to when you refer to the
9 clinical director in the first sentence?

10 A. That's what I meant, the clinical director.
11 There is two. There is the clinical director,
12 the research director in the clinical setting,
13 but usually in a reference -- in a research lab.
14 I apologize if that language is misleading.

15 There is one -- and I thought it
16 was very clear. The other director is, so there
17 is two director types: One is the clinical
18 director, and the other the research director.

19 Q. Okay. The clinical director you are referring
20 to in paragraph 13, what does that person do?

21 A. The clinical director is the one that we have
22 been talking about for the last few hours, who

1 is running the IVD lab. The research director
2 is over here running the research who is
3 responsible for running research on products,
4 usually in a separate entity, running RUOs and
5 things like that.

6 Q. Now, I thought I understood from you that there
7 are a number of clinical diagnostic labs at a
8 hospital or reference lab?

9 A. Correct.

10 Q. So why would you say here there is two
11 director-type positions within the --

12 A. Again, I am focused on the infectious disease
13 area when I talk about this clinical director.
14 There are tons of different directors within the
15 hospital. Here I am focusing on specifically
16 the individuals responsible and the clinical
17 director when I talk about that is the director
18 who is responsible for the infectious disease
19 management using IVDs, and there is a research
20 director.

21 Q. Is there a research director that is responsible
22 only for infectious disease?

1 A. There usually is, yes.

2 Q. Okay.

3 A. Yes. Those are usually two separate distinct
4 people. That goes back to your question
5 earlier, have I seen it combined? Every once in
6 a while; pretty rare.

7 Q. So a larger hospital, if I am understanding
8 correctly, a large reference lab would have
9 multiple clinical directors and multiple
10 research directors?

11 A. I can't answer for any other department except
12 infectious diseases. There may be hundreds of
13 research directors within a hospital. I don't
14 know. I am only focusing on and apologize for
15 that area we that sell into.

16 Q. So you are saying infectious disease has two
17 sides, a clinical side and research side?

18 A. Right. And usually, they are totally separate.
19 There are hundreds of research areas within a
20 University Hospitals, hundreds.

21 Q. So if you go to paragraph 7 in your declaration
22 and you talk about -- you say "there are

1 typically several specializations within a
2 clinical diagnostic laboratory, for example,
3 microbiology, chemistry, hematology, special
4 chemistry, and others"?

5 A. Uh-huh.

6 Q. When you use "clinical diagnostic laboratory" in
7 that sentence, what are you referring?

8 A. In that area, I am referring to divisions that
9 help patient management, specifically
10 microbiology, chemistry, hematology. I don't
11 know how I am not being clear.

12 Q. How are you using the term clinical diagnostic
13 laboratory in that sentence?

14 A. Any laboratory in this case that is generating
15 clinical data relative to patient management
16 would be what I consider a clinical diagnostic
17 laboratory, chemistry, hematology. All those
18 are FDA cleared products.

19 Q. So when you use the term "clinical diagnostic
20 laboratory" in paragraph 7, you are not
21 specifically referring to an infectious disease
22 clinical diagnostic laboratory?

1 A. I am absolutely including that.

2 Q. No. Specifically referring to that.

3 A. No. I believe -- no.

4 Q. Okay. So when you use the term "clinical
5 diagnostic laboratory" in paragraph 7 you are
6 not referring only to infectious disease?

7 A. No, because I mention after that chemistry,
8 hematology, that's not an infectious disease by
9 definition.

10 Q. So maybe when we go through this, sometimes you
11 refer to clinical diagnostic lab, and I get a
12 little confused, whether you are referring to an
13 infectious disease clinical diagnostic lab or
14 the regular clinical diagnostic lab, and that's
15 what I want to understand, the organizational
16 structure.

17 So looking at paragraph 7, you have
18 got chemistry, hematology, special chemistry,
19 would each of those divisions have a separate
20 clinical director and research director?

21 A. I can't answer that. I can answer for
22 infectious disease microbiology area. Meridian

1 doesn't go into hematology. I can't answer how
2 they are structured there. I can focus on what
3 I know.

4 Q. At the bottom of the last sentence --

5 A. Which paragraph?

6 Q. Paragraph 13, which happens to be here at the
7 bottom, you say "Meridian's marketing and sales
8 focus is only to one of those two distinct
9 touch-points - the clinical diagnostic lab"?

10 A. Correct.

11 Q. I assume there you mean the infectious disease
12 clinical diagnostic lab?

13 A. Right, correct.

14 Q. How do you know whether Meridian is able to
15 channel its advertising and marketing only
16 to the infectious disease clinical diagnostic
17 lab?

18 A. How do I know? First of all, we target when we
19 meet with customers in those areas. We actually
20 give them our specific literature. So we are
21 meeting with specific touch points of people
22 within that institution.

1 And then, obviously, if we are
2 advertising or at a trade show or something like
3 that where we have a big booth with a lot of
4 stuff, anybody can read what we have; just as I
5 can walk past the Illumina booth and read what
6 they have?

7 But when we meet with those
8 individuals, we bring out specifics with the
9 product that relate to those. We don't go into
10 the hematology lab and drop off our literature.
11 That's not how we operate.

12 MR. HANKINSON: Good time for
13 lunch?

14 MR. HORNE: Sure.

15 MR. HANKINSON: I didn't mean to
16 interrupt.

17 (Luncheon recess taken.)

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AFTERNOON SESSION

8

MR. HORNE: Back on the record.

9

BY MR. HURST:

10

Q. Earlier today we were talking about Lab Corp.,

11

and you mentioned somebody there named Barbara?

12

A. Barbara Bode, B-o-d-e.

13

Q. And Meridian interacts with Barbara Bode?

14

A. Uh-huh.

15

Q. And she has responsibility for infectious

16

disease clinical diagnostic side of it?

17

A. Uh-huh.

18

Q. Do you know if Barbara Bode has any

19

responsibilities for the research operations at

20

Lab Corp.?

21

A. I don't --

22

MR. HANKINSON: Objection. Asked

1 and answered.

2 A. I don't know.

3 Q. Why don't you know?

4 A. Because I only deal with Barbara on the areas
5 which we focus, which is selling our products to
6 her.

7 Q. Paragraph 15 of your declaration, the first
8 sentence, do you see "the relevant consumers in
9 the clinical diagnostic laboratories of hospital
10 labs and reference labs have been familiar with
11 Meridian's infectious disease clinical
12 diagnostic products for more than 25 years and
13 certainly well prior to 2008."

14 Who are you referring to when you
15 say the "relevant consumers"? Actually, stop.

16 Who are you referring to when you
17 say "the relevant consumers in the clinical
18 diagnostic laboratories"?

19 A. Again, we are back to individuals who buy our
20 IVD products in the infectious disease areas in
21 that specific lab.

22 Q. And who are those individuals by title?

1 A. Again, they would be what I mentioned early.
2 They would be directors, managers, those type of
3 titles who are responsible for making the
4 decisions of purchasing our IVD products in the
5 infectious disease labs.

6 Q. So how do you know that those relevant consumers
7 have been familiar with Meridian's infectious
8 disease products for 25 years?

9 A. Because Meridian has been in business for a lot
10 longer than that. We had been focusing on that
11 area specifically, and our name is well known
12 and well respected in the industry for
13 infectious disease diagnoses in our target
14 markets.

15 Q. So for lack of a better word, you are drawing a
16 conclusion that all of these relevant customers
17 or consumers are familiar with Meridian's --

18 A. I am not drawing --

19 MR. HANKINSON: Objection. Form.

20 A. I am not drawing -- excuse me. You said I am
21 drawing what?

22 Q. A conclusion?

1 A. I am drawing a conclusion based on my
2 interactions with individuals over the course of
3 that history when I walk into the lab saying "I
4 am with Meridian Bioscience," and they say "oh,
5 yes, I know you. Oh, yes, I have worked with
6 some of your products. Oh, Ken, did you develop
7 this product?" So I have personal knowledge of
8 that.

9 Q. Go ahead to the end of paragraph 15, last few
10 sentences, "given Meridian's marketing and sales
11 strategy and strict separation of the clinical
12 and research disciplines within a given hospital
13 lab or reference lab, the relevant consumers on
14 the research side of labs, i.e., the consumers
15 of Illumina's products probably very little, if
16 any, familiarity with Meridian."

17 And again, how do you know whether
18 these people on the research side have any
19 familiarity with Meridian?

20 A. Because we don't target them specifically. We
21 target the customers who are specifically
22 responsible for buying our IVD products. We

1 don't go into the research lab areas and sell
2 stuff.

3 Q. And you say the relevant consumers on the
4 research, i.e., the consumers of the Illumina's
5 products, are you saying -- are you testifying
6 that Illumina's customers or consumers are only
7 people on the research side of the labs?

8 A. If you are using the word "only," I have to
9 interpret that based on what I have seen from
10 Illumina's websites. Illumina had two FDA
11 cleared products of which, at least one I know,
12 is not on the market any more, but Illumina's
13 business model, in essence, has been selling RUO
14 products into the research labs.

15 Q. I want to focus on the second part of that
16 sentence. How do you know that Illumina's focus
17 has been selling those products into the
18 research side of labs?

19 A. Basically, from just looking at what I see from
20 websites, from their booths, the type of
21 equipment they use, not having IVD products to
22 any great extent.

1 Q. And then, you say "Meridian's relevant consumers
2 on the clinical diagnostic side of such labs
3 probably have a little, if any, familiarity with
4 Illumina," and you say "probably." Why do you
5 use the word "probably"?

6 A. Once again, if we are talking specifically --
7 talking specifically to the infectious disease
8 diagnostic lab, Illumina, even with their FDA
9 cleared products would not place that product in
10 that setting. It doesn't belong there.

11 However, the only reason why I use
12 the word "probably" is, they go to a booth, and
13 they walk around at a meeting. They may see the
14 word "Illumina." They may see a big booth with
15 "Illumina." They have been at a lot of trade
16 shows.

17 Q. When you say "they," you mean the infectious
18 disease --

19 A. The consumers, yeah, the infectious disease
20 consumers. Do they have any reason to buy from
21 them? Probably not.

22 Q. I will go back and maybe ask you a similar

1 question.

2 You say the consumers on the
3 research side of labs probably have very little
4 familiarity with Meridian. Again, why do you
5 use the word "probably" there?

6 A. Once again, the researchers go to the same type
7 of meetings for other purposes. They may have
8 come up to a Meridian booth where we have given
9 away a free pen. So they may see what we are
10 doing. They may have a curiosity about the LAMP
11 technology, but they would never purchase a
12 product from us.

13 Q. It is possible that the consumers on the
14 research side would come across Meridian's
15 marketing materials, either through meetings or
16 journals or ads?

17 MR. HANKINSON: Objection to form.

18 A. Well, obviously, if there is a marketing piece
19 placed in a journal, anybody can read a journal.

20 Q. Can you define Meridian's competitors for its
21 ILLUMIGENE and ILLUMIPRO products?

22 A. I need you to help me define the word "define."

1 Q. Okay. I don't mean list number of specific
2 entities. Can you describe who you would
3 consider, who Meridian would consider to be a
4 competitor for its ILLUMIGENE products?

5 MR. HANKINSON: Objection to form.

6 A. Okay. Once again, for clarity, are you asking
7 me what those general characteristics are?

8 Q. Yes.

9 A. Okay. In my opinion, it is a company focused on
10 infectious disease diagnostics who are currently
11 operating in that arena, who have technologies,
12 either molecular or immunological based or cell
13 culture based, that could -- could detect the
14 same targets that we are looking for.

15 Q. What about a lab that offers an LDT to test for
16 any disease for which an ILLUMIGENE product can
17 test?

18 A. Is that a competitor?

19 Q. Yes. Would Meridian consider that a competitor?

20 A. No. I believe we consider that an opportunity.

21 Q. Why wouldn't you consider it to be a competitor?

22 A. Because most labs who have LDTs if a product

1 comes on the market that is FDA cleared that can
2 do the same thing that their LDT is, they will
3 switch to it because of all the Government
4 regulations, because of all the difficulties
5 they have to manage to get that LDT developed
6 and put on line. When you buy the Meridian
7 product, you buy the QSR; you buy all that as
8 well.

9 Q. Uh-huh. So going back to your definition of a
10 competitor for Meridian's ILLUMIGENE products,
11 if there was a company operating outside of that
12 space and that company named its product
13 ILLUMIGENE, do you think Meridian would have an
14 objection to that?

15 MR. HANKINSON: Objection to form.

16 A. If it is outside what our trademark is, I can't
17 answer that, but if it is within our trademark
18 definition, by all means because it is our exact
19 name.

20 Q. How about within your definition used to have a
21 competitor?

22 MR. HANKINSON: Objection to form.

1 Uses definition in a different way.

2 A. Please repeat the question. I'm sorry. Don't
3 repeat the question. I don't understand it.

4 Q. I asked you how you would characterize a
5 competitor to Meridian --

6 A. Uh-huh.

7 Q. -- for the ILLUMIGENE products. I want to ask
8 you if there was a company operating outside of
9 that space, outside of your description of what
10 a competitor to the ILLUMIGENE products are but
11 called its product ILLUMIGENE --

12 MR. HANKINSON: Is the question
13 complete?

14 MR. HORNE: No. Let me ask you
15 again.

16 BY MR. HORNE:

17 Q. Sorry.

18 A. You are -- go ahead.

19 Q. Go ahead.

20 A. No. I want you to finish the question,
21 please.

22 Q. Okay. So I asked you to describe how you would

1 -- I asked you to describe a competitor for
2 Meridian's ILLUMIGENE products.

3 A. Uh-huh.

4 Q. And you gave that description. If there was a
5 company offering a product that did not fit that
6 description and that product was called
7 ILLUMIGENE, do you believe Meridian would take
8 issue with that?

9 MR. HANKINSON: Objection. Calls
10 for a legal conclusion. Is an
11 incomplete hypothetical.

12 A. That's where I was going. If we saw that and it
13 was the exact the same name, I am not a lawyer,
14 I would call our attorneys and ask them that
15 specific question.

16 Q. Okay. Can you identify the competitors --
17 actually, I am talking about specific
18 competitors now. Can you identify competitors
19 for your ILLUMIGENE products?

20 A. I can identify many of them. I probably can't
21 identify all of them as we sit here today.

22 Q. Okay?

1 A. We have Alere.

2 Q. Can you spell that?

3 A. A-l-e-r-e. They have manufactured common
4 antigen tests, C. difficle toxin tests,
5 immunological based, Bartels as a cytotoxin
6 assay for C. difficle toxin. Then we have
7 companies like Cepheid, BD -- off the top of my
8 head, I am drawing a blank now -- I drew a
9 blank.

10 Q. Okay. Do you know how the competitors -- let me
11 go through them one by one -- how the
12 competitors' pricing compares to the
13 ILLUMIGENE-ILLUMIPRO products?

14 A. We generate market research to look at how
15 pricing costs are. Some of that we get from our
16 sales force. Some customers will tell us point
17 blank what they are buying their Cepheid product
18 for and what they will purchase from us.
19 Research is done that way. I don't know all the
20 pricing on all the points. I don't focus on
21 that.

22 Q. Okay. Then, do you know what Cepheid sells its

1 products for?

2 A. No, I don't, off the top of my head.

3 Q. How about the Alere?

4 A. The Alere product is approximately \$ something a
5 test.

6 Q. \$14?

7 A. Uh-huh.

8 Q. And is that -- does Alere use a reader similar
9 to an ILLUMIPRO?

10 A. No. It is not even a molecular test. They are
11 old style immunoassays.

12 Q. What about Bartels?

13 A. Bartels is a cytotoxin test, which I believe is
14 somewhere in the neighborhood between \$4 and \$7
15 a test.

16 Q. Is there any reader required for the Bartels?

17 A. You need a microscope. So you can see when we
18 look at a competitor landscape, it is just not
19 molecular to molecular. It is how do you
20 diagnose that disease and how does our product
21 fit in? We have multiple products that detect
22 C. difficile at Meridian. ILLUMIGENE is one of

1 them.

2 Q. How many other products does Meridian have that
3 detect C. difficile?

4 A. At least four.

5 Q. Could you name them?

6 A. Premier Toxins A and B, ImmunoCard, Toxin A and
7 B, ImmunoCard, common antigen, ILLUMIGENE and
8 Premier common antigen.

9 Q. And are all of Meridian C. difficile products
10 sold to infectious disease clinical labs?

11 A. That buy IVDs, yes, they are all FDA cleared.

12 Q. And are the consumers for all of Meridian's
13 infectious C. difficile products the same?

14 MR. HANKINSON: Objection to form.

15 A. If you define "consumer" as an individual lab
16 looking to diagnose C. diff with an FDA cleared
17 assay, yes.

18 Q. Why have the multiple products for C. diff, I
19 guess, is my next question?

20 A. Because multiple price points, multiple people
21 like different kinds of technologies. People
22 may want to run a more inexpensive test first to

1 screen positives or negatives and then reflux to
2 a more expensive test. There is a lot of
3 strategies to diagnose various diseases.

4 So we offer a multitude of these
5 tests. Historically, we have offered C. diff
6 from 1982, and the latest in the line is the
7 ILLUMIGENE product. So multiple customers like
8 it, multiple formats, and we will develop
9 assays to detect the same disease to offer them
10 flexibility.

11 Q. Go to paragraph 16 of your declaration. Second
12 sentence you say "because of the line of
13 business Illumina is in, Illumina's consumers,
14 where they otherwise overlap in the larger
15 hospital lab and reference lab, channel of
16 trade, are those on the research side of such
17 labs. Outside of this channel, Illumina also
18 markets to and serves dedicated research
19 institutions where human genomes are sequenced
20 on massive scale for, among other things, drug
21 development purposes."

22 My question is: Are you testifying

1 that the consumers described in these two
2 sentences I just read represent all of
3 Illumina's customers?

4 A. Once again, you are trying to, I believe, pin me
5 down to the word "all." And I can't address
6 every customer Illumina has ever sold a product
7 to. These are some of the areas I know Illumina
8 has a great deal of focus in. But is that every
9 customer they have ever had on the planet earth?
10 I don't know.

11 Q. Besides infectious disease clinical labs, do you
12 know whether Illumina's consumers, Illumina has
13 consumers in other types of clinical labs
14 besides the infectious disease clinical
15 diagnostic lab?

16 A. I didn't know Illumina had products in the
17 infectious disease area. They only had two FDA
18 clear products, and those were for --

19 Q. Sorry. Go ahead.

20 A. Cystic fibrosis and clotting factors, which are
21 not in the infectious disease area. So did I
22 miss something?

1 Q. I think there was a miscommunication. That's
2 when I said "beside." Set aside the "infectious
3 disease" for a second?

4 A. I see. Okay.

5 Q. Do you know whether Illumina has customers in
6 other types of clinical diagnostic labs?

7 A. Then I will ask you to define "clinical
8 diagnostic labs." Are you talking like
9 hematology?

10 Q. Any other type of clinical diagnostic lab
11 besides the infectious disease clinical
12 diagnostic lab?

13 MR. HANKINSON: Objection. Vague
14 as to time.

15 A. Can you rephrase the question, please?

16 Q. Can you give me --

17 A. I just got lost. I'm sorry. I got lost in your
18 whole line of questioning, and I apologize for
19 that.

20 Q. Well, let's set aside -- well, let me make sure
21 we are on the same page.

22 We talked about infectious disease

1 clinical labs.

2 A. Uh-huh.

3 Q. Are there other types of clinical labs besides
4 clinical diagnostic labs, besides infectious
5 disease clinical diagnostic labs?

6 A. Right. I thought we talked about that earlier
7 today. The clinical labs in the hospital, there
8 is a myriad of those. Meridian is here. We
9 know that.

10 Q. Right.

11 A. Illumina is out here, but we know they are not
12 there.

13 Q. Okay. Can you for the record maybe distinguish
14 between here and there?

15 A. Oh, I apologize. Meridian is in the infectious
16 disease IVD clinical lab. Illumina is outside
17 of that area; could be in multiple different
18 areas within the hospital setting, but it is not
19 in the area that we are in nor are we in the
20 area that they are in.

21 Q. Okay. And do you know definitively what area
22 Illumina is in?

1 A. I know some of the areas they are in because
2 they make it very clear they are in sequencing
3 and buy their products. So they purchase
4 companies who make enzymes or bits and pieces so
5 that you can use those in your research.

6 Q. And maybe I can cut to the chase: Are you
7 testifying that, setting aside infectious
8 disease clinical labs, is it your testimony that
9 Illumina is not in any other type of clinical
10 diagnostic lab?

11 MR. HANKINSON: Objection to form.

12 A. I don't know what you mean "not in any other
13 clinical diagnostic lab." I don't know what
14 that means when you say that.

15 Q. Sells its products to --

16 A. Sells its products to other diagnostic labs in
17 the hospital?

18 Q. Yes.

19 MR. HANKINSON: Objection to form.

20 A. And by definition, a diagnostic, it is outside
21 of the infectious disease area?

22 Q. For this question, yes.

1 MR. HANKINSON: Objection to
2 form generally and vague as to time
3 period.

4 A. So I would say they are outside in other
5 diagnostic areas, outside of the infectious
6 disease area as the duration of the dispute over
7 the trademark.

8 Q. What time frame are we referring to in paragraph
9 16 of your declaration when you say "Illumina's
10 consumers are those on the research side of such
11 labs"?

12 A. It is from my knowledge from the time of --
13 well, over my 27 years, I have never ever seen
14 an Illumina product in an infectious disease lab
15 anywhere. So from my personal perspective, it
16 encompasses my career at Meridian.

17 Q. Say from 2007 to present.

18 A. 2007 to present?

19 Q. Can you comment as to whether Illumina's
20 products have been in a clinical diagnostic lab
21 aside from an infectious disease clinical
22 diagnostic lab?

1 A. I don't know. I have not seen an Illumina
2 product anywhere in a hospital setting because I
3 focus on the labs that I focus on. I know from
4 their business model, I know from what they sell
5 when you talk to people at the booth what they
6 are doing, but I have not seen any Illumina
7 equipment anywhere or instruments.

8 Q. Because you focus on the infectious disease
9 clinical labs within reference labs and
10 hospitals?

11 MR. HANKINSON: Objection to form.

12 Q. Correct?

13 A. Correct.

14 (Pause.)

15 A. I just saw Prodesse and Quidel, competitor
16 products.

17 Q. And the competitors listed in paragraph 17 are
18 not intended to be an exhaustive list?

19 A. No, they are not.

20 Q. Do you know which of Meridian's competitors use
21 a separate reader?

22 A. What do you mean by separate reader?

1 Q. Like the ILLUMIPRO instead of just using under a
2 microscope?

3 MR. HANKINSON: Objection to form.

4 A. I am not quite sure what you mean by that, but
5 any competitor that is building an Elisa assay
6 would have to use an Elisa plate reader, general
7 laboratory equipment. Everybody is either a
8 visual read, so there is no instrumentation
9 involved, or the instrumentation is directly
10 linked to their assays, SmartCycler, Cepheid has
11 a closed system, put the device in, and the data
12 spits out.

13 Q. Would you go to paragraph 21 of your
14 declaration? I guess it is the fourth sentence
15 in kind of in the middle of the paragraph.

16 "RUO products may not be used in
17 clinical diagnostic laboratories to diagnose
18 patients unless the lab itself performs its own
19 validation studies, studies which Illumina, by
20 its own admission, takes no part in."

21 What type of clinical diagnostic
22 laboratories are you referring to in that

1 sentence?

2 A. Once again, back to the infectious disease
3 laboratories.

4 Q. So would it be accurate -- go ahead.

5 A. And for that matter, then, if Illumina is
6 selling products to any laboratory in the
7 hospital, to use your definition, and if it
8 is not FDA cleared or validated by the lab,
9 they couldn't report on it. They couldn't use
10 it.

11 Q. But if Illumina was selling a product that
12 wasn't FDA cleared but it was used in a test
13 that was validated by the lab, that test could
14 be used to diagnose a patient, correct?

15 A. If it was validated appropriately, the
16 instrumentation was validated appropriately and
17 it is on record, they have that potential.

18 Q. And so if I read this sentence to say that an
19 RUO product cannot be used to diagnose in the
20 clinical diagnostic lab -- and by this, you mean
21 an infectious disease clinical diagnostic lab to
22 diagnose --

1 A. Well, in this case, it could be any lab because
2 this is a generality. An RUO cannot be used for
3 patient diagnoses regardless of where it is
4 unless it is validated.

5 Q. Okay. But if it is, if an RUO product is
6 validated, it could be used in a test in an
7 infectious disease clinical diagnostic lab,
8 correct?

9 MR. HANKINSON: Objection.

10 A. Please repeat that. It could be used in an
11 infectious disease lab now? I think the way
12 this sentence reads, if it was validated,
13 regardless where it is, it could be used. And
14 that would be on the research side of it, not
15 the IVD side as we discussed earlier today.

16 Q. Why do you say in a clinical diagnostic lab?

17 A. Well, here we are going into semantics. In our
18 IVD market, the research lab we have and then
19 the IVD portion. So outside of that area, I
20 don't know, but as long as it is validated with
21 equipment, maintained assay, it could be used
22 for patient diagnoses. Is that clear?

1 Q. Yes.

2 A. Thank you.

3 Q. And let me go one more step further: It is
4 possible for an RUO product, if properly
5 validated, to be used to diagnose patients
6 within the infectious disease clinical
7 diagnostic lab setting, correct?

8 MR. HANKINSON: Objection to form.

9 A. RUO product converted to an IVD, maybe I should
10 be clear here, an RUO product could be an
11 enzyme. That's not a diagnostic test. So if
12 you are selling a component, the lab would have
13 to validate the use of that component within the
14 whole structure of the assay.

15 So in other words, if somebody
16 wanted to use an Illumina DisplaceAce, that's
17 just the component, and they would have to
18 validate the rest of that whole assay. So a
19 research use only product usually is a
20 component. An LDT, a laboratory developed test,
21 is the whole complete test.

22 Q. Right. And an LDT --

1 A. And if you have a product, a whole product put
2 together RUO, it can't be because we don't sell
3 RUOs.

4 Q. Understood. But an LDT could take place within
5 the infectious disease clinical diagnostic lab
6 setting, correct?

7 A. In the research area, yes.

8 Q. But why would you use the term "clinical
9 diagnostic lab" in paragraph 21 if you were
10 referring to the research area?

11 A. Because in this case for Illumina's business
12 model, it could be used other places because
13 Illumina was trying to sell into the hematology
14 lab with their Factor V assays.

15 Q. Was that a clinical diagnostic lab, or was that
16 the research lab?

17 A. It was an FDA cleared product. I can't answer
18 what they do in hematology, but that's where you
19 are operating, and this is a general statement
20 saying, if you use some of those other
21 components somewhere else in the hospital, it
22 could be done.

1 Q. Within the infectious disease setting, are LDTs
2 always operated in a separate division than FDA
3 cleared IVDs?

4 A. As I mentioned this morning, usually, in most
5 hospitals, they are segregated. There is an
6 occasional time they are together but usually
7 physically separated within the same lab. I
8 think I went through that this morning.

9 Q. How far away are they separated, do you know?

10 A. It could be by room. Usually, they are
11 separated because of the complexity and because
12 of containment reasons for free DNA, things like
13 that. So normally, they are isolated because
14 they are a research area, because that area can
15 be used for other things besides IVD
16 diagnostics.

17 Q. If you could go to the end of paragraph 22, top
18 of page 8, you use this bolt manufacturer
19 competing in the automotive industry analogy,
20 and first, is that your analogy?

21 A. It is an analogy that we discussed.

22 Q. Okay.

1 A. But I have no issues with that analogy.

2 Q. Do you know what type of products, components,
3 or equipment from Illumina are used to create
4 LDTs?

5 A. It would be Illumina makes enzymes. There are
6 bits and pieces. I could take Illumina's
7 DisplaceAce and make an assays out of it. It is
8 the bolt. It is a bolt, for example.

9 Q. Do you know what other type of Illumina
10 products?

11 A. You have sequencers; you have different types of
12 very, very large instruments that you could put
13 in a research lab and since they are open
14 systems manipulate and do other things with
15 them.

16 Q. If a sequencer was used to help create an LDT,
17 would you consider that sequencer just to be the
18 bolt of the LDT?

19 A. Absolutely.

20 Q. Why?

21 A. Because it is not a separate entity. You can't
22 build an LDT without all the pieces together.

1 Everything that makes up the assay makes up the
2 assay.

3 Q. So the assay would only be made of bolts?

4 A. You have enough bolts together, you have a car.

5 Q. Don't you need an engine and a frame?

6 A. Now I think we are being facetious because a
7 bolt is a piece. You need multiple pieces to
8 build the assay.

9 Q. Do you think all of the pieces have equal
10 importance?

11 A. If a bolt fell off the car and your wheel off,
12 absolutely. Every piece in an airplane is very
13 important. Every piece in a car to me is very
14 important. If any one fails, the assay fails.
15 One is not more important than another.

16 Q. Would you agree that in a car some components
17 are more of a commodity than others?

18 MR. HANKINSON: Objection to form.

19 A. If we are talking about the basic structure of a
20 car, talking about a radio, I agree with you.
21 But if you are talking about a steering wheel or
22 tire or engine or brake, no one is more

1 important than another, and if a bolt fell off
2 holding the engine or bolt fell off holding the
3 brake, we would be in trouble.

4 Q. Do you think it would be more likely for an
5 engine manufacturer to be in manufacturing cars
6 than bolt manufacturing?

7 A. That's a personal opinion versus -- so I don't
8 know why an engine manufacturer is not making
9 engines for cars. Ford makes their own engines
10 in Cleveland, but they also are the car
11 manufacturer.

12 Q. Okay. Go to paragraph 24, and I am going to
13 focus on the sentence "I agree with this part of
14 Ms. O'Grady's testimony," but I just want to
15 summarize what you are saying up to there, and
16 if you think I mischaracterize what you are
17 saying and want to cut it short, feel free to
18 correct.

19 My understanding in paragraph 24,
20 we are talking about the fact that when labs use
21 Illumina's product to make a diagnostic LDT,
22 Illumina's name is not on the output report?

1 MR. HANKINSON: Objection to form.

2 A. Could you repeat that question, please?

3 Q. 24, we are talking about a situation in which an
4 Illumina product is used to make a diagnostic
5 LDT. There is an output report, and Illumina's
6 name is not on the report or doesn't have
7 control over the report's branding or control
8 over the report's content.

9 A. And what's the question?

10 Q. I am leading up to it.

11 That's what you are talking about
12 in the sentence I am going to read, which is "I
13 agreed with this part of Ms. O'Grady's
14 testimony, and it means that Illumina's RUO
15 components or equipment used in LDTs would not
16 have given Illumina any market presence or
17 reputation whatsoever in a clinical diagnostics
18 field."

19 The "it" is the lack of Illumina's
20 presence on the report. Are we on the same
21 page?

22 A. It means that Illumina's name does not appear on

1 the final report that goes to physicians. In
2 addition, Illumina doesn't have a reputation in
3 the diagnostic field, especially as it relates
4 to infectious diseases for detecting and
5 managing patients with infectious disease
6 diagnoses. They make parts.

7 Q. Why would the fact that Illumina's name is not
8 in the report mean that Illumina has no market
9 presence or reputation whatsoever in the
10 clinical diagnostic fold?

11 A. Because in my opinion, there is no branding of
12 that. There is pieces and chunks making up a
13 total. Now I have an LDT.

14 Q. Wouldn't the people putting together in
15 making an LDT know that they are using Illumina
16 parts?

17 A. They would be buying Illumina parts, but there
18 is no branding for the LDT.

19 Q. Okay.

20 A. There is no product when you are done. There is
21 parts.

22 Q. But why wouldn't the -- "manufacture" is the

1 wrong word. Who makes the LDT?

2 A. The lab.

3 Q. The lab. Wouldn't the personnel in the lab
4 that made the LDT be aware they were using
5 Illumina products?

6 A. Yes. They would be buying a specific product,
7 but the kit itself, the final brand of that is
8 not branded with Illumina. It is a component
9 within.

10 Q. Why would the personnel at the clinical
11 diagnostic lab that created the LDT need the lab
12 test to be branded in order to understand that
13 it used Illumina products?

14 MR. HANKINSON: Objection.

15 Embedded mischaracterization of prior
16 testimony and a compound question.

17 BY MR. HORNE:

18 Q. You can answer.

19 A. We are trying to make a point or you are trying
20 to make a point to say Illumina has a presence;
21 that they have a brand recognition within the
22 clinical lab setting, and what I am saying I

1 don't see that.

2 I see that you use a component just
3 as much as CIGNA or anybody else, but when the
4 day is done, there is no brand that says "oh,
5 "look, there is an Illumina-branded test that I
6 used to detect this patient."

7 What we have is lab developed test
8 used to detect that patient.

9 Q. Do you know whether Meridian's branding is
10 present on tests generated, test reports
11 generated from the ILLUMIGENE product?

12 A. The reports that go out to the physician does
13 not have Meridian's branding on that specific
14 report. The kit itself is branded, and that's
15 what are used to generate the data that goes
16 into that report. So that kit is branded.

17 Q. But the report to the physician is not branded
18 with Meridian's --

19 A. No. They order a report for disease X; they get
20 a result for disease X.

21 Q. Go to the last sentence in paragraph 26.

22 "Someone trying to diagnose" -- last sentence of

1 paragraph 26 -- "someone trying to diagnose the
2 presence of an infectious disease in a clinical
3 diagnostic lab cannot use DisplaceAce by itself
4 for this purpose nor would such person be aware
5 whether DisplaceAce was being used as a
6 component within a kit."

7 What person are you referring to
8 here? Who is the someone?

9 A. So if you are the lab running an assay, let's
10 say an IVD cleared assay, no one in the lab
11 would know if we had DisplaceAce in our product.
12 They would know we have Meridian's product used
13 to detect this. They know that there is an
14 enzyme in there. They have no idea what that
15 enzyme is.

16 Q. If someone in a lab was using an Illumina
17 sequencer in an LDT, do you think the person at
18 the lab would be aware they were using an
19 Illumina sequencer?

20 MR. HANKINSON: Objection to form.

21 Vague as to lab.

22 A. If you walked up to an instrument and had

1 Illumina branding on it, they would know, but
2 again, a sequencer is not a kit; it is a box.
3 By itself, it does nothing.

4 Q. Understood. So we can use the right
5 terminology, is "operate" the right verb? Who
6 operates an LDT? Am I asking it --

7 A. Well, LDT is a multitiered assay. It is
8 building all the components. It is building all
9 the mixes. It is building all the controls. It
10 is running everything. It is putting it on the
11 instrument to get the right data back out. This
12 is a multifaceted -- LDT is full of many
13 different components to build an assay.

14 Q. What would the difference be between using an
15 ILLUMIPRO -- and is it proper -- is it
16 ILLUMIPRO, would you call that a reader, or what
17 would you call it?

18 A. We call it an incubator reader.

19 Q. What would the difference be between using an
20 ILLUMIPRO incubator reader as part of a kit to
21 run a test versus using an Illumina sequencer as
22 part of an LDT?

1 A. Because our reader and our kit are married
2 together. You cannot run one without the other.
3 It is a completely closed system. No one else
4 can get on it.

5 Q. From the standpoint of the operator, whether it
6 be at the clinical diagnostic lab or a research
7 lab, would they equally know -- strike that.

8 Wouldn't it be just as likely for
9 someone in a clinical lab or research lab who is
10 using an LDT with an Illumina sequencer,
11 wouldn't it be just as likely for that person to
12 know that they were using an Illumina sequencer
13 in the LDT as it would for somebody who is using
14 an ILLUMIPRO incubator reader to know that they
15 were using a Meridian ILLUMIPRO incubator
16 reader?

17 MR. HANKINSON: Objection to form.

18 Massively compound and misleading.

19 A. All right. So if I understand correctly, you
20 are asking me if somebody is using an ILLUMIGENE
21 complete system, would they know they are using
22 an ILLUMIGENE complete system? My answer is

1 been nor are they in the infectious disease
2 arena with complete diagnostic kits for that.
3 Illumina has chosen to go down a path of
4 making equipment available, parts and pieces
5 available.

6 Q. Now, you said Illumina has not been in the --

7 A. Infectious disease FDA cleared arena.

8 Q. Okay. You said "Illumina has not been in the
9 infection disease arena with complete diagnostic
10 kits."

11 Do you know whether Illumina has
12 been in infectious disease for making other than
13 a complete diagnostic kit?

14 A. I need you to define what you are interpreting
15 there. They have no FDA cleared products.
16 That's what I was referring to.

17 Q. Right.

18 A. Okay.

19 Q. If we can go to the second sentence -- actually,
20 the third sentence of paragraph 28 --

21 A. 28?

22 Q. Yeah.

1 A. Okay.

2 Q. You say "as discussed above, consumers of such
3 services and products are research laboratories,
4 not clinical diagnostic laboratories," and I
5 assume there you mean not infectious disease
6 clinical diagnostic laboratories?

7 A. In that respect, yes.

8 Q. And this may save time today:

9 Would it be reasonable for us to
10 assume that every time in your declaration you
11 say that Illumina is not in a clinical
12 diagnostic laboratory, you mean it is not in an
13 infectious disease clinical diagnostic
14 laboratory?

15 MR. HANKINSON: Objection to form.

16 Q. You can answer.

17 A. In my opinion, yes.

18 Q. I don't have to keep asking that every time?

19 A. Exactly. The same -- if I could have the same
20 courtesy back when you say it, that that's what
21 you are referring to as well. You are asking me
22 a question about diagnostic laboratories as

1 well, so I want to make sure --

2 Q. I am going a little broader sometimes, so let's
3 make sure --

4 A. Okay. So as long as you are clear with me, I
5 would appreciate that, too, so I am answering
6 your question clearly.

7 MR. HANKINSON: I am just going to
8 object because that is massively
9 unclear, and it has been unclear all day
10 long. So I still don't know after that
11 exchange what the rules are going
12 forward for it. So I think we should
13 just try to ask clear questions and give
14 clear responses.

15 A. Okay. I will do my best.

16 Q. You say in paragraph 30 "even if Illumina were
17 given the benefit of the doubt about having an
18 IVD product in the marketplace with its VeraCode
19 Genotyping Test or MiSeqDx cystic fibrosis
20 assays," what do you mean by "given the benefit
21 of the doubt"?

22 A. If Illumina is saying they are in the IVD market

1 and saying that our area of focus and Illumina's
2 area of focus are totally and completely
3 different, you are in hematology, pathology,
4 oncology, areas with two FDA cleared products at
5 the time, it is not in the infectious disease
6 area.

7 Q. Okay. And those areas that you just described
8 would be considered clinical diagnostic
9 laboratories; they just would not be considered
10 infectious disease clinical diagnostic
11 laboratories?

12 MR. HANKINSON: Objection. Vague
13 as to time period.

14 A. Okay. Again, yes.

15 MR. HORNE: Why don't we take a
16 break.

17 (Recess had.)

18 BY MR. HORNE:

19 Q. Would you turn to paragraph 35 of your
20 declaration? First sentence you say "the
21 decision-maker in setting up a pricing contract
22 with Meridian for purchasing Meridian's clinical

1 diagnostic products, including ILLUMIGENE
2 products, and in this case the relevant consumer
3 of Meridian's products, is typically a clinical
4 director, the head of a clinical laboratory."

5 What do you mean in that sense when
6 you say "clinical laboratory"?

7 A. Once again, we are talking about the infectious
8 disease laboratory, IVD.

9 Q. And if I understand correctly, you do not know
10 whether the clinical director of the infectious
11 disease clinical laboratory also has
12 responsibilities for the other divisions such as
13 chemistry, hematology?

14 A. No. I know that they have responsibility for
15 the IVD, but I don't know about the other areas,
16 usually not that I know of, but I've never
17 heard one mention that they manage a hematology
18 lab. I have never heard it mentioned
19 personally.

20 Q. Next paragraph.

21 A. Are you talking 36 now?

22 Q. Yes. "The clinical director and the purchasing

1 agents that work with him are both very familiar
2 with what diagnostic tests are available for
3 various infectious diseases and what companies
4 provide or offer those tests."

5 How does the clinical director know
6 or how does he become familiar with what
7 diagnostic tests are available and what
8 companies provide and offer those tests?

9 A. It is his job to know. A clinical director
10 infectious diseases needs to know the state of
11 the art of how things are being diagnosed
12 today.

13 Q. Do you know how he becomes familiar with what's
14 available and from whom?

15 A. Usually, it is from his workings with companies
16 that sell directly into that area. It is from
17 working with other clinical directors in the
18 microbiology area to name two.

19 Q. How would -- you say other clinical directors in
20 the microbiology area. Do you mean different
21 entities?

22 A. Uh-huh. They have on the ASM website, they have

1 specific areas where clinical directors can talk
2 to each other.

3 MR. HANKINSON: Ken, I will note
4 that you said "uh-huh" there instead of
5 "yes." Try to stay vigilant

6 THE WITNESS: I'm sorry. I will
7 try to stay vigilant.

8 BY MR. HORNE:

9 Q. Next sentence: "it is their job to know, and
10 although some of the product names are complex
11 or somewhat similar to one another, they have
12 repeated with enough frequency that they are
13 thoroughly learned."

14 And how do you know that the
15 product names are repeated with enough frequency
16 that they are thoroughly learned by the clinical
17 director?

18 A. Well, I have had personal experience with that.
19 We sell products called ImmunoCard. We sell
20 products that are called ImmunoCard STAT. So if
21 I go into Larry Gray's lab and I mention I have
22 an ImmunoCard STAT product, he knows what that

1 is. We have personal knowledge of that.

2 Premier, he knows what that product
3 line is. Other companies have immuno-based
4 products, but he knows that's one of ours.

5 Q. So when you say the product names are complex or
6 somewhat similar, you are referring to product
7 names within one company?

8 A. No. There is other companies that have product
9 names similar to some of our products.

10 Q. Okay. So how do you know that the clinical
11 director can always keep those separate names
12 straight?

13 A. Again, you are using the word "always," but in
14 my personal interactions with these clinical
15 directors where I have had that opportunity,
16 there was no mistaking our products from -- even
17 within our company have a similar name between
18 other products from other companies.

19 Q. And when you say "they are repeated with enough
20 frequency that they are thoroughly learned," do
21 you know how much along and how much repetition
22 it takes?

1 A. So again, unit per unit or how many times per
2 unit, so you are asking me how many times does
3 an individual learn something? We are at them
4 every -- usually every sales meeting we are
5 going through our product lines with them. So
6 if we meet with a lab two or three times, it is
7 two or three times. If we meet with a lab 20
8 times, it is 20 times.

9 Q. Paragraph 38, the second sentence you say "in
10 all circumstances these individuals are highly
11 knowledgeable of which company" paren" by name"
12 end paren "can source a particular product."

13 A. Uh-huh.

14 Q. How do these individuals become highly
15 knowledgeable?

16 A. Once again, we provide them information on our
17 product line. When they place a call, they are
18 going to place the call to Meridian Bioscience;
19 not going to place a call to ILLUMIGENE. No
20 company exists. They can go to our website. It
21 is all clearly laid out the products we have by
22 name and by disease state.

1 Q. And you believe they are highly knowledgeable
2 very early on in the sales process?

3 A. I believe so, yes.

4 Q. Why is that?

5 A. Because I have been there very early in the
6 process. We walk in as Meridian. We have
7 product portfolios. Ahead of time it is
8 arranged that we are going to talk to you about
9 a new product or new assay we have. We leave
10 the literature with them. There is follow-up
11 calls, internal people that call, and the sales
12 reps call.

13 Q. Do you know how long it takes for the customers
14 to be fully aware of the types of customers
15 Meridian can offer?

16 A. In my 27 years at Meridian, every time I have
17 gone to a customer they are well aware of our
18 capabilities and what we do. We are
19 strategically focused in infectious diseases.
20 Our sales reps constantly update and go into the
21 clinical infectious disease labs.

22 Q. What about a new customer that Meridian hasn't

1 been selling to, a brand new account? Is that
2 customer, the first touch, fully aware of what
3 types of products Meridian can offer?

4 A. When we leave, they are fully aware.

5 Q. But not at the initial contact?

6 A. I can't always answer that. Even though they
7 may not buy a Meridian product, our name is well
8 known in the infectious disease area and always
9 has been. I never recall running into a
10 customer that did not know Meridian in the
11 infectious disease clinical lab.

12 Q. Paragraph 40, the bottom of page 12 continuing
13 to page 13, you say "in this context it is the
14 company's brand that is foremost in the
15 consumer's mind, not the names of the products
16 that the company offers to meet a particular
17 need."

18 How do you know what's foremost in
19 the consumer's mind?

20 A. Because I have met with consumers. Again, we
21 walk in and say "we are from Meridian." We
22 don't walk in saying we are from Illumina or

1 Premier or Tru.

2 Q. If another company besides Meridian made an
3 infectious disease IVD product and named it
4 ILLUMIGENE, do you think that the clinical
5 directors would be confused between that product
6 and Meridian's ILLUMIGENE product?

7 MR. HANKINSON: Objection to form.

8 Calls for speculation.

9 A. I can't answer that, but -- I can't answer
10 that.

11 Q. Is there a reason they would be confused?

12 MR. HANKINSON: Objection to form.

13 A. I am not sure what that question means. You are
14 asking me if I would think that somebody would
15 think.

16 Q. Uh-huh?

17 A. I know what I would think.

18 Q. What would you think?

19 A. I wouldn't if they said somebody else's name in
20 front of the ILLUMIGENE. As we say, it is
21 Meridian's ILLUMIGENE. Those things go
22 together. If you tell me it was brand or

1 Company X ILLUMIGENE, I know it would not be
2 Meridian. Somebody would get a phone call, and
3 then one of these two would get a phone call,
4 and by these two, I refer to the legal team.

5 Q. Another company made a product and that product
6 was not sold in the -- into the infectious
7 disease clinical labs but it was sold to other
8 divisions of the clinical labs we discussed
9 earlier like hematology or chemistry and that
10 product was called ILLUMIGENE, do you think
11 there would be potential confusion between that
12 product and Meridian's ILLUMIGENE product?

13 MR. HANKINSON: Objection to form.
14 Incomplete hypothetical and calls for
15 speculation.

16 A. Right. Once again, I thought we answered that
17 question earlier, but I can't answer what
18 another lab, how they would respond.

19 Q. If Illumina from 2007 to present would have
20 taken any of its products that were on the
21 market and named one of those products
22 "ILLUMIGENE," do you think there would have been

1 any confusion with consumers between the
2 Meridian ILLUMIGENE product and the
3 Illumina product that would have been called
4 ILLUMIGENE?

5 MR. HANKINSON: Objection to form.
6 Vague. Calls for speculation.

7 A. Right. I am very lost in this question now.

8 Q. Okay.

9 A. Because aren't we talking about November of 2008
10 with our trademark forward? You are pushing us
11 back to 2007.

12 Q. Okay. Fair enough. So let's go from November
13 2008 forward.

14 A. Now, you are asking -- repeat the question, or
15 rephrase the question for me.

16 Q. Absolutely. From November 2008 until the
17 present, if Illumina would have sold any of the
18 products that it had sold, same products,
19 nothing different within the products that would
20 have named any of those products ILLUMIGENE, do
21 you think there could have been any confusion
22 with consumers between the hypothetical Illumina

1 ILLUMIGENE products and Meridian's ILLUMIGENE
2 products?

3 MR. HANKINSON: Objection to form.
4 Incomplete hypothetical.

5 A. I can't answer that.

6 Q. Paragraph 54 of your declaration, you say, just
7 going to the end of the second line, "there have
8 been no reported incidents of confusion between
9 these products and Illumina or its products, and
10 had there been instances of actual confusion, I
11 would beware of them."

12 When you say no reported incidents
13 of confusion, how do you know there have been no
14 reported incidents of confusion?

15 A. In my position, I am required, as part of the
16 work that I have been doing on trademarks, I
17 would be alerted in my position and the
18 executives would be alerted that there was
19 confusion in the marketplace and -- relative to
20 that. No reports have come in to us.

21 We have technical support who
22 monitors all complaints within the company. All

1 those are reviewed by regulatory, the quality
2 review board looks at all complaints and all
3 inquiries, and every one gets posted. So we
4 have complete matrix on every concern, on every
5 product that we manufacture, and we never heard
6 a complaint, either coming in through the tech
7 support team or through our sales team.

8 Q. So when you say "there have been no reported
9 incidents of confusion," you mean no reported
10 incidents of confusion reported to Meridian?

11 A. Correct.

12 Q. Paragraph 57, last clause or last sentence
13 "there have still been absolutely no accounts of
14 purchasers or others confusing the source of
15 ILLUMIGENE as being Illumina nor confusing
16 Meridian as being the source of any Illumina
17 products," and when you say "there have been
18 absolutely no accounts, you mean there have been
19 no accounts to Meridian, correct?

20 A. Correct.

21 Q. Paragraph 58 "in my position, I would expect to
22 hear about any reported confusion from a

1 consumer related to our trade shows or sales in
2 clinical laboratories." And again, you mean
3 reported confusion reported to Meridian,
4 correct?

5 A. Correct. And by Meridian, it is any vehicle
6 that comes into Meridian through sales force,
7 through clinical trial teams, to tech support.

8 Q. And I also want to clarify in paragraph 58 of
9 your declaration when you say sales and clinical
10 laboratories, you are referring to infectious
11 disease clinical laboratories?

12 A. Correct.

13 Q. Paragraph 63 of your declaration, when you say
14 "the fact that Illumina and Meridian have
15 attended the same trade shows and that the
16 companies have experienced absolutely no
17 confusion from the attendees at those trade
18 shows," when you say "the companies have
19 experienced absolutely no confusion from the
20 attendees," you are meaning no confusion has
21 been reported to Meridian or Illumina.

22 A. This one is a little different. I would say

1 plus when I visit the Illumina booth, no one
2 confuses me with an Illumina person. No one is
3 brought up to me when I visit the Illumina booth
4 looking at what's new, no one said oh, we have
5 products that are signature, products that are
6 the same as Illumina's.

7 Q. So paragraph 63, when you are referring to
8 "experienced absolutely no confusion," you
9 mean nothing --

10 A. Nothing reported to Meridian or that I have
11 observed personally at the meetings that I have
12 attended. Is that clear?

13 Q. It is. Thank you.

14 Has Meridian ever had to do
15 document remediation for a product?

16 A. I don't know what you mean -- if you said go
17 back and reengineer a product and put it under
18 design control, absolutely.

19 Q. Well, you used document remediation in paragraph
20 68.

21 A. Yeah. That's what I heard from one of -- the
22 O'Grady deposition, I believe.

1 Q. Uh-huh. Well, 68 you say "document remediation
2 means a process of taking an existing designed
3 product and then going back through all of its
4 parts to validate that." Has Meridian ever gone
5 through that document remediation process?

6 A. Yes.

7 Q. In what context?

8 A. In the late '90s, early 2000s, Meridian had
9 substantial 483s issued by the FDA, which
10 required us to revalidate every product we had
11 on the market that was manufactured after design
12 control implementation because they felt our
13 documentation was not up to standards.

14 Q. What's a 483 for us ignorant people?

15 A. 483 is a warning that the FDA would issue a
16 company because they are not in compliance with
17 QSR. We pulled multiple products off the
18 market. It was a difficult time.

19 Q. And in one of your answers, you referred to
20 "after design control implementation," what did
21 you mean by that?

22 A. The QSR regulations.

1 Q. So these were things that were manufactured
2 before the regulation came in place?

3 A. No. They were manufactured after the
4 regulations came into place; that the FDA did
5 not see us as completely compliant. We then had
6 to bring all those products into compliance.

7 Q. Do you know whether companies ever start out
8 making products for the research space and then
9 progressing, selling diagnostic products?

10 A. Do I know of any companies that do that that
11 aren't already there?

12 Q. What do you mean they aren't already --

13 A. That aren't already in the IVD market space?

14 Q. That have progressed from research products to
15 IVD space.

16 MR. HANKINSON: Objection to form.

17 A. As I sit here today, I can't recall one right
18 now.

19 Q. Do you know if a company was making RUO products
20 and that company eventually planned to seek FDA
21 clearance for a subset of its products, do you
22 think that company would develop all of its

1 products using design control?

2 A. In today's marketplace, if you want to use them
3 for IVD in the United States, you have no other
4 choice but to do so.

5 Q. Okay.

6 A. You need to be under complete design control.

7 Q. I think we talked passed each other.

8 Let's say I am running a company
9 and making RUO products and my plan is to get in
10 the diagnostic space. I don't know right now
11 which of my products I am going to seek FDA
12 approval for. Say I am making ten RUO products
13 and I have a plan to go into a subset, say five,
14 and seek FDA clearance for some of those, not
15 all of those, five instead of ten, would I want
16 to design all of my products under design
17 control?

18 A. You are asking me for a subjective answer here.

19 Q. Uh-huh.

20 A. But I don't know how you can't because the FDA
21 is going to come and look at all your quality
22 systems. The FDA is not going to just look at

1 how you are manufacturing; it is the complete
2 quality system that has to be upgraded,
3 everything from inception to launch of the
4 product, monitoring the product on the outside,
5 and every component within the internal quality
6 system, executive management review, there is
7 multiple tiers and facets to this.

8 So if you are upgrading your
9 quality system, are you going to do it for five
10 and leave the other five off to the side? It
11 gets extremely difficult to operate your
12 business that way in my opinion. Your quality
13 system has to be completely retooled.

14 Q. Let's say I am going to develop RUO products and
15 I have a vision that one of them is going to be
16 -- we are going to seek FDA clearance, but I
17 don't know which one. Would I be better off
18 making all the products using design control or
19 using document remediation for the one once I
20 determine which that one that is?

21 A. Clarify one thing for me here.

22 Q. Uh-huh.

1 A. When you say RUO product, are you talking about
2 a bolt or the complete car?

3 Q. The complete car.

4 A. The complete car. It is a business decision you
5 have to make, but you have to know that there
6 are problems by only doing a few because now you
7 are going to come under FDA scrutiny, and the
8 FDA is cracking down on RUO only products as a
9 complete diagnostic kit just like they are ASRs.

10 Q. How much longer does it take to -- fingers are
11 cramping -- how much longer does it take to
12 design a product under design control than
13 not?

14 A. 

15

16

17

18 Q. Okay.

19 A. And that's with the quality system already
20 operational. That's a trade secret, too.

21 MR. HURST: Maybe we can go off the
22 record.

1 (Discussion held off the record.)

2 MR. HORNE: I have no more
3 questions.

4 MR. HANKINSON: We need a break.

5 MR. HORNE: Okay.

6 MR. HANKINSON: We will take a
7 break and see if we any other questions.

8 (Recess had.)

9 MR. HANKINSON: Sorry for the
10 delay. We are not going to have any.
11 We have no questions.

12 MR. HORNE: Go off the record.

13 (Discussion off the record.)

14 (Signature not waived.)

15 (Deposition concluded at 3:30 p.m.)

16 - - - -

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1 State of Ohio,)
) SS: CERTIFICATE
2 County of Cuyahoga.)

3 I, George J. Staiduhar, a Court Reporter
in and for the State of Ohio, duly commissioned
and qualified, do hereby certify that the within
4 named witness, Kenneth J. Kozak, was by
me first duly sworn to testify to the truth, the
5 whole truth, and nothing but the truth in the cause
aforesaid; that the testimony then given by him was
6 by me reduced to stenotypy/computer in the presence
of said witness, afterward transcribed by me, and
7 that the foregoing is a true and correct transcript
of the testimony so given by him as aforesaid.

8 I do further certify that this deposition was
taken at the time and place in the foregoing caption
9 specified.

10 I do further certify that I am not a relative,
counsel, or attorney of either party, or otherwise
interested in the event of this action.

11 IN WITNESS WHEREOF, I have hereunto set my
12 hand and affixed my seal of office at Cleveland,
13 Ohio, on this 11th day of March, 2015.

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**George J. Staiduhar, Notary Public in
and for the State of Ohio. My commission
expires August 1st, 2017.**

1 Kenneth J. Kozak/o
2 KEATING MUETHING & KLEKAMP, PLL
3 One East 4th Street, Suite 1400
4 Cincinnati, OH 45202

5
6 Case: Illumina Inc. v. Meridian Bioscience, Inc.
7 Date of deposition: March 9, 2015
8 Deponent: Kenneth J. Kozak

9
10 Please be advised that the transcript in the above
11 referenced matter is now complete and ready for signature.
12 The deponent may come to this office to sign the transcript,
13 a copy may be purchased for the witness to review and sign,
14 or the deponent and/or counsel may waive the option of
15 signing. Please advise us of the option selected.
16 Please forward the errata sheet and the original signed
17 signature page to counsel noticing the deposition, noting the
18 applicable time period allowed for such by the governing
19 Rules of Procedure. If you have any questions, please do
20 not hesitate to call our office at (202)-232-0646.

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3
SIGNATURE PAGE

4
Case: Illumina Inc. v. Meridian Bioscience, Inc.
5 Witness Name: Kenneth J. Kozak
Deposition Date: March 9, 2015

6
7 I do hereby acknowledge that I have read
and examined the foregoing pages
8 of the transcript of my deposition and that:

9
10 (Check appropriate box):
11 () The same is a true, correct and
complete transcription of the answers given by
me to the questions therein recorded.
12 (X) Except for the changes noted in the
attached Errata Sheet, the same is a true,
13 correct and complete transcription of the
answers given by me to the questions therein
14 recorded.

15
16 3-23-15
17 DATE


18 WITNESS SIGNATURE

19
20
21 3-23-15
22 DATE



NOTARY

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 3 Washington, D.C. 20036
 4 (202)232-0646

ERRATA SHEET

7 Case: Illumina Inc. v. Meridian Bioscience, Inc.
 Witness Name: Kenneth J. Kozak
 8 Deposition Date: March 9, 2015
 Page No. Line No. Change

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Please see Errata listed on the attached APPENDIX A


 Signature

3-23-15
 Date

APPENDIX A to Errata for Kenneth J. Kozak

Page(s)	Line(s)	Correction
7	10	Change “MR. KOZAK” to “MR. HANKINSON”
9	2	Change “Dr. Slav Elagin” to “Dr. Slava Elagin”
9	10	Change “Slav Elagin” to “Slava Elagin”
11	17	Change “I remember from your declaration you the” to “I remember from your declaration you”
14	20	Change “MR. KOZAK” to “MR. HANKINSON”
19	8	Change “shall and those trials” to “and those trials”
20	3	Change “by Joel Morteson” to “by Joel Mortensen”
		Change “Illumina” to “Illumigene”
43	6	
43	8	Change “Group A strip” to “Group A Strep”
43	13	Change “Illumina” to “Illumigene”
44	21	Change “ILLUMIGEN-ILLUMIPRO” to “ILLUMIGENE-ILLUMIPRO”
45	16	Change “Group A strip” to “Group A Strep”
45	17	Change “Group B strip” to Group B Strep”
46	7	Change “pertusis” to “pertussis”
46	8	Change “pertusis” to “pertussis”
49	18	Delete “BCO”
53	4	Change “Eiken and lamp” to “Eiken and Lamp”
54	6	Change “1955” to “1985”
68	13	Change “Do you have any understanding what other” to “Do you have any understanding what her”
83	1	Change “ESOP” to “E-Swab”
83	2	Change “ESOP” to “E-Swab”
100	14	Delete “and apologize for”
105	9	Change “MR. HURST:” to “MR. HORNE:”
116	5	Change “Bartels as a cytotoxin” to “Bartels has a cytotoxin”
138	3	Change “CIGNA” to “Sigma”
153	22	Change “Illumina” to “Illumigene”
159	7	Change “to tech support” to “through tech support”
165	21	Change “MR. HURST:” to “MR. HORNE:”

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL APPEAL BOARD

ILLUMINA, INC.,)	
)	Opposition No. 91194218 (parent)
Opposer/Petitioner,)	Ser. No. 77/768176
)	
-v-)	Opposition No. 91194219
)	Ser. No. 77/775316
)	
MERIDIAN BIOSCIENCE, INC.,)	Cancellation No. 92053479
)	Reg. No. 3887164
Applicant/Registrant.)	
)	Cancellation No. 92053482
)	Reg. No. 3868081
)	

DECLARATION OF KENNETH J. KOZAK

I, Kenneth J. Kozak, hereby state and declare as follows:

1. My name is Kenneth J. Kozak, I am over eighteen (18) years of age, and I have personal knowledge of the facts stated in this Declaration.
2. I graduated from Miami University in 1976 with a bachelors degree in Microbiology.
3. I am employed by Meridian Bioscience, Inc. ("Meridian") as its Chief Technical Officer. I have been with Meridian since 1987, starting as a Senior Research Associate in Product Development and working my way up to my current position. Among other positions, I was Meridian's Vice President, Research and Product Development, from May 1999 to May 2007. I have held my current position as Chief Technical Officer since May 2007.
4. In connection with my duties and responsibilities for Meridian, I supervise and direct Meridian's Clinical, Verification, and Product Support teams. In performing my duties at Meridian, I work closely with clinical laboratories that typify Meridian's customers for diagnostic kits (including ILLUMIGENE kits) and diagnostic machines (including ILLUMIPRO and ILLUMIPRO-10). I have personally managed clinical trials for Meridian's new products in such



clinical laboratories, and I have considerable experience meeting with the personnel in those laboratories who purchase and use ILLUMIGENE kits. I have gained substantial personal knowledge, through my work, of our customers' organizational structures and needs. I have also been involved in planning product launches and am made aware of Meridian's marketing strategies, branding and product literature in the course of my job duties. I am also personally aware of Meridian's competitors in the diagnostic field and the products that they offer.

The Differing Consumers of Meridian's Products versus Illumina's

5. Meridian has been in the clinical diagnostics field since its founding in 1977. Meridian has been a leader in the field of clinical diagnostics long before it pioneered its first *C. Difficile* enzyme immunoassay in 1992.

6. Within the broader category of infectious disease, Meridian's clinical diagnostic products are focused in the microbiology space. Meridian's "molecular diagnostic" products test for and identify the microbial invader; Meridian's products do not focus on or have any relationship with the genetics of the *human* patient.

7. There are typically several specializations within a Clinical Diagnostics Laboratory, including for example Microbiology, Chemistry, Hematology, Special Chemistry, and/or others. Each department has a manager or supervisor.

8. The manager/supervisor of each department identifies products needed for the department's work. The manager/supervisor gives the product description, or often a catalog number and supplier name, to a purchasing agent or the laboratory's purchasing department. The purchasing agent or purchasing department identifies a supplier for the product (if none was specified) and places an order under a pre-negotiated contract with the supplier that includes set pricing. Put differently, a supplier like Meridian will have already marketed its products and product capabilities to both the purchasing department and the manager/supervisor, and a contract will have already been entered into between Meridian and

the relevant purchaser, before the purchasing department goes to place an order. As a result, laboratory managers/supervisors and purchasing departments or agents are often aware of vendors and their available product lines from being contacted personally by sales representatives from the vendors. In this context, Meridian and Illumina are the “vendors” or “suppliers.”

9. Purchasing departments typically support the selection of manufacturers and vendors and negotiate contracts with them under which the individual orders for products are placed. The managers/supervisors of the laboratory departments request the products that are needed, but the purchasing personnel of the laboratory typically help select the vendor to supply the products and set up the contracts if more than one vendor provides the same product.

10. When there is more than one vendor of the type of product that a purchasing agent needs to procure, he or she will usually solicit bids from the multiple vendors that might offer that product and select the best overall option based on a number of different criteria including performance characteristics of the product and price.

11. The actual consumers, then, of clinical diagnostic products in the microbiology space – the space that Meridian targets as its primary market for its ILLUMIGENE and ILLUMIPRO products – are typically the Clinical Directors of clinical diagnostic laboratories, who acquire such products often at the request of personnel in the laboratories’ “Infectious Disease” or “Microbiology” departments or with the purpose to supply them to such departments. Since 1977, Meridian has sold diagnostic products to clinical diagnostic laboratories to assist them in diagnosing infectious diseases – specifically, microbiological infectious diseases.

12. The people within the clinical diagnostic laboratories who use Meridian’s clinical diagnostic products are typically situated in a “Microbiology” or “Infectious Disease” group or department. The products sold into this environment must be FDA-cleared for “*in vitro*” use, often referred to as “IVD” products. The ultimate decision-maker for buying Meridian’s clinical

diagnostic products – including Meridian’s ILLUMIGENE products – is typically the head of a clinical diagnostic laboratory, i.e. the Clinical Director (sometimes with input or required consent or “sign-off” from financial personnel such as a Purchasing Department, Materials Management department, or CFO or Director of Finance for the laboratory)

13. The Clinical Director is typically one of two (2) “director-type” positions within the larger laboratory setting of a hospital or reference lab environment. The other director at this level is the “Research Director.” Meridian does not market or sell to, and rarely if ever has any interaction with, the Research Director in a hospital or reference lab setting. As a result, to say that Meridian markets and sells its products to “hospital labs” or “reference labs” is an oversimplification of how the relevant consumer market is structured. In reality, there are two separate and distinct “touch-points” within any “hospital lab” or “reference lab;” the research lab and the clinical diagnostic lab. Meridian’s marketing and sales focus is only to one of those two distinct touch-points – the clinical diagnostic lab.

14. While hospitals and reference labs generally do purchase microbiological clinical diagnostic products, those products are purchased specifically for and by the microbiology departments within the clinical diagnostic labs of such hospitals and reference labs. Put another way, the consumers within a hospital or laboratory who interact with the relevant products in this case – who select products and drive the purchase of products – within each of those markets can be and, in actuality, are very different and very specific.

15. The relevant consumers in the clinical diagnostic laboratories of hospital labs and reference labs have been familiar with Meridian’s infectious disease clinical diagnostic products for more than twenty-five (25) years, and certainly well prior to 2008. Meridian has spent a great deal of money advertising and selling its clinical diagnostic products specifically to such consumers. In 2009, Meridian spent almost \$350,000 in marketing diagnostic products in the United States, with approximately \$250,000 of that expenditure dedicated to promoting

ILLUMIGENE products. The marketing and promotion for ILLUMIGENE's initial launch cost approximately \$100,000, which included both advertising and promotional funds. In 2012, Meridian spent about \$15,000 per month in advertising ILLUMIGENE products in the United States, and Meridian spends an additional \$75,000 annually in trade show promotion of Meridian. Attached as Exhibit A is a copy of Meridian's P&L for the ILLUMIGENE product for FY 2010 and FY 2011 which summarizes its sales revenue and marketing spend for the ILLUMIGENE product during those years. Given Meridian's marketing and sales strategy and the strict separation of the clinical and research disciplines within any given hospital lab or reference lab, the relevant consumers on the research side of such labs – i.e. the consumers of Illumina's products - probably have very little if any familiarity with Meridian. Conversely, Meridian's relevant consumers on the clinical diagnostics side of such labs probably have very little if any familiarity with Illumina.

Meridian's Competitors in the Clinical Diagnostic Space

16. Illumina is not and has not been a competitor of Meridian in the diagnostics field and does not offer diagnostic goods to the same consumers as Meridian. Because of the line of business Illumina is in, Illumina's consumers, where they otherwise overlap in the larger hospital lab and reference lab channel of trade, are those on the research side of such labs. Outside of this channel, Illumina also markets to and serves dedicated research institutions where human genomes are sequenced on a massive scale for, among other things, drug development purposes. Meridian has no involvement in that space whatsoever.

17. In working at Meridian for approximately 27 years, I have encountered many competitors and other companies who offer clinical diagnostic products and services, but I have never once heard of Illumina operating in the clinical diagnostic space, never once heard a customer refer to Illumina or its products, and never once encountered Illumina as a competitor. Specifically, Meridian's main competitors currently in the clinical diagnostic space are

BD/GeneOhm, Prodesse, Alere, Quidel, and Cepheid. Attached as Exhibit B are representative documents summarizing how the ILLUMIGENE product compares to the offerings from Meridian's competitors across various, relevant performance metrics. These competitors were identified by Meridian during the very early stages of the development of the ILLUMIGENE product, and competitor branding was considered when developing the ILLUMIGENE branding as shown in the attached Exhibit C.

18. I am personally familiar with Meridian's competitors in the diagnostic field because my work leads me to encounter competitors in a few different ways. For decades, I have had responsibilities related to the development of new diagnostic products, and the prioritization and funding of the research and development of such products is always pursued in the context of market research about the clinical need, and the other products that are currently fulfilling that need, if any. Moreover, in managing clinical trials and supervising the management of clinical trials, Meridian compares its products to the existing standard(s) of care within the clinical laboratories – testing to see if Meridian's products are as effective (or better) than the other available clinical solutions, and whether they are as safe (or safer). This, also, leads me to be keenly aware of the other companies that operate in the clinical diagnostics market.

19. In 2008, Illumina did not offer any FDA-cleared clinical diagnostic products whatsoever and did not offer any products or services related to infectious diseases or microbiology. Rather, Illumina was a company that offered human genetic sequencing services and supplied equipment and components for companies and laboratories to construct their own "assays" (scientific tests). Those products and services are directed toward and used by an entirely different category of consumers from consumers of FDA-cleared clinical diagnostic products.

20. The consumers of Illumina's products have been distinct from the consumers of Meridian's products since Illumina's inception, and were certainly distinct in 2008 and 2009. Today, the relevant consumers of Meridian's and Illumina's products remain distinct notwithstanding Illumina's recent addition of new products.

21. Since its inception, and certainly in the 2008-2009 time frame, Illumina's market for its human genetic services, components, and equipment for assays included research laboratories, *not* infectious disease clinical diagnostic laboratories. These research laboratories would purchase Illumina's human genetics services by sending away samples to be analyzed, and/or would buy components and equipment from Illumina to construct in-house assays ("Lab Developed Tests" or "LDTs"). None of Illumina's products at the time was FDA-cleared, IVD products. Rather, all of Illumina's products were approved for "Research Use Only," often referred to as "RUO" products. RUO products may not be used in clinical diagnostic laboratories to diagnose patients unless the lab itself performs its own validation studies – studies which Illumina by its own admission takes no part in. Illumina's market also includes academic laboratories, government research entities, and large pharmaceutical companies who do substantial research; none of these entities has a clinical laboratory component or uses clinical diagnostic products of the type that Meridian markets.

22. It is inaccurate for Illumina to broadly assert that its consumers were or are part of the "diagnostics" market. The only connection to "diagnostics" that would be possible in this context exists in very few laboratories, and does not involve any overlap between the *consumers* of clinical diagnostic products and the *consumers* of Illumina's products. In a few research laboratories, researchers create their *own, in-house* LDTs. They may use Illumina's products, along with components from many other suppliers, to *build* these assays. But those researchers and the people working with them are not buying "ready-made" clinical diagnostic products such as Meridian's – they are buying components and then *building* in-house

diagnostic assays themselves. Asserting that Illumina's components and equipment compete with Meridian's clinical diagnostic test kits based on this logic would be much like saying a bolt manufacturer competes with an automobile manufacturer because bolts are used to build cars.

23. And just as a consumer would not expect a bolt manufacturer to begin making cars, the personnel working in research laboratories who used Illumina's services and products since Illumina's inception, and certainly in 2008 and 2009, would not have expected Illumina to begin selling "ready-made" IVD diagnostic products. Personnel within clinical diagnostic laboratories in 2008 and 2009 would probably never have even heard of Illumina at all because *Illumina made no products for such personnel to use or purchase.*

24. I have reviewed the deposition testimony of Naomi O'Grady, an employee of Illumina and who gave a statement in this case on behalf of Illumina. Ms. O'Grady, at her deposition, testified that when laboratories use Illumina's products to make diagnostic LDTs, the output is a "test report" sent by the laboratory to the ordering physician, and that Illumina would not review the report, would have no control over the report's content, and would have no control over the report's branding. (O'Grady Deposition, at 92-94) I agree with this part of Ms. O'Grady's testimony, and it means that Illumina's RUO components or equipment used in LDTs would not have given Illumina any market presence or reputation whatsoever in the clinical diagnostics field. The entity providing and branding the diagnostic answer, to the extent this answer is "branded" at all, would always be the laboratory or the institution who has built the LDT – not Illumina – and the recipient of that diagnostic answer would not be aware of the source of any of the equipment used in arriving at the answer.

25. Put differently, and by way of example, if a clinician were to request Johns Hopkins to run a test on a patient sample in its clinical diagnostic laboratory, Johns Hopkins would communicate the results of the test to the clinician in the form of a report. This "deliverable" would carry Johns Hopkins branding, if it carried any branding at all, and nowhere

on this report would Johns Hopkins refer to or indicate the source or the name of the components it used to build its LDT that derived the information appearing in the report. As an analogy, the LDT phenomenon is not unlike the situation where one hires a contractor to build a bathroom in one's home. The consumer in this analogy is not aware of whether the contractor used Black & Decker or Stanley tools to build the bathroom; he is only aware that at the end of the job, he now has a bathroom. As a result, it simply would not make sense to say that the sale of RUO products to laboratories that were making LDTs, in and of itself, somehow puts Illumina in "the diagnostics market." It does not.

26. Illumina's purchase of Epicentre Technologies Corporation, the maker of "DisplaceAce" is only a further example of this dynamic, i.e., the difference between the consumers of Meridian's products and the consumers of Illumina's products. DisplaceAce is a component – a bolt for the car – not a test or kit that can be used to determine whether a particular patient is afflicted with a particular infectious disease. Someone trying to diagnose the presence of an infectious disease in a clinical diagnostic laboratory cannot use DisplaceAce by itself for this purpose, nor would such person be aware whether DisplaceAce was being used as a component within a kit.

27. In November 2008, Meridian applied to register its ILLUMIGENE mark for diagnostic *kits* – FDA-cleared "ready-made" IVD assays to diagnose infectious diseases in Clinical Diagnostic Laboratories. In April 2009, Meridian applied to register its ILLUMIGENE MOLECULAR SIMPLIFIED & design mark for the same products directed to the same market. At the time of Meridian's filings, consumers in the clinical diagnostic laboratory would not have had any awareness of Illumina or its products because Illumina did not offer any products they could use; Illumina had no IVD products in its product portfolio, but rather only RUO products for use by consumers working in research laboratories.

28. Even today, the consumers of Meridian's clinical diagnostic products and the consumers of Illumina's products are not the same. From its website, Illumina's product line still appears to consist of human genetic services and components and equipment for assays. As discussed above, consumers of such services and products are research laboratories, not clinical diagnostic laboratories. It is true that Illumina received FDA approval on April 28, 2010 for the "Illumina VeraCode Genotyping Test for Factor V and Factor II" ("VeraCode Genotyping Test"), but Illumina's website does not appear to market that product, and I have not encountered it in my interactions with consumers in clinical diagnostic laboratories or through my or my staff's attendance at tradeshow in the industry. My understanding is that Illumina has discontinued that product and that it is no longer available.

29. It is also true that Illumina has two current IVD products called the MiSeqDx Cystic Fibrosis 139-Variant Assay and the MiSeqDx Cystic Fibrosis Clinical Sequencing Assay (the "MiSeqDx Cystic Fibrosis Assays"). But the FDA clearance for the MiSeqDx Cystic Fibrosis Assays did not issue until late 2013, years after the 2008-2009 time period.

30. Even if Illumina were given the benefit of the doubt about having an IVD product in the marketplace with its VeraCode Genotyping Test or MiSeqDx Cystic Fibrosis Assays, the fact remains that the consumers of those assays are very different from the consumers of Meridian's infectious disease diagnostic products. The VeraCode Genotyping Test and MiSeqDx Cystic Fibrosis Assays test *human genes* in an effort to identify genetic markers/mutations. Meridian's molecular diagnostic products attempt to identify microbial pathogens, not particular sequences of human DNA.

31. The personnel who would perform tests using Illumina's VeraCode Genotyping Test or MiSeqDx Cystic Fibrosis Assays are found in the clinical diagnostic laboratories' "Hematology," "Oncology," or "Pathology" groups or departments. Such groups or departments are usually separate from the "Infectious Disease" or "Microbiology" departments or groups who

are the consumers of Meridian's clinical diagnostic products. Purely by the nature of the answers each department is seeking in the analysis of a particular sample, the work and tools of the two kinds of clinicians will not typically overlap.

The High Level Of Sophistication And Attention Of Meridian's and Illumina's Consumers

32. Although they are distinct groups of people, everyone involved in purchasing and using either Meridian's clinical diagnostic products or Illumina's services and products has an extremely high level of education and sophistication.

33. The user of a Meridian clinical diagnostic product is an educated and highly trained person within an "Infectious Disease" or "Microbiology" department or group in a Clinical Diagnostic Laboratory. He or she would usually have a bachelor's degree in a scientific field and training as a Medical Technologist.

34. The user of Illumina's VeraCode Genotyping Test or MiSeqDx Cystic Fibrosis Assays, to the extent that those products were/are on the market, would also be educated and highly trained. He or she would usually have a bachelor's degree in a scientific field and training in molecular research. The needs of the users of these products would drive the clinical diagnostic laboratory's decision to purchase them. Both of these types of users pay close attention to the product they are selecting and using. The users' ability to use the products at issue are restricted by FDA regulations pertaining to the intended uses of the products, and the users also must take great care because they are diagnosing medical conditions of patients.

35. The decision-maker in setting up a pricing contract with Meridian for purchasing Meridian's clinical diagnostic products, including ILLUMIGENE products, and in this case the relevant consumer of Meridian's products, is typically a Clinical Director, the head of a clinical laboratory. The people in that position typically have even more education and credentials, usually including a Masters degree or Ph.D. They typically have a great deal of experience in clinical laboratories and sophisticated knowledge of the industry. Clinical Directors pay close

attention to the pricing contracts entered into by their laboratories and the products they make available to their personnel through those contracts.

36. The Clinical Director, and the purchasing agents that work with him, are both very familiar with what diagnostic tests are available for various infectious diseases and what companies provide or offer those tests. It is their job to know, and although some of the product names are complex or somewhat similar to one another, they are repeated with enough frequency that they are thoroughly learned.

37. For Clinical Directors, it is a requirement of their job to be well informed about the products that are available, the names of those products, and the companies that offer them.

38. Both the Clinical Director and the purchasing agents working with him pay close attention to the products they buy, the sources of those products, and the price per test. In all circumstances, these individuals are highly knowledgeable of which company (by name) can source a particular product.

39. Further, it typically requires multiple meetings and/or calls between Meridian and its customers to enter into a contract for Meridian's clinical diagnostic products. Meridian and the relevant consumer will engage in significant negotiation over products, volumes, and prices. At all times, Meridian's customers are fully aware of what types of products Meridian can offer and what types it does not offer, as well as the names of those products.

40. I cannot over-emphasize the fact that during these meetings and/or calls, the relevant consumer understands that he is interacting *with Meridian Bioscience* to determine which of Meridian's products, including without limitation the ILLUMIGENE product, are suitable for the consumer's needs. Similarly, the relevant consumer understands that he is interacting *with Illumina* to determine which of Illumina's products, including without limitation its MiSeq, MiSeq, and TruSeq products, might be suitable for the consumer's needs. In this context, it is

the *company's* brand that is foremost in the consumer's mind – not the names of the products that the company offers to meet a particular need.

41. The purchasers of Meridian's diagnostic products are not only very sophisticated, but they seek to answer a very detailed set of questions prior to purchasing. Lab Directors who make purchasing decisions examine in detail, among other things:

- the product's diagnostic target
- the product's intended use
- the product's sensitivity
- the product's specificity
- the product's price
- whether the instrument to read the product costs money to purchase and/or run, and how much
- the sample type the product uses (e.g., throat swabs vs. nasal swabs)
- the type of media used for transfer of the sample or other component
- the available insurance reimbursement
- turnaround time of a result
- required education and training of the technical staff who will run the test
- whether the product will fit with the lab's current work flow.

In conducting this detailed analysis, it would be absurd to even suggest that the Lab Director would look no further than the name(s) appearing on the product and conclude, on that basis, that one product is similar to, related to, compatible with, or a substitute for, another.

42. The consumers of Illumina's human genetics services, and Illumina's components and equipment for assays, are *researchers* in research laboratories, hospital research labs, academic laboratories, government research entities, or large pharmaceutical companies. Such personnel usually have a bachelor's degree in a scientific field and training in

molecular and genetic research, and often have doctorate-level scientific degrees. They are highly trained scientists and laboratory technologists who pay close attention to the equipment, components and services that they use, in part because their results must be precise, verifiable and reproducible. They typically disclose the equipment and components that they use when they write scientific papers that include their methodologies.

The Substantial Price Differences Between Meridian's Products And Illumina's Products

43. Even if the same consumer encountered both Meridian's clinical diagnostic products (such as the ILLUMIGENE molecular diagnostic kits and the ILLUMIPRO instruments that read/interpret the test results) and Illumina's products (such as Illumina's VeraCode Tests and the BeadXPress equipment that reads them, or MiSeqDx Cystic Fibrosis Assays and the MiSeq platform that reads them), they would not be likely to confuse the source of the products, in part because of the extreme price difference between them.

44. Meridian's ILLUMIGENE molecular diagnostic products are marketed for between \$1,250 and \$3,000 per kit of 50 tests (\$25 to \$60 per test). Meridian's ILLUMIPRO instruments **are included at no additional charge with the purchase of the initial kit**. The pricing strategy for Meridian's ILLUMIGENE and ILLUMIPRO products was carefully thought out from the beginning of the product's development. Attached as Exhibit D is the output of a study Meridian commissioned during development to determine the best possible price point for its ILLUMIGENE and ILLUMIPRO products. Documents summarizing Meridian's resulting and current pricing strategy for its ILLUMIGENE and ILLUMIPRO products are attached as Exhibit E.

45. I understand from Illumina's website and the deposition testimony of Illumina's employees Karen Possemato and Naomi O'Grady: (a) that Illumina's BeadXPress readers, used to interpret the VeraCode test results at the time those tests were on the market, were priced at about \$95,000; (O'Grady Deposition, at 104, and Possemato Deposition, at 54); and

(b) that Illumina's MiSeqDx platform, used to interpret the MiSeqDx Cystic Fibrosis Assays, is priced at about \$125,000. (O'Grady Deposition, at 22-25). This price does not include the cost of the components used in the actual test itself. Clearly a purchaser would be very likely to note the dramatically different order of expense between the two companies' products, even apart from the major, obvious differences in what the products are and what they do, as discussed above.

Prefixes In Product Names In the Medical Products Field

46. I understand Illumina argues that the prefix "ILLUMI" is somehow more noticeable or more entitled to weight than the suffix that follows it in ILLUMIGENE, ILLUMIPRO, and ILLUMIPRO-10. Based on my extensive experience in the field of medical products and knowledge of competitive diagnostic products, I disagree with Illumina's position.

47. In the medical field, the prefixes of product names are often the same or very similar across different companies who compete with each other. For example, "Immuno" is an extremely common prefix used in the product names of many different companies, such as the Quest Immunocap, the Allere ImmunoComb, and the Meridian ImmunoCard. Because of this pattern of concentrations on the same prefixes, consumers of medical products do not merely focus on the prefixes of words more so than, or at the expense of, the suffixes and/or the entirety of the word, or give the prefixes special weight or attention. If anything, given the consequences of using the wrong product by casually focusing on only part of a product name, consumers of medical products are attuned to the need to take in and consider the entirety of the product names.

48. The individuals responsible for purchasing decisions in the relevant channels of trade have a keen awareness of the company names used by the suppliers of the products they purchase. When they request or order products, they focus on and use the name of the supplier of the product as well as the full name of the product itself. They appreciate that

mistakes in medical supply orders are potentially very costly, and they proceed carefully and according to the purchasing process; not impulsively or in a great hurry.

49. An especially clear example of the dynamic described above can actually be found in another product name prefix that *Illumina itself* began using years after Meridian began using it. Meridian has registered the marks TRU RSV, TRU FLU, TRU EBV-M, and TRU EBV-G, TRU BLOCK, TRU LEGIONELLA, and TRU HSV 1 AND 2 IGG. The earliest uses of these marks were in 2006 and 2007 and the earliest registrations of them were in 2008. All of these registrations are in International Class 5, and recite "diagnostic tests" or "diagnostic test kits."

50. Subsequently, Illumina has registered the mark TRUSEQ, with a claimed first use date of November 22, 2010, and TRUSIGHT, with a claimed first use date of September 1, 2012, and now owns an allowed application for TRUGENOME, a mark which it is currently using. Illumina's TRUSEQ registration covers "reagents and reagent kits" for use in "diagnostic and clinical research"; "product development" within the "fields of scientific, diagnostic and clinical research"; and "scientific instruments" within the "fields of scientific, diagnostic and clinical research," and its TRUSIGHT registration covers "reagents, enzymes, and nucleotides for nucleic acid sequencing for medical purposes." Similarly, its TRUGENOME application (and its use of the mark) covers "nucleic acid sequencing and analysis services for medical purposes."

51. It is not surprising to me that Illumina did not view the "TRU-" prefix shared by its and Meridian's marks as particularly problematic for both entities to be using or think that its TRU- mark was too close to Meridian's TRU- marks based on Meridian's prior registration and use of several marks with this same prefix. Not only were the products different, but Illumina's mark had a different suffix, rendering its TRUSEQ, TRUSIGHT, and TRUGENOME marks sufficiently different from Meridian's TRU RSV, TRU FLU, TRU EBV-M, and TRU EBV-G, TRU BLOCK, TRU LEGIONELLA, and TRU HSV 1 AND 2 IGG.

52. Illumina's apparent position in using and registering its TRU-formative marks, notwithstanding Meridian's prior use and registration of its own TRU-formative marks, makes sense. Its apparent reversal of its position in the current dispute does not make sense. The parties' respective TRU-formative marks cover *the same types of goods and services that are at issue in this proceeding*. Illumina's own efforts in selecting, applying for, using, and registering its TRU-formative marks directly contradict the position it is trying to assert in this proceeding. Consumers of medical and medical research products are careful and sophisticated, and they do not give undue weight to just the beginnings of product names, or ignore the endings.

53. I am not aware of any instances of actual confusion between Illumina's TRU-formative marks and any of Meridian's TRU-formative marks, nor would I expect there to be any confusion, despite the fact that both parties' TRU-formative marks are product marks; not house marks.

There Is No Actual Confusion Between Meridian's Trademarks And Illumina.

54. To my knowledge, after extensive marketing of Meridian's ILLUMIGENE clinical diagnostic products and the ILLUMIPRO readers over the course of 6+ years, there have been *no* reported incidents of confusion between these products and Illumina or its products, and had there been instances of actual confusion, I would be aware of them.

55. Meridian first used the ILLUMIGENE name in connection with clinical trials in December 2008. Meridian has promoted ILLUMIGENE under that name since then, at all times, including at trade shows, individual meetings and customer presentations. Representative examples of Meridian's use of its ILLUMIGENE and ILLUMIPRO brands are attached as Exhibit F. Trade shows where Meridian introduced its ILLUMIGENE products to prospective purchasers included: (a) the 2009 Clinical Virology Symposium ("CVS") conference held 19-22 April 2009 in Daytona Beach, Florida; (b) the 2009 American Society for Microbiology ("ASM") conference held 16-18 May 2009 in Philadelphia, Pennsylvania; (c) the 2009 American

Association for Clinical Chemistry (AACC) conference held 19-23 July 2009 in Chicago, Illinois; and (d) the 2009 Association for Molecular Pathology (AMP) conference held 19-22 November 2009 in Orlando, Florida. Internal summaries of Meridian's participation at these trade shows are attached as Exhibit G. Photographs representative of Meridian's presentation of the ILLUMIGENE brand at these trade shows are attached as Exhibit H.

56. I understand that Meridian's public marketing of its ILLUMIGENE and ILLUMIPRO products at these trade shows, in particular the 2009 CVS and 2009 ASM conferences, predates Illumina's filing of its ILLUMINADX application – the first trademark application filed by Illumina which made reference to "clinical diagnostic" products or services.

57. Since obtaining FDA clearance and launching ILLUMIGENE products in July of 2010, Meridian has promoted them through trade shows, advertisements in trade magazines, promotion on Meridian's website, individual meetings, brochures, and customer presentations. Meridian has sold ILLUMIGENE products to more than 700 different accounts in the United States. Beyond those who have actually purchased ILLUMIGENE products, over 4000 potential consumers have been exposed to the ILLUMIGENE and ILLUMIPRO products through our marketing efforts. I estimate that Meridian's ILLUMIGENE advertising and promotion has reached almost 100% of the possible accounts in the marketplace, particularly since ILLUMIGENE is advertised in trade publications that reach virtually every clinical laboratory. With all of this marketing and sales activity, there have still been absolutely no accounts of purchasers or others confusing the source of ILLUMIGENE as being Illumina, nor confusing Meridian as being the source of any Illumina products.

58. In my position, I would expect to hear about any reported confusion from a consumer related to our trade shows or sales in clinical laboratories.

Attendance At Broad-Based Trade Shows In This Industry Does Not Mean There Is Any Overlap In Consumers.

59. I understand Illumina argues that simply because it has attended some of the same trade shows as Meridian, the consumers for both Illumina's and Meridian's products are somehow the same. However, in the medical industry, attendance at broad-based trade shows does not mean, in and of itself, that all the companies at the shows are competitors or even sell products to the same consumers.

60. For example, the American Association for Clinical Chemistry Annual Meeting is a broadly-focused trade show where the vast majority of products and services on display, including such things as blood analyzers and gas analyzers, have nothing to do with the clinical diagnostics field. Further, many products on display are designated for Research Use Only ("RUO" products).

61. Similarly, the Association for Molecular Pathology trade show, although it is in the molecular pathology field generally, includes many companies who offer human genetic and polymorphism products and services which are not similar to Meridian's clinical diagnostic products and which do not have the same users. The same is true of the Clinical Lab Expo and the Deutsche Bank Annual Health Care conferences: a wide array of products and services are presented at those conferences to a wide variety of professionals and potential consumers, and simply attending or having a marketing presence at them does not mean that companies are marketing to the same consumers or are competitive with one another.

62. In short, Meridian's clinical diagnostic products are marketed and sold to different consumers than Illumina's products and services, and mere attendance at some of the same trade shows does not change that.

63. What is more, the fact that Illumina and Meridian have attended the same trade shows *and that the companies have experienced absolutely no confusion from the attendees of*

those trade shows only goes to show that the customers and potential customers are *not* confused and are by no means *likely* to be confused between the trademarks discussed above.

If A Company Planned To Market Products In The Diagnostic Market, It Would Design And Manufacture Those Products Under Strict, FDA-Regulated "Design Control" Standards From The Outset.

64. I understand that Illumina may argue in this proceeding that it always intended to progress seamlessly from RUO products to IVD products and that such progression was natural and expected. I have reviewed the deposition testimony of Illumina's employee Naomi O'Grady, and portions of that testimony lead me to conclude, based on my experience in the diagnostics industry, that Illumina's attempt to move into the diagnostic market was by no means natural or expected, and instead was an unexpected pivot.

65. To explain, I need to discuss the term "design control," which is a way of designing products to meet the rigorous regulations of the FDA for IVD products.

66. To obtain FDA clearance, IVD products must be designed, manufactured and verified according to very strict requirements, sometimes referred to as being made "under design control." The FDA requirements include, but are not limited to:

- Design and Development Planning: This defines the activities required for the new product design. This must be updated throughout the design development process.
- Design Inputs/Design Outputs: We need to establish and maintain documents which adequately evaluate that a design output meets the requirements for the design input.
- Design Verification/Design Validation: We are required to maintain procedures which verify or validate the products design.
- Design Transfer: We need to develop procedures which insure that device design is correctly translated into product specification
- Design History File ("DHF"): All documentation must be contained or referenced in this file, including any design changes.
- qualifying vendors/suppliers to be certified to ensure that their products and quality systems are suitable for our design and conform to regulations

- testing and validation of various kinds, including the stability of the product as a whole as well as the stability of the individual components
- developing and maintain manufacturing specifications for every component of an assay
- end user interface validation to ensure that the product can be run correctly and generate appropriate results
- mitigation of potential problems in risk assessment (FEMA)
- ensure that all software is compliant
- conducting clinical trials on the products and submitting that information to the FDA to obtain clearance to sell in the United States
- keeping detailed records of all of the above activities in the DHF and being prepared for an FDA audit

These requirements are set forth in 21 CFR §8.20.1 et seq. Examples of some of the many, detailed, internal design control documents Meridian produced during the development of its ILLUMIGENE and ILLUMIPRO products are attached as Exhibit I.

67. At pages 169 to 174 of Ms. O'Grady's deposition, she discusses a product that Illumina had designed and built named iScan. Ms. O'Grady testified that in July 2009, iScan was being sold and labeled as an RUO product. She then testified that in making a plan to build an IVD iScan system that could be submitted to the FDA in a 510(k) submission, Illumina would have to do something called "document remediation," or alternatively a new scanner would need to be designed under "design control." (O'Grady Deposition, at 168-174)

68. "Document remediation" in this context means a process of taking an existing, designed product, and then going back through all of its parts, suppliers and processes to validate them to the same extent as if they had been originally designed under FDA-mandated "design control." It is not a simple process, and carries with it a great amount of risk and cost. Even assuming that every part, vendor, and process coincidentally meets the regulatory requirements, the process would carry a large cost, as each aspect must be re-validated and re-

qualified. On top of that, there is a very significant risk that the parts, vendors, and processes, when tested, will not meet the regulatory requirements. If that is the case, not only would the non-qualifying aspect need to be replaced with one that can be sufficiently validated, but also the parts and processes that interact with the non-qualifying would need to be re-designed and re-validated to accommodate the change.

69. For these reasons, designing a product for RUO purposes originally, and then doing "document remediation" to make the design records suitable for submission to the FDA for potential clearance as an IVD product, would likely cost 1.5x to 2x what it would cost to design a product under "design control" from the beginning (and perhaps much more). And there is a risk that a complex problem with a vendor, process, or part would arise that would make it many times more expensive.

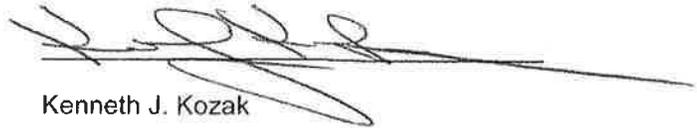
70. Because of the costs and risks involved with "document remediation," a reasonable company that planned *from the beginning* to make an IVD product would not design it outside of "design control" principles. If a reasonable company is considering "document remediation" for a product, it is because they never intended to make it an IVD product at the outset, and only thought about the IVD field later, after the RUO product had already been designed.

71. At pages 215-216 of Ms. O'Grady's deposition, she testified about potential "delays in QSR compliance" as a risk to the achievement of some revenues that were being forecasted. "QSR compliance" is another aspect of "design control" principles, in this case specific to manufacturing techniques. The FDA requires QSR (Quality System Regulation) compliance in the manufacturing of devices that it clears. Again, if a reasonable company is "backing up" in a sense and changing its existing manufacturing techniques to be QSR compliant, it is unlikely that it intended from the beginning to operate in the IVD, FDA-regulated market. Otherwise, the manufacturing would be designed to be QSR compliant from the outset,

at much less cost than setting up the manufacturing in some other way and then going back to fix it.

Pursuant to 37 C.F.R. § 2.20, the undersigned being warned that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements and the like may jeopardize the validity of the application or document or any registration resulting therefrom, declares that all statements made of my own knowledge are true; and all statements made on information and belief are believed to be true.

Executed on February 6, 2015.



Kenneth J. Kozak

CERTIFICATE OF SERVICE

I hereby certify that a true and complete copy of the foregoing **OPPOSER'S**
TESTIMONY has been served on Applicant's attorney of record by sending one copy on April 6,
2015 via first-class mail to:

J Michael Hurst
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Sarah Beno Couvillion