1 UNITED STATES PATENT AND TRADEMARK OFFICE
2 BEFORE THE PATENT TRIAL AND APPEAL BOARD
3 ----------X
4 MERCK SHARP & DOHME, LLC,
5 Petitioner,
6 Case No. IPR2024-00240
7 -against- Patent No. 11,591,393
8
9 THE JOHN HOPKINS UNIVERSITY,
10 Patent Owner.
11 ----------X
12 HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY
13 DEPOSITION OF
14 BRIAN J. SEGERS
15 NEW YORK, NEW YORK
16 DECEMBER 17, 2024
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20
21 REPORTED BY: KIARA MILLER
22 FILE NO.: 562906

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13 Deposition of BRIAN J. SEGERS, taken on behalf
14 of PETITIONER, at REMOTE LOCATION, New York,
15 New York, commencing at 12:02 PM, DECEMBER 17,
16 2024, before Kiara Miller.
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18
19
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21
22

1 A P P E A R A N C E S:

2

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16 BY: MADELYN MCCORMICK, ESQ.

17

18 ALSO PRESENT:

19 ZOOM TECH, KELI WELCH

20 SEAN SHERIDAN, ESQ. CHARLES RIVER ASSOCIATES

21 WAYNE E. LE BLANC, JR. (PARALEGAL)

22 KAREN MOREIRA, IN-HOUSE COUNSEL, MERCK

1 TECH WELCH: Please make sure that you
2 don't speak over one another. Zoom
3 tends to only allow one person at a
4 time to speak. So in order to make
5 sure everyone is able to get a clear
6 record, please wait until one person
7 is finished speaking before you begin
8 to speak. If anyone does have any
9 technical issues at any time, I'm
10 going to put my contact information in
11 the chat. Please feel free to reach
12 out to me either by email or by phone,
13 if you need any assistance with
14 anything, I'll be happy to help with
15 that. I have also created a shared
16 folder, I'm going share the link to
17 that. Any exhibits that are
18 introduced will be uploaded to that
19 folder as they are introduced. There
20 should be a test exhibit there just to
21 make sure that you are able to see or
22 download anything that is uploaded.

1 So that will be available. You may
2 need to refresh your screen or refresh
3 your browser tab as something is
4 introduced and then it should appear,
5 but if you do need assistance, please
6 feel free to reach out to me, I'll be
7 happy to help.
8 And with that, I'll pass it over to
9 Ms. Miller to get us started.
10 B R I A N J. S E G E R S, after having first been
11 duly sworn by a Notary Public of the State of New
12 York, was examined and testified as follows:
13 COURT REPORTER: Please state your
14 name and address for the record.
15 THE WITNESS: Brian Segers. My
16 address is 5213 Cascades Drive,
17 College Station, Texas 77845.
18 EXAMINATION BY
19 MR. ZEILBERGER:
20 Q Good morning, Mr. Segers. How are you?
21 A I'm well. Good morning.
22 Q My name is Daniel Zeilberger. I'm with

1 the Paul Hastings law firm, and I'm appearing
2 today for petitioner Merck. I'm joined by
3 Preston Ratliff, Jessica Stauring, and
4 Elizabeth Moore, also with Paul Hastings, and
5 appearing for petitioner Merck. In addition
6 Merck in-house counsel Karen Moreira is also
7 on the line, and it is possible, at some
8 point today, Mark Stewart, also in-house
9 counsel of Merck, will join. And in
10 addition, Dr. Sean Sheridan has also joined
11 the line.
12 How are you feeling today?
13 A I'm well. How are you?
14 Q Well, thank you.
15 Is there any reason you cannot testify
16 today, truthfully and accurately?
17 A There is not.
18 Q And you understand you're under oath
19 today?
20 A I do.
21 Q You are a consultant, correct?
22 A Yes. That's -- I'm an economist and I

1 do economic consulting.
2 Q And you work for Coherent Economics; is
3 that right?
4 A That's right.
5 Q How long have you been working for
6 Coherent?
7 A I think my first day was August
8 1st, 2022.
9 Q What's your standard hourly rate for
10 work as an expert?
11 A $675.
12 Q And is that how much you're being
13 compensated for this proceeding?
14 A I believe so.
15 Q Approximately, how much time have you
16 spent working on this matter?
17 A I'm not sure. I haven't totaled up the
18 hours. I'd have to look.
19 Q Was it more than 10 hours?
20 A Yes.
21 Q More than 20 hours?
22 A I believe it is, yes.

1 Q More than 50 hours?
2 A I don't know. I'd have to look.
3 Q You don't have a -- kind of a rough
4 estimate of how many hours you worked on?
5 A It may be in that ballpark. Like I
6 said, I'd have to look at the invoices to
7 give you a more precise number.
8 Q Before working on this matter, have you
9 ever done work for JHU?
10 A No, I have not.
11 Q Before working on this matter, had you
12 ever worked with the Fish & Richardson law
13 firm?
14 A I have.
15 Q In what context?
16 A So I've worked as expert for cases for
17 Fish twice before.
18 Q Which cases?
19 A There was a Hatch-Waxman case for
20 Exeltis involving a drug called Slynd, and
21 there was a patent damages case involving
22 testosterone replacement therapy for

1 Lipocine.
2 Q Do you have any documents in the room
3 with you today, whether in hard copy form or
4 loaded on to a computer?
5 A I have a hard copy of my report. And I
6 believe it has the appendices to my report,
7 as well.
8 Q Do you have anything else?
9 A No.
10 Q Is the copy of your declaration that you
11 have with you a clean copy or does it have
12 any notes or tabs?
13 A It's clean. It's a print of the IPR
14 stamped document.
15 Q Can you please tell us who's in the room
16 with you today?
17 A Yes. Counsel Madelyn McCormick.
18 Q Anyone else?
19 A That's all.
20 Q Did you spend any time preparing for
21 today's deposition?
22 A I did.

1 Q How much time?
2 A I met with Ms. McCormick yesterday and
3 spent maybe a couple of hours after I
4 arrived.
5 Q Did you spend any time preparing for
6 today's deposition before yesterday?
7 A Some. I think I read through my report
8 and the attached documents.
9 Q How much time did you spend before
10 yesterday preparing for today's deposition?
11 A Again, just a few hours; maybe a day in
12 total.
13 Q To prepare for today's deposition, other
14 than the lawyers representing JHU, did you
15 speak with anyone about this case?
16 A I think I spoke with a couple of members
17 from my team who assisted me with the report.
18 Q And who are they?
19 A So one would be Sebastian Peinado. And
20 another is Tuna Coluk.
21 Q Other than those two individuals and
22 JHU's lawyer, did you speak with anyone to

1 prepare for today's deposition?
2 A No.
3 Q As you alluded to a few moments ago, you
4 prepared a declaration for this case,
5 correct?
6 A Yes.
7 Q And you signed that declaration on
8 October 4th, 2024; is that right?
9 A Yes.
10 Q Your declaration including the copy you
11 have with you today is stamped JHU 2191 at
12 the bottom right; is that correct?
13 A Yes. That's the stamped number on the
14 copy I have with me.
15 Q And the copy you have with you is 48
16 pages long?
17 A Yes. The last page number is 48.
18 Q Did you read your declaration carefully
19 before you signed it?
20 A I did.
21 Q Did you understand every statement,
22 opinion, and conclusion included in your

1 declaration before you signed it?
2 A Yes. I made every effort to.
3 Q Are you confused by any of the wording
4 contained in your declaration?
5 A I don't believe so.
6 Q Are you familiar with the content of the
7 documents that you reference in your
8 declaration?
9 A Yes.
10 Q Are there any errors in your
11 declaration?
12 A As I sit here right now, not that I'm
13 aware of.
14 Q And you don't have any corrections to
15 make to your declaration that you wish to
16 make today?
17 A Not at present; no, I don't.
18 Q In preparing your declaration, did you
19 have any conversations with any JHU employees
20 or scientists?
21 A No. I did not.
22 Q You're retained to analyze commercial

1 success relating to the use of KEYTRUDA for
2 the treatment of MSI-high CRC, correct?
3 A That's correct, yes.
4 Q When analyzing commercial success, what
5 factors do you typically consider?
6 A Well, I list some of those in my
7 declaration. But some of the ones that the
8 declaration covers are the sales, the number
9 of patients being treated, the profits, as
10 well as market share.
11 Q Appendices 2 through 10 of your
12 declaration contain various graphs and charts
13 illustrating your analysis; is that fair to
14 say?
15 A Yes.
16 Q Did you independently verify the
17 accuracy of the data used in your analysis?
18 A So it's limited on the data that I had
19 available, but yes, I looked at the data that
20 was given to me, which was a limited set, and
21 it created those appendices based on the
22 data.

1 Q So what did you do to verify the data
2 that you used is accurate?
3 A You have a particular data set you're
4 referring to?
5 Q Did you engage in a different process
6 for verifying the accuracy of the data that
7 you used for different data sets?
8 A Well, it could be depending on what it
9 was, yes. So if it's information out of
10 10Ks, that's one thing. If it's data
11 provided to us from Merck and it's revenue
12 for KEYTRUDA, or whether it's the IQVIA
13 patient data, you know, those are all from
14 different sources.
15 Q Okay. What did you do verify the
16 accuracy of the IQVIA data that you just
17 referenced?
18 A Well, so by -- what I did was I looked
19 at the data, and I examined the fields and I
20 guess I would say my ability to sort of
21 verify the accuracy of IQVIA's data is
22 limited, other than I understand they're in

1 the business of providing this sort of data
2 and have a reputation for providing that
3 data.
4 Q Did you only rely on data that was
5 provided to you to perform your analysis?
6 A No. I think I just mentioned my
7 analysis also relies on some publicly
8 available data like 10Ks, both from Merck and
9 from Bristol Myers Squibb.
10 Q So the 10K data, is that data you
11 independently retrieved; is that right?
12 A Yes.
13 Q In your summary of opinions in your
14 declaration at Paragraph 8, you note that
15 KEYTRUDA has been approved as a last-line
16 treatment for MSI-high solid tumors and as a
17 second-line treatment for MSI-high colorectal
18 cancer; is that correct?
19 A Do you mind if I take a look at it?
20 Q Please.
21 A Okay. Yeah.
22 Can you point me to where you're reading

1 it?
2 Q Paragraph 8.
3 A Okay. On Page 6.
4 Q I believe Paragraph 8 bridges between
5 Pages 5 and 6.
6 A Yep. Okay. So, I -- I don't recall
7 exactly how you worded it, but, yes, it does
8 talk about those things.
9 Q In Paragraph 8, you don't reference any
10 first-line treatment for MSI-high colorectal
11 cancer, correct?
12 A That paragraph does not reference it,
13 that's correct.
14 Q So did you not rely on first-line
15 treatment for MSI-high colorectal cancer in
16 preparing your opinions?
17 A I'm sorry. How do you mean did I not
18 rely on it? I guess I'm confused by the
19 wording of your question.
20 Q Did you rely on first-line treatment for
21 MSI-high colorectal cancer using KEYTRUDA for
22 purposes of your opinions?

1 A I would say that for the purpose of my
2 opinions, as they're expressed in the report,
3 I relied on sales of KEYTRUDA for MSI-high
4 CRC. So I think that would include even
5 first-line treatment.
6 Q Okay. So is there a reason why you
7 didn't mention first-line treatment in
8 Paragraph 8?
9 A I don't know about that paragraph. I
10 think I do mention it later on in the report.
11 I think -- sorry. I'll just add to
12 that.
13 I think this paragraph in particular was
14 talking about these particular FDA approvals
15 that were cited.
16 Q What do you mean?
17 A I'm just looking at the footnotes. That
18 it's cited to here, actually, I guess it's
19 citing to KEYTRUDA's website, so...
20 Q Right. And is there -- is that why you
21 don't mention first-line treatment in
22 Paragraph 8, because it's your understanding

1 it doesn't have an FDA approval?
2 A No. That's not my understanding.
3 As I said, I think I mentioned
4 first-line treatment later on in the report.
5 Q Right. And I was just trying to
6 understand if there is a reason why you don't
7 mention it in your summary of your opinions,
8 whereas you do mention second-line treatment
9 and last-line treatment?
10 A No. I don't believe there's a reason.
11 Q If you go back a couple pages to
12 Paragraph 5 of your declaration.
13 A Okay.
14 Q You state in Paragraph 5 that you
15 understand that the use of Merck's branded
16 cancer drug KEYTRUDA for the treatment of
17 microsatellite instability high or mismatch
18 repair deficient colorectal cancer practices
19 the invention claimed the '393 Patent,
20 correct?
21 A That's correct.
22 Q What's the basis for your understanding

1 that this use practices the invention claimed
2 in the '393 Patent?
3 A Well, first of all, I understand that's
4 the allegations for the -- that's what's
5 asserted by the patent owner in this case.
6 I've also talked the Dr. Goldberg, who I
7 referenced throughout the report.
8 So those two sources I think would form
9 my understanding.
10 Q And is it your view that Dr. Goldberg is
11 someone you can rely on?
12 A Yes.
13 Q Someone you can Trust?
14 A I believe so.
15 Q It's your understanding that you cannot
16 use KEYTRUDA for treatment of MSI-high
17 colorectal cancer without practicing the
18 invention claimed in the '393 Patent,
19 correct?
20 A Yes. I believe that's what I say in my
21 declaration, that is my understanding.
22 Q What impact would it have on your

1 opinions if it were possible to treat
2 MSI-high colorectal cancer with KEYTRUDA
3 without practicing the claimed invention?
4 A I'm not sure. That's not something I've
5 analyzed as I sit here today. I'd have to
6 think about it.
7 Q Can you turn to Paragraph 37 of your
8 declaration.
9 A Okay. I'm there.
10 Q You state that, "As such, none of the
11 sales and profits generated in patients
12 treated, which I've presented as evidence of
13 commercial success, would be possible without
14 the claimed invention"
15 Do you see that?
16 A Yes, I do.
17 Q Your analysis of the commercial success
18 factor does not rely on sales and profits of
19 KEYTRUDA associated with use for treatment of
20 anything other than MSI-high colorectal
21 cancer, correct?
22 A I'm sorry. Can you repeat the question?

1 Q Your analysis of the commercial success
2 factor does not rely on sales and profits of
3 KEYTRUDA associated with use for treatment of
4 anything other than MSI-high colorectal
5 cancer, correct?
6 MS. MCCORMICK: Object to form.
7 A I think I broadly agree with that for
8 the -- for the '393 Patent, yes.
9 Q Did you independently review the patent
10 claims?
11 A I don't know what -- I have reviewed
12 them. I don't know what you mean by
13 "independently" reviewed them. I've look at
14 them on my own, but that's not my subject
15 matter of expertise.
16 Q You are familiar with the patent claims;
17 is that fair?
18 A I've seen them, yes.
19 Q Are you able to identify the specific
20 elements of the '393 Patent claims that you
21 believe are responsible for KEYTRUDA's
22 commercial success?

1 A I don't believe I've done that
2 independently on my own.
3 Q Are you familiar with the concept of the
4 prior art?
5 A Generally speaking. I'm not an
6 attorney, but I have a general idea of what
7 that means.
8 Q What is your understanding of what the
9 concept of the prior art refers to?
10 A Well, again, I'm not an attorney. So
11 I'm not giving -- by no means, am I giving a
12 legal definition or opinion.
13 But just, generally speaking, that it's
14 prior disclosure of the technology before the
15 patent.
16 Q In your analysis of the commercial
17 success factor, how did you rule out that
18 commercial success of KEYTRUDA was not due to
19 the features already present if the prior
20 art?
21 MS. MCCORMICK: Object to form.
22 A I think examining the prior art and

1 determining what that involves is beyond my
2 scope. So since it was beyond my scope, I
3 don't think that applies to my analysis.
4 Q You are aware that KEYTRUDA is approved
5 and marketed for various types of cancer; is
6 that right?
7 A Yes.
8 Q Do you know when KEYTRUDA was first
9 approved for any type of cancer?
10 A I think it was 2014.
11 Q Let's turn to your appendices from your
12 declaration, and specifically starting at
13 Appendix 2.
14 A Okay.
15 Q Please let me know when you're there.
16 A Okay. I have it.
17 Q Appendix 2 provides a chart you created
18 showing annual US sales for KEYTRUDA,
19 correct?
20 A That's correct.
21 Q Appendix 2 includes data for sales that
22 are not related to MSI-high colorectal cancer

1 patients, correct?
2 A That is correct, yes.
3 Q And you agree that sales not associated
4 with MSI-high colorectal cancer patients is
5 not relevant to the commercial success factor
6 in this case, correct?
7 A I'd say I agree that the relevant sales
8 are those within the CRC indication, yes.
9 Q Can you turn to Appendix 3 on the next
10 page of your declaration, Page 41.
11 A Yes.
12 Q In Appendix 3 you provide a chart
13 showing annual US sales for KEYTRUDA as a
14 percentage of Merck's total US sales,
15 correct?
16 A Yes. Yes, that's the title on the
17 appendix.
18 Q Appendix 3 also includes data for sales
19 that are not related to MSI High colorectal
20 cancer patients, correct?
21 A Yes, yeah.
22 Q Can you turn to the next page,

1 Appendix 4.
2 A Okay.
3 Q In Appendix 4 you provide a chart
4 showing quarterly US sales for KEYTRUDA,
5 correct?
6 A That's correct.
7 Q And again, Appendix 4 includes data for
8 sales that are not related to MSI-High
9 colorectal cancer patients, correct?
10 A That's right. Well, in all these it
11 includes both, so it doesn't exclude the CRC
12 revenue, but it includes all of KEYTRUDA
13 sales.
14 Q If you turn to the next slide or the
15 next page, Appendix 5, Page 43 of your
16 declaration.
17 A Yes.
18 Q In Appendix 5 you have a chart that
19 purports to show annual US KEYTRUDA sales
20 tied to MSI-High colorectal cancer, correct?
21 A That's right.
22 Q At the bottom of Appendix 5 you have a

1 notes section, correct?
2 A That's correct.
3 Q And in the notes to Appendix 5 you say
4 monthly KEYTRUDA US sales attributed to
5 MSI-High dMMR/CRC are estimated as monthly US
6 KEYTRUDA sales times monthly number of CRC
7 patients divided by monthly total number of
8 patients across all cancer types, correct?
9 A Yes.
10 Q Where do you show the monthly number of
11 CRC patients divided by monthly total number
12 of patients across all cancer types?
13 A That part of the input wouldn't be
14 reflected on this graph. Those are inputs to
15 this graph.
16 Q Where in your declaration can I find
17 that information?
18 A I don't know. So this note explains how
19 this was calculated, I don't know that
20 precise -- each of those data points for that
21 calculation would be found in this
22 declaration.

1 Q What did you rely on to determine
2 monthly number of CRC patients divided by
3 monthly total number of patients across all
4 cancer types?
5 A That would be the source displayed at
6 the bottom of this document, the IQVIA, so
7 it's the AEO document 12, EX2188, so it comes
8 from that. And that --
9 Q Please go ahead.
10 A I'm just saying the patients would be
11 identified from that dataset.
12 Q Your calculation in Appendix 5 assumes
13 that KEYTRUDA costs the same to administer
14 for patients of all cancer types, correct?
15 A I think that's correct. Because it's
16 just multiplied by the US KEYTRUDA sales
17 data, which is the only data I had for
18 KEYTRUDA sales, I didn't have their revenue
19 by indication.
20 Q What is your basis for assuming that
21 KEYTRUDA costs the same to administer for
22 patients of all cancer types?

1 A I think my basis is I didn't have reason
2 to believe one way or the other that it was
3 more or less than other cancer types.
4 Q Why was your default assumption that it
5 cost the same?
6 A I think that's a function of the limits
7 of the data that I was provided from Merck.
8 As I said, I had IQVIA data on the number of
9 patients. What I did not have is any sort of
10 revenue for the sales breakdown or even
11 pricing by cancer type.
12 Q What did you do to investigate whether
13 KEYTRUDA costs the same to administer for
14 patients of all cancer types?
15 A I can't recall as I sit here.
16 Q Do you know whether patients of all
17 cancer types received the same amount of
18 KEYTRUDA over the course of treatment?
19 A I don't know that, I think -- No, I
20 don't know.
21 Q Did you do anything to investigate
22 whether patients of all cancer types received

1 the same amount of KEYTRUDA over the course
2 of treatment?
3 A Not for KEYTRUDA, so I know I did look
4 within the CRC, I looked at the dosage
5 strengths for KEYTRUDA and OPDIVO.
6 Q You also indicate in the notes to
7 Appendix 5 that although KEYTRUDA received
8 FDA approval for the MSI-High dMMRC
9 indication on May 23, 2017, IQVIA data shows
10 that [redacted]
11 [redacted]?
12 A Yes.
13 Q What is your understanding as to how
14 [redacted]
15 [redacted]
16 [redacted]?
17 A I don't know that I have the exact
18 explanation [redacted]
19 [redacted]
20 [redacted].
21 Q Did you do anything to investigate how
22 it was that there were [redacted]

1 [redacted]
2 [redacted]
3 A Again, I relied on IQVIA data, not data
4 from Merck directly. So I investigated to
5 the extent that I could. As the note shows,
6 I don't have a complete explanation for that
7 discrepancy.
8 Q The IQVIA data that you cite is
9 contained in Exhibit 2188, correct?
10 A That's correct.
11 Q Are you able to explain the methodology
12 used by IQVIA to collect and report this
13 data?
14 A It may be listed on their website. I've
15 used IQVIA data many times in the past. I
16 don't know that I used this specific data
17 type from IQVIA before. I'm familiar with
18 who they are and I know they do publish some
19 of their methodologies.
20 Q Is IQVIA data based on actual patient
21 records or estimates?
22 A It may depend on which data series we're

1 talking about. And I'm not as -- I'll just
2 leave it at that, it may depend on which data
3 series we're talking about.
4 Q Is the data in the IQVIA data that you
5 relied upon as cited in your notes to
6 Appendix 5, is that based on actual patient
7 records or estimates?
8 A I'm not sure as I sit here right now.
9 Q Are you familiar with any limitation
10 inherent to the IQVIA dataset that could
11 affect the accuracy of your analysis?
12 A Not as I sit here right now. I mean, of
13 course, data from Merck directly I think
14 would be better.
15 MR. ZEILBERGER: Can the tech please
16 share as a file not on the screen,
17 Exhibit 2188?
18 TECH WELCH: Uploading to the shared
19 folder now.
20 (Whereupon, Document 12, 14
21 pages (Bates No. IPR2024-00240)
22 was marked as Exhibit 2188 for

1 identification as of this date.)
2 Q Do you have Exhibit 2188?
3 A I do. I've opened it.
4 Q Do you recognize Exhibit 2188?
5 A Wait, no, this is the 2118. I'm sorry.
6 MS. MCCORMICK: Yeah, Counsel, we have
7 Exhibit 2118 in the shared folder.
8 TECH WELCH: I apologize. One moment,
9 please.
10 Q Do you recognize Exhibit 2188?
11 A Yes. It's quite small, but yes, it
12 looks familiar.
13 Q I assume you're able to zoom in to make
14 it larger on your screen?
15 A Yes. And I think I'll rotate it as
16 well, okay, yes.
17 Q At Page 2 of Exhibit 2188, do you see a
18 large table?
19 A Yes.
20 Q [redacted]
21 [redacted]
22 [redacted]?

1 A I do.
2 Q [redacted]
3 [redacted], correct?
4 A It seems to, yes, [redacted]
5 [redacted]
6 [redacted], yes.
7 Q What is your understanding of what
8 [redacted] means in Exhibit 2188?
9 A Well, I think just generally, again, I
10 was not provided definitions for this IQVIA
11 data file, but I would take [redacted]
12 [redacted].
13 Q [redacted]
14 [redacted], correct?
15 A It does.
16 Q [redacted]
17 [redacted]
18 [redacted]?
19 A Which page are you on? Are you seeing
20 both of these on the same page?
21 Q No. [redacted]
22 [redacted]

1 A Okay, yes, I see there [redacted]
2 [redacted], yes.
3 Q Do you know what 20240131 refers to?
4 A Again, I wasn't given a definition file
5 or even a letter explaining this data from
6 Merck, so that field, no, I do not know.
7 Q Do you [redacted] refers to?
8 A Again, I do not.
9 Q Did you ask anybody to explain to you
10 what [redacted] referred to in this chart?
11 A I believe we did ask for information
12 just broadly about this document and how to
13 understand the different fields and terms,
14 but this is all I was given.
15 Q But you felt like you could rely on this
16 document for purposes of preparing your
17 opinion, correct?
18 A I felt like this was the best available
19 information I had on whether it be patients
20 or sales or prescriptions by cancer type.
21 Q Who did you ask to explain the fields in
22 Exhibit 2188 that you did not understand?

1 A Well, again, I think I just asked for
2 information broadly on what this is and how
3 to interpret it. But what I was given was
4 this dataset as it is, and any request I made
5 would have gone through counsel.
6 Q Are you saying you did make a request to
7 explain certain fields in this document that
8 you do not understand?
9 A I believe there were numerous requests
10 made for sales by indication and that would
11 include information about this document.
12 Q I'm asking after you received this
13 document, did you personally raise questions
14 about fields that you did not understand?
15 A I'm not sure that there was time to go
16 back to Merck at that point. I think I got
17 this very soon before the declaration was
18 filed.
19 Q Did you ask JHU about fields that you
20 did not understand in this exhibit?
21 A I did not have conversations with JHU,
22 as I said earlier.

1 Q Did you ask anybody about fields in this
2 Exhibit that you do not understand?
3 A Not about this version field, no.
4 Q How soon before you signed your
5 declaration did you receive the data
6 contained in Exhibit 2188?
7 A My recollection is it was soon before,
8 although I recall the filing date got
9 extended so I'm not sure if it was soon
10 before the original deadline or if it was
11 soon before it was actually filed, and soon
12 as in a few days.
13 Q Despite those issues, you nevertheless
14 felt comfortable relying on the data in
15 Exhibit 2188 to render your opinions?
16 A Yes. It was the best information I had
17 available.
18 Q Can you show me where in Exhibit 2188 it
19 shows the [redacted]
20 [redacted]?
21 A Well, that would be in numerous spots
22 here, but there are -- so when you look at

1 the [redacted]
2 [redacted]
3 [redacted]
4 [redacted]
5 [redacted]
6 [redacted]
7 [redacted]
8 [redacted]
9 [redacted]
10 [redacted]
11 [redacted]
12 [redacted]
13 [redacted].
14 Q So are you referring to, for example,
15 the [redacted]
16 [redacted]
17 [redacted]?
18 A Yes. You're on Page 2; is that correct?
19 Q Correct.
20 Where in that [redacted]
21 [redacted]
22 [redacted]?

1 A Well, there's [redacted]
2 and then I think that would be have to be
3 used in conjunction with [redacted]
4 [redacted]
5 [redacted].
6 Q What does [redacted] refer to?
7 A What it says, it's [redacted].
8 Again, keep in mind [redacted]
9 [redacted]
10 [redacted].
11 Q I see. So you interpret [redacted]
12 [redacted]
13 [redacted]
14 [redacted]?
15 A That I'm not sure if I interpret that
16 exactly as [redacted]
17 [redacted] Again, as you can tell
18 if you look [redacted]
19 [redacted]
20 [redacted]
21 [redacted]
22 [redacted],

1 [redacted]
2 [redacted]
3 [redacted]
4 [redacted]
5 Q So you did not rely on the data in the
6 chart that begins on Page 2 to generate your
7 appendices; is that right?
8 A No. I think that's incorrect. I think
9 it's -- I relied on this as a raw data
10 source. I took some intermediate steps to
11 aggregate and sum these things up.
12 Q What were those intermediate steps?
13 A So those would be reflected in the, I
14 guess in the workbooks that we used to create
15 the charts that are the Appendix 1 through
16 10. So those would be done in Excel.
17 Q Where can I see those workbooks here?
18 A They're not on this Exhibit 2188. Those
19 would be things that I and my team had
20 created.
21 Q You referred to weightings earlier, how
22 did you decide what weightings to apply?

1 A I did not. [redacted]
2 [redacted]
3 [redacted].
4 Q And using this [redacted]
5 [redacted], how do you decide what weightings
6 to apply?
7 A What I'm saying is I believe [redacted]
8 [redacted].
9 Q Where?
10 A I believe they -- [redacted]
11 [redacted]
12 [redacted]
13 [redacted] I
14 don't know, I'm not IQVIA, I didn't construct
15 that number.
16 Q But you used the [redacted]
17 [redacted]
18 [redacted]
19 [redacted], correct?
20 A Well, I also [redacted]
21 [redacted]
22 [redacted]. So a

1 [redacted]
2 [redacted]
3 [redacted].
4 Q Why don't we do it this way. You used
5 this data and ended up with Appendix 5;
6 correct?
7 A That's -- yes, this was one of the
8 inputs to Appendix 5.
9 Q What processing to this Exhibit 2188 did
10 you perform to arrive at the data that you
11 used for Appendix 5?
12 A So broadly speaking without looking at
13 the workbook where all this was done, it
14 would have summed up the patients,
15 [redacted]
16 [redacted]
17 [redacted]
18 [redacted]
19 [redacted]
20 [redacted]
21 [redacted]
22 [redacted].

1 Q So you said as part of your answer that
2 you [redacted]
3 [redacted], correct?
4 A Well, I believe I would have [redacted]
5 [redacted]
6 [redacted]
7 [redacted]
8 [redacted]
9 [redacted]
10 Q But you [redacted]
11 [redacted]; is that right?
12 A Yes.
13 Q What does the [redacted] represent?
14 A I believe what it does is [redacted]
15 [redacted]
16 [redacted]
17 [redacted]
18 [redacted].
19 Q You said [redacted]
20 [redacted], correct?
21 A That's right. [redacted]
22 [redacted]

1 [redacted]
2 [redacted].
3 Q How are you comfortable [redacted]
4 [redacted]
5 [redacted]
6 [redacted]?
7 A I think [redacted]
8 [redacted]
9 [redacted]
10 [redacted]
11 [redacted].
12 Q What's the basis for your understanding
13 that [redacted]
14 [redacted]?
15 A [redacted]
16 [redacted]
17 [redacted]
18 [redacted]
19 [redacted]
20 [redacted]
21 [redacted]
22 [redacted]

1 [redacted]
2 [redacted]
3 [redacted]
4 [redacted]
5 [redacted]
6 [redacted]
7 [redacted]
8 [redacted]
9 [redacted]
10 [redacted]
11 [redacted]
12 Q If you can turn to Appendix 7 of your
13 declaration, please.
14 A Yes.
15 Q In Appendix 7 you purport to show the
16 total patients receiving KEYTRUDA for
17 MSI-High colorectal cancer by month, correct?
18 A That's correct.
19 Q And you, again, rely on Exhibit 2118 as
20 support for this chart; is that right?
21 A Yes.
22 Q Where in Exhibit 2188 does it show the

1 [redacted]
2 [redacted]
3 A So you would have to [redacted]
4 [redacted]
5 [redacted]
6 [redacted]
7 [redacted]
8 [redacted]
9 [redacted]
10 [redacted]
11 [redacted]
12 [redacted]
13 [redacted]
14 [redacted]
15 [redacted]
16 [redacted]
17 [redacted]
18 [redacted]
19 Q What does [redacted]
20 [redacted] of
21 Exhibit 2188?
22 A Those might [redacted]. I may

1 have categorized that incorrectly, I guess.
2 Q Appendix 7 to your declaration is not
3 [redacted], correct?
4 A No. [redacted], that's right.
5 Q So where in Exhibit 2188 does it [redacted]
6 [redacted]
7 [redacted]
8 [redacted]?
9 A Sorry. Do you mind if I flip through
10 it.
11 Q Please, go ahead.
12 A Thank you. So as I flip through here,
13 all of these appear to [redacted]
14 [redacted]
15 [redacted]. But I believe the -- which I'm
16 confused by, because I believe the Excel file
17 had other values. [redacted]
18 [redacted] So I don't know that I'm
19 looking at the entire data set in 2188.
20 Q Did you review Exhibit 2188 before you
21 cited it and relied on it for your
22 declaration?

1 A Well, I did not rely on a PDF version of
2 this. I had an Excel version that then I
3 assumed was ultimately produced as 2188.
4 But as I sit here and look at this PDF
5 version, I'm not sure it has all of the info
6 in it. In other words, it may be filtered or
7 something.
8 Q I see. Just to be clear, you did not
9 review what's been submitted by JHU as
10 Exhibit 2188 before you signed and submitted
11 your declaration?
12 A I reviewed the Excel file that this was
13 based on.
14 Q But not the PDF that's marked as
15 Exhibit 2188, correct?
16 A I agree with that, yes, I reviewed the
17 Excel file.
18 Q If you turn to Appendix 8 of your
19 declaration.
20 A Yes. I'm there.
21 Q In Appendix 8 you purport to show [redacted]
22 [redacted]

1 [redacted], correct?
2 A That's right.
3 Q And you again rely on Exhibit 2188 to
4 generate Appendix 8; is that right?
5 A With the same clarification that I
6 relied -- what I relied on to create this is
7 the Excel file that underlies Exhibit 2188.
8 Q Are you familiar with the terms
9 correlation and causation?
10 A Sure, yes.
11 Q Is correlation synonymous with
12 causation?
13 A No. It's not.
14 Q Does correlation imply causation?
15 A No. Certainly not on its own.
16 Q Can you turn to Paragraph 26 of your
17 declaration.
18 A Okay.
19 Q In Paragraph 26 you state:
20 "Appendix 4 shows that the timing of
21 KEYTRUDA's FDA approval for the treatment of
22 adults and pediatric patients with

1 unresectable or metastatic MSI-High or dMMR
2 solid tumors coincides with an apparent
3 inflection point in KEYTRUDA's sales
4 trajectory," correct?
5 A Yes.
6 Q So is it fair to say you believe the two
7 are correlated?
8 A That's fair, yes.
9 Q Beyond correlation, have you found a
10 direct causal link between the timing of the
11 FDA approval and this so-called inflection
12 point in KEYTRUDA's sales trajectory?
13 A I think the causal link I talk about in
14 this report is to the sales of KEYTRUDA
15 within the CRC indication.
16 Q Do you know what other indications were
17 approved for KEYTRUDA in 2017?
18 A I believe there were several others.
19 There was the agnostic indication as well at
20 that same time, but there were a few others
21 also, yes.
22 Q Those other indications that were

1 approved for KEYTRUDA in 2017 would have lead
2 to increased sales of KEYTRUDA, correct?
3 A I would expect so.
4 Q Do you know what other indications were
5 approved for KEYTRUDA in 2016?
6 A Not as I sit here right now.
7 Q If it is the case that KEYTRUDA was
8 approved for additional indications in 2016,
9 those approvals would have lead to increased
10 sales of KEYTRUDA, correct?
11 A Yes. Beginning in 2016, I would
12 suspect.
13 Q Is it your opinion that sales of
14 KEYTRUDA associated with MSI-High colorectal
15 cancer make up a majority of the sales of
16 KEYTRUDA in the US?
17 A No. No, it's not.
18 Q Sales of KEYTRUDA associated with
19 MSI-High colorectal cancer make up a minority
20 of the US sales of KEYTRUDA, correct?
21 A Yes. I believe I just said they're not
22 a majority, so that would make them a

1 minority.
2 Q What percentage of sales of KEYTRUDA in
3 the US are associated with MSI-High
4 colorectal cancer?
5 A What percentage of sales of KEYTRUDA?
6 Q What percentage of sales of KEYTRUDA in
7 the US are associated with patients having
8 MSI-High colorectal cancer?
9 A Okay. So I know my declaration
10 discusses Merck has made statements that
11 5 percent are associated with MSI-High or
12 dMMR, and I think a significant portion of
13 those would also be associated with
14 colorectal cancer. So 4 to 5 percent.
15 Q So when we look at the data in your
16 Appendixes 2 through 4, approximately
17 95 percent of that data is not relevant to
18 the commercial success factor of this case,
19 correct?
20 MS. MCCORMICK: Object to form.
21 A I don't know that it has complete
22 irrelevance, but my analysis, as I said

1 earlier, focuses on the CRC indication. So,
2 yes, I am focused on that portion of the
3 sales.
4 Q When we look at Appendixes 2 through 4
5 of your declaration, approximately 95 percent
6 of the figures that we see are coming from
7 data not associated with MSI-High colorectal
8 cancer, correct?
9 A Well, I mean, they're coming from
10 KEYTRUDA, which is used to treat MSI-High
11 colorectal cancer. And, yes, as I said just
12 a moment ago, the portion of those sales that
13 I focused on for my analysis is the CRC
14 indication, which is not the majority of
15 those sales.
16 Q Do you disagree with my statement that
17 95 -- excuse me. Let me start over.
18 Do you disagree with my statement that
19 when we look at the data in Appendixes 2
20 through 4 of your declaration, 95 percent or
21 approximately 95 percent of the numbers that
22 we see are associated with sales of KEYTRUDA

1 for patients that do not have MSI-High
2 colorectal cancer?
3 A I don't disagree. Although, the
4 totality of my analysis here, as I said, I do
5 focus on the CRC portion.
6 Q In Paragraph 30 of your declaration, you
7 refer to Merck's operating profit margins,
8 correct?
9 A That's right.
10 Q And you rely on Merck's operating profit
11 margins in support of your commercial success
12 finding; is that right?
13 A In part, yes.
14 Q What factors could have contributed to
15 Merck's profit margins?
16 A Well, Merck has other products. So
17 that's one obvious factor.
18 Q Are there any others?
19 A I'm sure there are. You know, I
20 mentioned some things, even deficiencies
21 about these profit margins that I think sort
22 of underestimate or likely underestimate the

1 percentages that I calculate here.
2 For example, these accounting margins
3 include things, as I note, like amortization,
4 depreciation and other non-related KEYTRUDA
5 expenses. So things like, there's some
6 restructuring costs, sales of intangible
7 goods, things like that. All of those, I
8 think, potentially make these profit margin
9 percentages that I've calculated here too
10 low. And that's what I've described here in
11 this paragraph.
12 Q Synergies from preexisting manufacturing
13 and distribution methods would have
14 contributed to Merck's profit margins for the
15 years that you considered, correct?
16 MS. MCCORMICK: Object to form.
17 A Could have. It depends. As I mentioned
18 one, in fact, as I mentioned in this
19 paragraph, one shortfall of what I don't have
20 here is I don't have a profit and loss
21 statement or something of that sort for
22 KEYTRUDA in particular. Which you would want

1 to see. But I -- well, I don't know what
2 synergies you would be talking about, as I
3 sit here either, and what products those
4 would apply to.
5 Q For example, Merck's preexisting
6 manufacturing and distribution methods for
7 KEYTRUDA from the time period before the '393
8 Patent existed, would have contributed to
9 Merck's profit margins, correct?
10 A As a whole?
11 I'm sorry, I take your question to be,
12 it would have contributed to Merck's profit
13 margins as a whole. And I agree that, that
14 maybe one of many different factors. If you
15 look at manufacturing costs, that would
16 contribute to their profit margins, yes.
17 Q It would also contribute to Merck's
18 profit margins for KEYTRUDA, correct?
19 A It could. I haven't seen that
20 information, but it could.
21 Q You do understand that Merck was selling
22 KEYTRUDA and had approvals for KEYTRUDA

1 before the '393 Patent existed, correct?
2 A Yes. And I understand, as I say in the
3 report, that it's not possible, broadly, to
4 sell for CRC without the '393 Patent.
5 Q Given that KEYTRUDA was being sold
6 before the '393 Patent existed, Merck would
7 have had preexisting manufacturing and
8 distribution methods for KEYTRUDA, correct?
9 MS. MCCORMICK: Object to form.
10 A Yes. But they would not have had the
11 opportunity to make those sales within that
12 indication. But, yes, on the manufacturing
13 side, yes, they were already manufacturing
14 it.
15 Q The '393 Patent would not have impacted
16 Merck's manufacturing of KEYTRUDA, correct?
17 MS. MCCORMICK: Object to form.
18 A Well, they would have to manufacture
19 more to make additional sales within that
20 indication. So, I mean, that's one way it
21 could impact it.
22 Q You understand that it's the same drug,

1 KEYTRUDA isn't different because of the '393
2 Patent, yes?
3 A Yes.
4 Q Where in your declaration did you take
5 into account the preexisting manufacturing
6 and distribution methods that Merck had in
7 considering the commercial success factor?
8 A I would say I took it into account by
9 focusing on the CRC indication itself.
10 Q In Paragraph 31 of your declaration, you
11 state that:
12 "The [redacted] patients
13 relying on KEYTRUDA for treatment each year
14 is evidence of its commercial success."
15 Do you see that?
16 A Yes. Yeah. That's the last sentence of
17 31.
18 Q Did you consider whether increased
19 awareness could have [redacted]
20 [redacted]?
21 A I did, yes.
22 Q In what way would increased awareness

1 have [redacted]?
2 A Well, if increased awareness, whether
3 it's through word of mouth about the benefits
4 of the patent, or whether it's through
5 Merck's own efforts to inform the marketplace
6 about the benefits of this patent, all of
7 those I would consider to be related to the
8 patent.
9 Q Would you consider Merck's efforts to
10 raise awareness of KEYTRUDA generally --
11 well, sorry, let me ask it this way.
12 Did you consider Merck's efforts to
13 raise awareness of KEYTRUDA generally?
14 MS. MCCORMICK: Object to form.
15 A I think, yes, I did. So I have some
16 discussion about Merck's marketing and
17 advertising efforts in my declaration. And I
18 see nothing sort of extraordinary or unusual
19 about those efforts that would lead you to
20 believe that these sales are all because of
21 that.
22 Q Did you consider whether changes to

1 availability of insurance coverage
2 [redacted]
3 [redacted]?
4 A To the extent I was available, or the
5 information was available and I was able to
6 find it, I considered what prices payors are
7 paying and what prices ultimately patients
8 are paying, and that's reflected in my
9 declaration as well.
10 Q So you're saying that the price of
11 KEYTRUDA let's you -- or gives you
12 information about availability of insurance
13 coverage?
14 A To some extent, yes. Yeah.
15 Q Please explain?
16 A Well, so prices paid by payors -- well,
17 for instance, I've got a lot of discussion in
18 here about Medicare and access to KEYTRUDA
19 through Medicare. So my declaration does
20 discuss that.
21 I don't believe I have full sort of
22 formulary information about KEYTRUDA itself

1 and by indication. But I did look at some of
2 this information and that's reflected in the
3 pricing section of my declaration.
4 Q Has insurance coverage for KEYTRUDA gone
5 up between 2017 and 2023?
6 A I don't know that I know that by
7 indication. So I don't know that I would
8 even know that for CRC in particular in that.
9 So, as I sit here right now, I don't know.
10 Q Do you know whether insurance coverage
11 for KEYTRUDA has gone up between 2017
12 and 2023 not by indication, just generally?
13 A Well, I think by indication is what I
14 would be most concerned with, but I don't
15 know, as I sit here.
16 Q What did you do to investigate whether
17 insurance coverage has gone up for KEYTRUDA
18 between 2017 and 2023?
19 A My investigation of prices that patients
20 pay, which is reflected by what their
21 coverage is, is in that section of my
22 declaration.

1 Q Did you investigate whether insurance
2 coverage has gone up for KEYTRUDA between
3 2017 and 2023?
4 A If it -- no, not beyond what's already
5 in the report.
6 Q How did you isolate the impact of the
7 '393 Patent from other potential drivers of
8 [redacted]?
9 MS. MCCORMICK: Object to form.
10 A So I isolated the impact of the '393 by
11 looking at Merck's sales of KEYTRUDA within
12 the CRC indication for dMMR patients.
13 Q Let's turn to Appendix 10 of your
14 declaration.
15 In Appendix 10, you provide a chart that
16 purports to show [redacted]
17 [redacted]
18 [redacted], correct?
19 A Yes.
20 Q Can you please explain what the
21 percentages in Appendix 10 are intended to
22 represent?

1 A Sure. So this is another way to think
2 about sort of what a market share would look
3 like within each of these indications. So
4 it's intended to control for basically the
5 available patient sizes within each of these
6 indications.
7 So, for example, the lung cancer line
8 that's up there at the top would say that of
9 [redacted], that
10 [redacted] are being prescribed
11 KEYTRUDA.
12 And you see sort of the same trends
13 whether it's with the MSI-High dMMR CRC,
14 which sort of the blue line that's sort of
15 the second-from-the-top, and then the other
16 two; melanoma and bladder are two other
17 indications that Merck talked about as
18 indications where KEYTRUDA does well.
19 And so what this shows is if you control
20 for the available patient size population, or
21 the size of the patient population where
22 KEYTRUDA can be prescribed, that KEYTRUDA is

1 penetrating [redacted] of patients for
2 CRC.
3 Q And for all of these cancer types that
4 you have in Appendix 10, for the total
5 available patient population you relied on
6 Exhibits 2223 through 2229; is that right?
7 A In part, yes. So those exhibits
8 informed the measure of new cancer patients
9 within each of these cancer types.
10 Q In 2023, for colorectal cancer, you have
11 KEYTRUDA as being prescribed to [redacted] of
12 available patients; is that right?
13 A Of MSI-High dMMR colorectal cancer
14 patients, yes.
15 Q For the other [redacted] of MSI-High
16 dMMR colorectal cancer patients, what did
17 they receive?
18 A I don't have information on what they
19 received.
20 Q Did you investigate what the other
21 [redacted] of MSI-High dMMR colorectal cancer
22 patients would have received in 2023?

1 A No. I don't think there's data specific
2 the MSI-High dMMR subpopulation of CRC to
3 allow that.
4 Q Did you ask anybody whether there was
5 data that showed what the other [redacted] of
6 MSI-High dMMR colorectal cancer patients
7 would have received in 2023?
8 A Well, I mean, I did investigate it. So
9 I know as this report discusses, there are
10 other drugs. So there's OPDIVO and YERVOY,
11 and so those are two of them. And I would
12 except that those two make up some portion of
13 it.
14 Others may be on other treatments and
15 not on immunotherapies at all.
16 Q Sitting here today, though, you don't
17 know what the other [redacted] of MSI-High
18 dMMR colorectal cancer patients would have
19 received in 2023, correct?
20 A Well, I as I just said, I know that some
21 of them were taking the Bristol Myers Squibb
22 products, and I did look at those and I

1 looked at their shares and their sales
2 relative to KEYTRUDA within CRC.
3 So I have some information on it, yes.
4 Q Are you saying that [redacted] of
5 MSI-High/dMMR colorectal cancer patients
6 in 2023, that were not receiving KEYTRUDA
7 were receiving one of the Bristol Meyer
8 Squibb drugs?
9 A No. In fact, in 2023, that [redacted]
10 [redacted] would be receiving those
11 products.
12 Q So if [redacted] of MSI-High
13 colorectal cancer patients are receiving
14 Bristol Meyer Squibb drugs, then that means
15 that [redacted] of MSI-High colorectal cancer
16 patients were neither receiving KEYTRUDA, nor
17 one of the Bristol Meyers Squibb drug,
18 correct?
19 A It's correct that I don't have
20 information on what the remainder of that
21 population would be treated with. The
22 purpose of this graph is to compare how

1 KEYTRUDA is doing in this indication to how
2 KEYTRUDA does in other indications.
3 Q [redacted],
4 correct?
5 A That's right.
6 Q So that would mean that at a minimum,
7 [redacted] of MSI-High colorectal cancer
8 patients received something other than
9 KEYTRUDA or one of the Bristol Meyers Squibb
10 drugs, correct?
11 A I'm not sure I agree with that
12 statement.
13 Another point about this chart is it's
14 focused on new patients. So, obviously, over
15 the course of treatment, patients received
16 different drugs. So this is -- I'm not sure
17 if you can draw that conclusion you're making
18 from it.
19 Q At a minimum, [redacted] of MSI-High
20 colorectal -- colorectal cancer patients that
21 are new patients would have received
22 something other than KEYTRUDA or one of the

1 Bristol Meyers Squibb drugs, correct?
2 A Again, I don't have information on what
3 treatments they were on. But when you
4 consider the population, as I've done in the
5 report, when you look at what the other
6 immunotherapies are, to target MSI-High/dMMR
7 populations, KEYTRUDA has the highest share
8 of those.
9 So I don't want to leave the impression
10 that there's some other immunotherapy for
11 MSI-High/dMMR that these patients are taking,
12 because I don't believe that's reflected in
13 this data.
14 Q But do you agree that [redacted] of new
15 MSI-High colorectal cancer patients -- or at
16 least [redacted], I should say, were not
17 receiving KEYTRUDA or one of the Bristol
18 Meyers Squibb drugs, correct?
19 A Yes.
20 Q You didn't think it was relevant to
21 analyze what a majority of new MSI-High
22 cancer -- colorectal cancer patients were

1 receiving?
2 MS. MCCORMICK: Objection to form.
3 A I felt it was relevant to analyze
4 KEYTRUDA's performance within it's drug class
5 of immunotherapies that are targeting
6 MSI-High populations.
7 So I compared it to, as I said, OPDIVO,
8 which would be its closest competitor.
9 MS. MCCORMICK: Counsel, we've been
10 going an hour and a half. Do you
11 think we could take a break soon, if
12 we're at a good stopping point?
13 MR. ZEILBERGER: Mr. Segers, would you
14 like to take a break?
15 MS. MCCORMICK: I'm happy to take a
16 break, yes.
17 MR. ZEILBERGER: Okay. Why don't we
18 take a break.
19 THE WITNESS: Okay.
20 (Whereupon, a recess was taken
21 from 1:27 PM until 1:36 PM.)
22 Q Mr. Segers, in Appendix 10, is your

1 point with respect to the MSI-High colorectal
2 cancer patients line that the [redacted]
3 [redacted] year to year from 2017
4 through 2023?
5 A Part of the point.
6 Q And you've relied on that in part to
7 prepare your opinions regarding the
8 commercial success factor?
9 A Yes. This was one metric by which I
10 could compare KEYTRUDA within MSI-High/dMMR
11 CRC to other of KEYTRUDA's indications.
12 Q Were you just comparing MSI-High
13 colorectal cancer use of KEYTRUDA to other
14 indications, or were you also attempting to
15 show the relevance of the allegedly
16 [redacted]
17 [redacted]?
18 A I believe it would do both.
19 MR. ZEILBERGER: Can the tech please
20 share Exhibits 2223 through 2229, the
21 whole sets of Exhibits.
22 TECH WELCH: 2223 through 2229, please

1 standby.
2 A I see them all there.
3 Q And I've provided them all to you at the
4 same time just to make it easier because each
5 exhibit refers to a different year.
6 Would you agree with that, that each
7 exhibit is intended to refer to data for a
8 different year?
9 A That's my recollection, yes.
10 Q So Exhibit 2223 provides data that you
11 used for 2017, correct?
12 (Whereupon, Cancer Statistics,
13 2017 (Bates No. IPR2024-00240)
14 was marked as Exhibit 2223 for
15 identification as of this date.)
16 A Let me open it. Yes, that's what it
17 says.
18 Q And Exhibit 2224 provides data you used
19 for 2018, correct?
20 A I believe so, yes.
21 (Whereupon, Cancer Statistics,
22 2019 (Bates No. IPR2024-00240)

1 was marked as Exhibit 2224 for
2 identification as of this date.)
3 Q Exhibit 2225 provides data you used for
4 2019, correct?
5 A Yes.
6 (Whereupon, Cancer Statistics,
7 2019 (Bates No. IPR2024-00240)
8 was marked as Exhibit 2225 for
9 identification as of this date.)
10 Q Exhibit 2226 provides data you used
11 for 2020, correct?
12 (Whereupon, Cancer Statistics,
13 2020 (Bates No. IPR2024-00240)
14 was marked as Exhibit 2226 for
15 identification as of this date.)
16 A That's right.
17 Q Exhibit 2227 provides data you used
18 for 2021, correct?
19 (Whereupon, Cancer Statistics,
20 2022 (Bates No. IPR2024-00240)
21 was marked as Exhibit 2227 for
22 identification as of this date.)

1 A Yes.
2 Q Exhibit 2228 provides data you used
3 for 2022, correct?
4 (Whereupon, Cancer Statistics,
5 2022 (Bates No. IPR2024-00240)
6 was marked as Exhibit 2228 for
7 identification as of this date.)
8 A Yes.
9 Q And, finally, Exhibit 2229 provides data
10 you used for 2023, correct?
11 (Whereupon, Cancer Statistics,
12 2023 (Bates No. IPR2024-00240)
13 was marked as Exhibit 2229 for
14 identification as of this date.)
15 A That's right.
16 Q If we look to Exhibit 2224, if you can
17 please pull that up.
18 A Okay.
19 Q The data that you relied on comes from
20 Table 1 of Exhibit 2224, correct?
21 A Yes.
22 Q And is it the case you relied on the

1 numbers provided in Table 1 for colon and
2 rectum new cases?
3 A Yes. That's correct.
4 Q At the top of this table, Table 1 of
5 Exhibit 2224, it says, "Estimated new cancer
6 cases," correct?
7 A That's right.
8 Q But these are not actual new cases.
9 They're estimates, correct?
10 A Yes. I agree with that.
11 Q If you look at the very bottom of Page 2
12 of Exhibit 2224, there is a sentence that
13 starts with "Note," correct?
14 A Yes.
15 Q That sentence provides, "These are
16 model-based estimates that should be
17 interpreted with caution and not compared to
18 those for previous years."
19 Do you see that?
20 A I do.
21 Q Why did you feel like you could compare
22 the data for 2018 with the -- for 2017, when

1 the actual data provider said that the data
2 should not be compared to previous years?
3 A Well, as we were just -- so we're
4 talking about Appendix 10 still, and as we
5 just discussed, the primary purpose of that
6 appendix is to not compare it, necessarily,
7 from year to year. Although, I admit, I do
8 show a trend in a graph. But I compare it
9 the other indications for KEYTRUDA. And so
10 within a given year, there's certainly no
11 note for that.
12 Q You would agree in view of this
13 statement, in Exhibit 2224, that one should
14 not compare the data you provide in
15 Appendix 10 on a year over year basis,
16 correct?
17 A Sure. And I don't know that I've done
18 that. Certainly, I've used data in other
19 places from other sources to make year to
20 year comparisons. As I said here on
21 Exhibit 10 (sic), I am making comparisons
22 across indications for KEYTRUDA within given

1 years.
2 Q I see. I wasn't --
3 A And --
4 Q -- aware of -- go ahead, please.
5 A Well, and, as you can tell on
6 Appendix 10, even as you look across the
7 years, it is [redacted]
8 [redacted],
9 which I think as the declaration points out,
10 Merck is on the record as touting the success
11 of those indications.
12 Q So you said -- and, please correct me if
13 I'm misunderstanding what you meant.
14 But you said you had other data to show
15 on a year by year basis the total number of
16 colorectal cancer patients?
17 A No, no. What I said was I had other
18 data to show KEYTRUDA MSI-High colorectal
19 cancer patients. And that other data also --
20 also shows [redacted].
21 So I might agree with you if this was --
22 if Appendix 10 was the only -- only data

1 series, only source that I had that showed [redacted]
2 [redacted] of KEYTRUDA's penetration
3 here, but it's not. It's not the only source
4 that I have.
5 Q Appendix 10 is built based on data that
6 cannot be compared on a year by year basis,
7 correct?
8 A The note on this page says that should
9 be done with caution, I agree with that. And
10 as I just said, Appendix 10 also provides
11 within year comparisons to other indications.
12 Q You read the statement in Exhibit 2224
13 that these are model-based estimates that
14 should be interpreted with caution and not
15 compared to those for previous years, as only
16 saying that the data should be interpreted
17 with previous years with caution?
18 A No. I agree with you, what it says.
19 Those -- the words you just read is what the
20 document says.
21 Q Well, A moment ago you said that the
22 note on this page says that should be done

1 with caution?
2 A Well, it does say it should be done with
3 caution. But I agree with you that the full
4 text of it says, "not compared to those for
5 previous years."
6 But what I also said is that this is not
7 my only year over year comparison in the 10
8 Appendices; and furthermore, the Appendix 10
9 does more than just compare year to year,
10 what it does is compare within a given year
11 across indications.
12 Q If you turn to Exhibit 2225 and go to
13 Page 4, please.
14 A All right.
15 Q Page 4 of Exhibit 2225 has a similar
16 Table 1, providing the data that you relied
17 on for Appendix 10, correct?
18 A Yes.
19 Q Exhibit 2225 has the same instruction
20 not to compare the data with those for
21 previous years, correct?
22 A It does.

1 Q And if you turn to Exhibit 2226.
2 And turn to Page 3 of the exhibit.
3 A Okay.
4 Q This page of Exhibit 2226 has a Table 1
5 that, again, provides the data you relied on
6 for Appendix 10, correct?
7 A Part of the data, yes.
8 Q And this exhibit, again, has the same
9 instruction not to compare the data with
10 those for previous years, correct?
11 MS. MCCORMICK: Object the form.
12 A I agree it has the -- largely the same
13 note.
14 Q What's the difference in the note?
15 A I -- so if we look back on the other
16 ones, my recollection was the other one had
17 the note -- well, I think the text that
18 you're reading is the same across each of
19 these. I'm just basically referring to the
20 note in its entirety on the table of each
21 table.
22 Q You were disputing the location of note.

1 Is that what you getting at?
2 A No. I just think the formatting of it
3 maybe a little bit different. But the
4 language that you are reading appears to be
5 the same across each of these.
6 Q If you turn to Exhibit 2227, Page 4.
7 A Okay.
8 Q At this page there is a Table 1 that
9 again provides part of the data that you
10 relied on for Appendix 10, correct?
11 A That's right.
12 Q And at the bottom of this table it,
13 again, has the same instruction not to
14 compare the data with those for previous
15 years, correct?
16 A Yes.
17 Q Turn to Exhibit 2228, Page 4?
18 A All right.
19 Q At this page of the exhibit there is,
20 again, a Table 1 providing a portion of the
21 data that you relied on for Appendix 10,
22 correct?

1 A Yes.
2 Q And at the bottom of this page there is,
3 again, the same instruction to not compare
4 the data with those for previous years,
5 correct?
6 A Yes. The document says the same thing.
7 Q And finally turning to Exhibit 2229,
8 Page 4 of the PDF.
9 A Okay.
10 Q There is again a Table 1 providing a
11 portion of the data that you relied on for
12 Appendix 10, correct?
13 A Yes.
14 Q And if you scroll down to Page 5, where
15 the table continues, there is, again, the
16 same instruction not to compare this data
17 with the data for previous years, correct.
18 A There's the same note, yes.
19 Q If you look back to Appendix 10 of your
20 declaration.
21 A Yes. I'm looking at it.
22 Q So we spoke earlier -- strike that.

1 Did you investigate whether the
2 frequency that OPDIVO and YERVOY were used
3 for MSI-High colorectal cancer patients went
4 up over time?
5 A What I did was I estimated the revenue
6 for OPDIVO and YERVOY within CRC over time.
7 Q So you did not investigate whether the
8 frequency that OPDIVO and YERVOY are used for
9 MSI-High colorectal cancer patients went up
10 over time, correct?
11 A Well, I, so if you look at my other
12 Appendices, I said that I looked at that on a
13 revenue basis and what you see is KEYTRUDA
14 within this indication or CRC MSI-High
15 population, KEYTRUDA is [redacted]
16 [redacted]
17 [redacted]
18 [redacted]
19 [redacted] but I don't have
20 patient level data for those other drugs.
21 Q Did you look for patient level data for
22 OPDIVO and YERVOY?

1 A I requested IQVIA data that I would hope
2 would show among other things not just
3 KEYTRUDA's sales in patients but also shares,
4 market shares.
5 Q Do you have any information as to
6 whether on a patient level basis OPDIVO and
7 YERVOY's market share went up or down over
8 the course of 2017 through 2023?
9 A Well, when I see their revenue share for
10 MSI-High CRC, decreasing compared to
11 KEYTRUDA, what -- and in the -- as I discuss
12 in the pricing analysis, there's been very
13 little change, little difference in the list
14 price or WAC prices between the two, that
15 would indicate that their patient shares are
16 doing something similar.
17 Q Well, in performing the revenue-based
18 analysis you're referring to, you assume that
19 OPDIVO and YERVOY's sales for MSI-High
20 colorectal cancer patients was always the
21 same percentage of total OPDIVO and YERVOY
22 revenue, correct?

1 A That's based on their own statements
2 where they classify their sales by indication
3 and they list several indications down to, I
4 forgot which one, but it accounts for
5 five percent and OPDIVO and YERVOY were
6 listed in the others meaning they're
7 presumably less than five percent. But I
8 conservatively just said let's say they're
9 five percent of OPDIVO and YERVOY's total
10 revenue and estimated it that way.
11 Q Your understanding is that Bristol
12 Meyers Squibb has made statements that for
13 the whole period of time between 2017
14 and 2023, OPDIVO and YERVOY made up less than
15 five percent of the revenue of OPDIVO and,
16 OPDIVO and YERVOY sales for MSI-High
17 colorectal cancer patients made up less than
18 five percent of total revenue for OPDIVO and
19 YERVOY?
20 A I don't believe that those statements
21 covered the entire time period. I think it
22 was 2018, '19, '20 or something in that

1 ballpark.
2 Q I see. And so for 2021, 2022, and 2023,
3 you don't know whether the market share for
4 OPDIVO and YERVOY with respect to MSI-High
5 colorectal cancer may have gone up, correct?
6 A I think I very much would have liked to
7 have seen market share information, whether
8 it's from Merck or other sources, but to the
9 knowledge that I had available, I'm not aware
10 of any other statements from Bristol Meyers
11 about those indiction percentages after 2020,
12 so the best available information I had.
13 Q The best available information you had
14 is you don't have information for 2021, 2022,
15 and 2023, correct?
16 MS. MCCORMICK: Object to form.
17 A I have information for the period
18 immediately before it, and I've used that to
19 estimate it.
20 Q For KEYTRUDA you're understanding is
21 that market share [redacted]
22 [redacted] for MSI-High colorectal cancer patients,

1 correct?
2 A Right.
3 Q And for OPDIVO and YERVOY, it's also
4 possible that the same would have occurred,
5 correct?
6 A Well, no, I think I disagree with that.
7 Market share as I'm measuring it among these
8 immunotherapies that target MSI-High
9 populations those -- if KEYTRUDA [redacted],
10 OPDIVO and YERVOY are [redacted], if you're
11 talking about the share of those products.
12 Q No, Mr. Segers, I'm talking about the
13 percentage of MSI-High colorectal cancer
14 patients. I think earlier today we spoke
15 about how even in 2023 KEYTRUDA was [redacted]
16 [redacted] of MSI-High
17 colorectal cancer patients, correct?
18 A Okay. So you're talking about share as
19 a percentage of a -- penetration of the
20 patient population, and what I would say is
21 that the data that I've seen would suggest
22 that if [redacted]

1 [redacted] says.
2 Q What's your basis for saying that?
3 A The other appendices in my report that
4 compare the sales of KEYTRUDA to OPDIVO and
5 YERVOY.
6 Q Those appendices are built on the
7 assumption that MSI-High colorectal cancer
8 associated sales of OPDIVO and YERVOY did not
9 increase on a percentage basis for
10 2021, 2022, and 2023, correct?
11 A I think that, yeah that the make up of
12 their indications, so I mean, it depends on
13 what we're saying increased, so what they
14 said specifically was MSI-High CRC accounted
15 for something less than five percent in the
16 statements that I had available to me. And
17 yes, my assumption is I haven't seen anything
18 to lead me to believe that as a portion of
19 OPDIVO and YERVOY over all that those have,
20 that that's increased within that indication.
21 Q When you look at your Appendix 10
22 Mr. Segers, we see that even for KEYTRUDA,

1 MSI-High colorectal cancer patients is
2 [redacted]
3 [redacted], correct?
4 A I think that's correct, but that doesn't
5 necessarily mean that the total number of
6 prescriptions are being -- [redacted],
7 right, this is a -- keep in mind that there's
8 a -- what the Appendix 10 does it controls
9 for the size of the patient populations and
10 not all of these lines are the same size.
11 And so yes, it's [redacted],
12 they're [redacted]
13 [redacted].
14 But that doesn't mean that when you
15 account for the size of these patient pools
16 that it's not actually [redacted]
17 [redacted].
18 Q It's possible that if you had all the
19 data you needed and charted OPDIVO and YERVOY
20 in a similar manner to what you prepared in
21 Appendix 10 that they would present similar
22 data, correct?

1 MS. MCCORMICK: Object to form.
2 A As I said, I believe that they -- if you
3 plotted OPDIVO and YERVOY on that line that
4 their share of patients would be [redacted]
5 [redacted]
6 [redacted]
7 [redacted]
8 [redacted].
9 Q But you don't have any data for
10 2021, 2022, and 2023 for MSI-High colorectal
11 cancer uses of OPDIVO and YERVOY, correct?
12 A Right. I have their total, total data
13 and total sales, which I believe KEYTRUDA
14 overall has [redacted]
15 [redacted].
16 Q You don't have any data that would
17 exclude the possibility that use of OPDIVO
18 and YERVOY for MSI-High colorectal cancer in
19 2021, 2022, and 2023 increased, correct?
20 MS. MCCORMICK: Object to form.
21 A Can you explain to me what you -- it's
22 unclear what you mean by just use of.

1 Q Sales of OPDIVO and YERVOY associated
2 with MSI-High colorectal cancer patients.
3 A That they increased?
4 Q You don't have any data that would
5 exclude the possibility that sales of OPDIVO
6 and YERVOY for patients with MSI-High
7 colorectal cancer patients went up in
8 2021, 2022, and 2023, correct?
9 MS. MCCORMICK: Object to form.
10 A I mean, their total sales may have gone
11 up. What I have pointed out in my
12 declaration is KEYTRUDA has been [redacted]
13 [redacted] against OPDIVO and YERVOY and so to
14 whatever extent [redacted], KEYTRUDA
15 [redacted] and that's the point of my
16 analysis.
17 Q Right, but you actually don't know that
18 because you don't have data for 2021, 2022,
19 and 2023 with respect to the use of OPDIVO
20 and YERVOY for MSI-High colorectal cancer?
21 A Well, I do. I have their total data, I
22 have OPDIVO's total sales from their public

1 statements and what I don't have are any
2 further statements CRC accounts for, but I
3 have no reason to believe that's made large
4 gains compared to the others.
5 Q What's your basis for saying that OPDIVO
6 and YERVOY haven't made any gains in
7 2021, 2022, 2023 for colorectal cancer?
8 A I don't think that's what I said. I
9 said I don't have any basis for believing
10 that MSI-High colorectal cancer accounts for
11 any larger portion of OPDIVO and YERVOY total
12 sales in those years than it did in the
13 earlier years.
14 Q Do you have any information to believe
15 that the opposite isn't true that it did not
16 increase?
17 A Well, as I've said, in the years that I
18 do have statements for, I have reason to
19 believe that it's actually less than
20 five percent of their total sales. And
21 that's for the period immediately prior to
22 that, what I see after that point is there's

1 no further statements about that from Bristol
2 Meyers Squibb.
3 Q You're not an expert in the treatment of
4 MSI-High cancer, correct Mr. Segers?
5 A That's, yes, that's certainly correct.
6 Q You don't have any personal independent
7 knowledge about the use of OPDIVO and YERVOY
8 for the treatment of MSI-High colorectal
9 cancer, correct?
10 Let me ask it this way.
11 You can only go by the data that is
12 presented to you, correct?
13 A That's right.
14 Q And for 2021, 2022, and 2023, you do not
15 have any data about how frequently OPDIVO and
16 YERVOY were used for MSI-High colorectal
17 cancer, correct?
18 MS. MCCORMICK: Object to form.
19 A I have data for the total usage of which
20 what you're asking about is a portion of that
21 and I have, like I said, statements from them
22 for the period immediately prior about what

1 percentage, what portion of their sales that
2 accounts for. And I think I've said that I
3 don't have further statements from them
4 during that time period.
5 Q It's your view that commercial success
6 here is not due to Merck's marketing or
7 promotional efforts because Merck's marketing
8 or promotional efforts were focused on
9 educating healthcare professionals; is that
10 right?
11 A I think I would phrase it the way it's
12 written in the declaration.
13 But broadly what I would say is if the
14 efforts are focused on educating and
15 informing the marketplace about the benefits
16 of the patent, then that's -- it's the patent
17 that's contributing to that success.
18 Q And is it your opinion that all of
19 Merck's efforts towards marketing and
20 promotion were directed to educating the
21 market about the benefits of the patent?
22 A No. I think I cite in the declaration

1 that statements from Merck indicating that
2 they were making an effort to do just that.
3 Q In your declaration -- one moment.
4 In your declaration at Paragraph 39, the
5 last sentence of that paragraph, you say
6 immediately following that approval, Merck's
7 marketing and promotional efforts were
8 focused on educating health professionals to
9 increase awareness for MSI testing and the
10 value of KEYTRUDA across tumor types,
11 correct?
12 A Yes.
13 Q You cite an earnings call Exhibit 2231
14 in support of your conclusion, correct?
15 A That's right.
16 Q And you reviewed Exhibit 2231?
17 A Yes.
18 Q You understood it?
19 A To the best of my ability, yes.
20 Q In the earnings call, Merck was not
21 speaking about it's marketing and commercial
22 efforts, correct?

1 A I'd have to look at it.
2 MR. ZEILBERGER: Can the tech please
3 share Exhibit 2231.
4 (Whereupon, Merck & Co. Inc.
5 NYSE:MRK FQ2 2017 Earnings Call
6 Transcripts, Friday, July 28,
7 2017 (Bates No. IPR2024-00240)
8 was marked as Exhibit 2231 for
9 identification as of this date.)
10 Q Can you please turn to Page 16 of this
11 Exhibit.
12 A All right.
13 Q At the bottom of Page 16 of Exhibit 2231
14 there is the question that prompted the
15 statement that you're relying on, correct?
16 A You're talking about what prompted the
17 answer that begins on Page 17?
18 Q Correct.
19 A Yes. It appears so.
20 Q The question doesn't discuss or mention
21 any marketing or promotional efforts,
22 correct?

1 A Sorry, I'm just going to read it for a
2 minute if you don't mind.
3 Q Please.
4 A Okay. I've read it. I agree that the
5 words marketing and advertising are not used
6 in the question.
7 Q Is it your opinion that there's words
8 that could be interpreted as referring to
9 marketing and promotional efforts in the
10 question?
11 A No. My opinion is that in the answer he
12 emphasized their efforts to increase
13 awareness and that could be categorized as
14 those types of things or education.
15 Q Where in the answer on Page 17 of the
16 exhibit does it say that marketing and
17 promotional efforts were focused on educating
18 health professionals to increase awareness
19 for MSI testing in the value of KEYTRUDA
20 across tumor types?
21 A I think when he says we're working
22 really hard that indicates that they have a

1 focus to do just that.
2 Q So when you used the word "focused" in
3 your declaration, what did you mean?
4 A I meant that was an area of focus, at
5 least according to this earnings call. That
6 what he says, again, these are his words,
7 that we're working hard -- sorry, we're
8 really working hard to increase awareness for
9 MSI testing and the value of KEYTRUDA across
10 the tumor types.
11 Q So when you used the word focused in the
12 last sentence of Paragraph 39 of your
13 declaration what you meant was that this was
14 one area of focus for Merck, correct?
15 A I think that's fair that this is one
16 area I was able to observe in their earnings
17 calls.
18 Q Did you investigate what other areas of
19 focus Merck had with respect to its marketing
20 and promotional efforts for KEYTRUDA?
21 A Well, again, I don't have KEYTRUDA's
22 specific marketing and advertising expenses.

1 I did look at Merck's overall expenses in
2 those categories. I looked at their earnings
3 call, I looked at this statement here, which
4 I'll note if we continue on through that
5 quote he's talking about, you know, he says
6 after the June approval there's certainly
7 healthcare professional awareness that we're
8 hearing, but it's too early to see that
9 translated in the sales. So they're talking
10 about increasing these efforts for the
11 reason, it seems like, for the reason of
12 increasing sales. So that's the kind of
13 activity I wanted to look at in terms of
14 evaluating commercial success to see whether
15 what they're talking about using the
16 increased sales has to do with the patent
17 itself or not. And what he's talking about
18 here is education and information about
19 the -- about MSI-High.
20 Q If you turn to Paragraph 40 of your
21 declaration, specifically the sentence that
22 starts four lines down on Page 26. You

1 state:
2 "Furthermore, Merck's advertising
3 and promotion expenses decreased in
4 2018 and 2019 to 4.97 percent and
5 4.48 percent of total revenue
6 respectively. Despite the continuing
7 growth in sales of KEYTRUDA for
8 treatment of MSI-High or dMMR CRC,
9 indicating that KEYTRUDA's increase in
10 sales are not correlated with increased
11 marketing and promotional efforts."
12 Correct?
13 A Yes. I see that.
14 Q The advertising and promotion expenses
15 that you refer to in that sentence are not
16 limited to KEYTRUDA, correct?
17 A That's right. I was not provided that
18 information by Merck.
19 Q Did you ask for information relating to
20 Merck's advertising and promotion expenses
21 for KEYTRUDA?
22 A Yes. I believe I asked for a profit and

1 loss statement for KEYTRUDA as a whole. That
2 would include that type of information, at
3 least on a cost basis.
4 Q When you say you asked for that
5 information, who did you ask?
6 A That would have been conveyed through
7 counsel at Fish & Richardson.
8 Q Did you consider Merck's marketing and
9 promotion expenses in 2014?
10 A I don't think it's cited in this report.
11 I may have looked at it. I would certainly
12 expect that were there some, given that they
13 launched in that time period.
14 Q And you agree that marketing and
15 promotion of KEYTRUDA that Merck would have
16 done in 2014 is relevant to considering
17 commercial success in this case?
18 A I think you would want to consider
19 whether it was some sort of extraordinary
20 level. And everything I've seen, I haven't
21 seen anything unusual about Merck's efforts
22 in advertising and marketing. But it's

1 certainly common to promote a new drug when
2 it first launches.
3 Q So it's your opinion that the only way
4 that marketing and promotion by Merck of
5 KEYTRUDA in 2014 would be relevant in this
6 case is if there was an extraordinary level
7 of marketing and promotion?
8 A That may be relevant. What was relevant
9 to me, what I focused on, was when they
10 gained this MSI indication, what did their
11 marketing efforts look like there. And is
12 that something that would potentially be
13 driving sales within the CRC indication.
14 What I found was statements from Merck
15 talking about increasing information and
16 awareness and that their expenditures
17 overall, because that's the data I had, don't
18 appear to be extraordinary or unusual. In
19 fact, they're even declining a little bit
20 after they get the indication.
21 Q Well, when you say that they declined a
22 little bit, you're talking about Merck's

1 advertising and promotion expenses as a
2 whole, correct?
3 A Yes. That's the information I had
4 available.
5 Q And the figures that we're talking about
6 here in terms of marketing and promotion are
7 in the billions of dollars on a yearly basis,
8 correct?
9 A That may be.
10 Q Well, that's what you say in the top of
11 Paragraph 40, correct?
12 A Oh, yes. Yeah. That's right.
13 Q Those dollar figures are significantly
14 higher than the revenue Merck generates from
15 the MSI-High colorectal cancer indication for
16 KEYTRUDA, correct?
17 A That's right.
18 Q So it would -- well, strike that.
19 When you're looking at $2.2 billion
20 versus $2.1 billion of advertising and
21 promotion expenses, if that entire budget was
22 directed for the MSI-High colorectal cancer

1 indication, that would be an extraordinary
2 marketing effort, correct?
3 MS. MCCORMICK: Object to form.
4 A As a percentage of sales, yes, it would
5 probably be much higher than the norm in the
6 industry, yeah.
7 Q And you don't actually know what
8 percentage of that budget was, in fact,
9 applied to the MSI-High colorectal cancer
10 indication, correct?
11 A Merck hasn't provided any information of
12 that sort.
13 Q It's possible that even if Merck's
14 overall advertising and promotion expenses
15 stayed the same year to year or even went
16 down, that Merck's advertising and promotion
17 expenses associated with the MSI-High
18 colorectal cancer indication went up,
19 correct?
20 A Well, as I just said, Merck hasn't
21 provided that information. It's possible,
22 but what I would say to that is, it also

1 matters the type of advertising and the type
2 of messaging that they're doing and whether
3 or not it's informative and educational and
4 related to the patent.
5 And the evidence I've seen from their
6 efforts, when they talked about really
7 working hard, have to do with just that.
8 Q Earlier today you mentioned how there
9 were sales of KEYTRUDA for sales or
10 associated with the MSI-High colorectal
11 cancer indication [redacted]
12 [redacted].
13 Do you remember that?
14 A I do.
15 Q And you stated earlier today that it
16 could be those were through clinical trials,
17 correct?
18 A Yes. I recall saying that.
19 Q If KEYTRUDA was being used for MSI-High
20 colorectal cancer in clinical trials, those
21 would not be considered sales, correct?
22 A I don't know. I don't know the answer

1 to that.
2 Q Is that something you attempted to
3 investigate when you prepared your
4 declaration?
5 A No.
6 Q In Appendix 5 of your declaration, you
7 attribute [redacted]
8 as sales, correct?
9 A I believe that's correct. Yes. I
10 believe that [redacted]
11 [redacted]. Hard to tell because this is not
12 monthly data on Appendix 5, but from the
13 note, yes.
14 Q But you prepared Appendix 5, correct,
15 Mr. Segers?
16 A Yes. I did.
17 Q So I assume you know what it reflects?
18 A Yes. In using the notes, it says it
19 reflects data [redacted].
20 Q Earlier today you mentioned how KEYTRUDA
21 received its first approval in 2014, correct?
22 A That's right.

1 Q Are you aware that KEYTRUDA received two
2 additional approvals in 2015?
3 A I'm aware there were others. As I sit
4 here right now, I don't recall the exact
5 timing, but that sounds correct.
6 Q Are you aware that KEYTRUDA received two
7 more approvals in 2016?
8 A Again, I don't have perfect
9 recollection, but if you're suggesting to me
10 that that's the case, I'll take your word for
11 it and it seems consistent.
12 Q That's not something you discuss in your
13 declaration, correct?
14 A I think I discussed the initial
15 approval, and then the MSI-High CRC approval
16 and the agnostic approval, I think those are
17 the ones I mentioned.
18 Q Are you aware that KEYTRUDA received
19 five additional approvals in 2017?
20 A Yes. That sounds correct.
21 Q And the majority of those approvals do
22 not relate to MSI-High colorectal cancer,

1 correct?
2 A Well, at least one other relates to the
3 MSI-High agnostic indication.
4 Q All right. So are you saying that the
5 majority of their approvals do relate to
6 MSI-High colorectal cancer?
7 A No. I'm just pointing out there was at
8 least one other that was agnostic.
9 Q So you agree that a majority of the
10 approvals do not relate to MSI-High
11 colorectal cancer in 2014 through 2017?
12 A Yes.
13 Q You would agree that Merck would have
14 invested in promoting and advertising
15 KEYTRUDA with respect to those other
16 indications for which it was approved; is
17 that right?
18 A I expect so, yes.
19 Q In your declaration, you don't analyze
20 the impact of those other promotion and
21 advertising efforts, correct?
22 A Well, again, I was limited on what data

1 I had in those advertising promotion efforts.
2 When I did see information from the earnings
3 call about the MSI-High specific efforts, I
4 looked at that. And, like I said, I found
5 those were focused on information about the
6 patented claims and education about it.
7 Q In Paragraph 40 of your declaration, you
8 say that you have seen no evidence that Merck
9 significantly increased its marketing and
10 promotional efforts following the FDA
11 approval for treatment of MSI-High or dMMR
12 cancers in 2017, correct?
13 A Yes.
14 Q Isn't the statement from the earnings
15 call that we were just talking about evidence
16 that Merck was in part focused on investing
17 in marketing the MSI-High indication?
18 A Yes. But it's not evidence to me that
19 they're doing anything out of the ordinary or
20 unusual in regards to marketing.
21 Q Well, this sentence in Paragraph 40,
22 you're not saying you've seen no evidence

1 that Merck did anything unusual, you're
2 saying that you've seen no evidence that
3 Merck significantly increased its marketing
4 and promotional efforts, correct?
5 A Right. But later on in the same
6 paragraph I also say I've seen no evidence
7 that they're advertising for this indication,
8 it's persuasive as opposed to educational.
9 Q Did you consider the possibility that
10 Merck may have shifted its marketing focus
11 and redirected resources to increase
12 promoting of KEYTRUDA for MSI-High cancers
13 without increasing its overall marketing
14 budget?
15 A I don't have the data available to
16 consider that. I don't disagree with you
17 that it's possible they may have done that.
18 The data would tell you.
19 Q In Paragraph 40, you state that
20 increasing sales are not correlated with the
21 increased marketing and promotional efforts,
22 correct?

1 A Right.
2 Q You don't actually have the data
3 necessary to draw that conclusion, correct?
4 A Well, that particular sentence is
5 referring to Merck's overall marketing and
6 advertising expenses. And so that's -- I
7 have the data for that. I agree one would --
8 I would want to see the data for KEYTRUDA
9 itself and specifically for the indication.
10 Q So when you refer to increased marketing
11 efforts in that sentence, you're just
12 referring to Merck's overall budget for
13 marketing and promotional efforts, correct?
14 A Right. The only data I have on this for
15 Merck is what's publicly available in their
16 10Ks.
17 Q And as we talked about earlier today,
18 those figures are in the billions of dollars
19 and dwarf the actual revenues of MSI-High
20 colorectal cancer associated sales of
21 KEYTRUDA, correct?
22 A Yes. I agree with that.

1 Q Merck's marketing and promotional
2 activities from before 2017 could have had a
3 lagging affect on future sales, correct?
4 A Sure. I agree with your premise.
5 Q Where in your analysis did you account
6 for the continuing impact of previous
7 marketing efforts?
8 A So, as I said before, my analysis
9 focuses on their marketing efforts at the
10 time of the new indication.
11 Q Merck's marketing efforts from before
12 2017 would have increased brand recognition
13 for 2017 and onwards, correct?
14 A Could have. Although, I'll note that
15 the statement and the earnings call we were
16 reviewing earlier talked about the fact that
17 Merck didn't have as much recognition as it
18 liked, and it seemed like they were trying to
19 work really hard to increase that for the
20 MSI Indication.
21 Q Is it your opinion that in 2017,
22 KEYTRUDA as a drug for all cancer types, did

1 not have significant brand recognition?
2 A No. That's not my opinion.
3 Q You would agree that even as of 2017,
4 before the '393 Patent came to be, KEYTRUDA
5 already had significant brand recognition,
6 correct?
7 MS. MCCORMICK: Object to form.
8 A I don't know that I've come to that
9 conclusion either. I'll agree that
10 they've -- KEYTRUDA had been on the market
11 for a few years and made sales, significant
12 sales.
13 Q In 2016, KEYTRUDA made [redacted] in
14 sales, correct?
15 A That sounds correct.
16 Q In 2017, KEYTRUDA made [redacted] in
17 sales, correct?
18 A That also sounds correct, yes.
19 Q Is it your opinion that a drug making
20 [redacted] or [redacted] does not have
21 significant brand recognition?
22 A No. I didn't say that was my opinion.

1 I said I haven't done an analysis of brand
2 recognition before 2017.
3 Q Sitting here today, can you agree that
4 KEYTRUDA already had significant brand
5 recognition before the '393 Patent?
6 MS. MCCORMICK: Object to form.
7 A I can agree that they have made
8 significant sales of KEYTRUDA and it was
9 known in the marketplace.
10 Q Why are you unable to agree that
11 KEYTRUDA had significant brand recognition?
12 A I think you'd want to look at documents
13 and see what Merck thought for itself in
14 terms of what their brand recognition is.
15 And I just haven't done a study of it yet.
16 That's not something I've done as part of my
17 analysis.
18 Q Are you saying that it's not possible to
19 determine whether a drug has significant
20 brand recognition on public documents?
21 A I'm not saying that either. I'm just
22 saying I haven't done an analysis to

1 determine the level of KEYTRUDA's brand
2 recognition before 2017.
3 Q You agree that you could have performed
4 that analysis if you were asked to, yes?
5 A Potentially. Limited to information
6 available, yes. I certainly looked at the
7 sales that they made before that time period.
8 Q You would agree that brand recognition
9 is relevant to a consideration of the
10 commercial success factor, yes?
11 A Well, again, I think it depends on how
12 that brand recognition is obtained. Is it
13 gaining recognition because of the patented
14 benefits and features or is it gaining it for
15 other reasons.
16 Q So you agree that an analysis of brand
17 recognition is relevant when considering
18 commercial success, correct?
19 A Potentially. I don't -- in regards to
20 what we're talking about here, brand
21 recognition alone was not enough to enable
22 Merck to make sales in the MSI-High CRC

1 patient population before 2017. It required
2 more than that. As I say, it's my
3 understanding they couldn't make those sales
4 at all without the patent. So it's not as
5 though brand recognition alone would allow
6 those sales.
7 Q Brand recognition would increase the
8 likelihood of a physician prescribing
9 KEYTRUDA over another drug such as OPDIVO,
10 correct?
11 A It could be one of the factors. As I've
12 already said and say in the declaration, what
13 I see is when the indication was granted
14 Merck is working really hard to educate the
15 marketplace about the benefits of the patent
16 and the MSI-High population.
17 Q And you did not consider brand
18 recognition in your declaration, correct?
19 A I think I consider it as part of their
20 marketing and advertising efforts and what I
21 observed about the nature of that. Like I
22 said, they're talking about the benefits of

1 the product itself, not counting the brand.
2 Q Was KEYTRUDA or OPDIVO more popular
3 across all cancer types in 2016?
4 A You would have to tell me how you're
5 defining popular.
6 Q Was KEYTRUDA or OPDIVO prescribed to
7 more patients across all cancer types in
8 2016?
9 MS. MCCORMICK: Object to form.
10 A So I don't have the total prescription
11 numbers for OPDIVO. The IQVIA data I was
12 given shows numbers for KEYTRUDA. Doesn't
13 show me shares, doesn't show me the number of
14 patients or prescriptions for other drugs.
15 The only thing I had to go by was the total
16 revenues of each product.
17 Q Did you consider whether physicians were
18 more likely to be willing to prescribe
19 KEYTRUDA to MSI-High colorectal cancer
20 patients because of its prior approvals for
21 other indications?
22 A I think so. Again, citing that the same

1 earnings call statements that they are making
2 efforts to talk to physicians about
3 prescribing in this MSI-High population. And
4 I believe that statement talked about they
5 had some expectations about how that -- I'd
6 have to look at the quote again. But it did
7 talk about some prior expectations and those
8 would be based on expectations prior to the
9 approval. So from other indications.
10 Q Right. So you would agree that
11 physicians were more likely to prescribe
12 KEYTRUDA for the MSI-High colorectal cancer
13 indications because of its early approvals
14 for other indications, correct?
15 MS. MCCORMICK: Objection to form.
16 A I don't know that I've seen anything one
17 way or the other that says they had an
18 inherent greater willingness to prescribe
19 KEYTRUDA than OPDIVO.
20 Q Okay. Then so --
21 A I think that OPDIVO was -- I think that
22 their approval date was just a little prior

1 to KEYTRUDA in the -- in the CRC indication.
2 Q I didn't ask you about OPDIVO,
3 Mr. Segers.
4 My question was: Would you agree that
5 physicians were more likely to prescribe
6 KEYTRUDA for the MSI-High colorectal cancer
7 indication because of its earlier approvals
8 for other indications?
9 A I'm not a physician. I mean, my
10 assumption was that physicians are
11 prescribing treatments for these cancers
12 based on what they think is best for their
13 patients.
14 Q I see. So it's your opinion that
15 earlier brand recognition in the
16 pharmaceutical industry doesn't play a role
17 in future sales for other indications?
18 MS. MCCORMICK: Object to form.
19 A I think it could. But, again, as I said
20 earlier, it depends on what the source of
21 this brand recognition is. Is it the
22 benefits and features of the product, or is

1 it advertising that may be more consumer
2 driven and sort of extraordinary or unusual.
3 And that's the sort of analysis I have in my
4 declaration here.
5 Q And we're here today, Mr. Segers, to
6 talk about KEYTRUDA, not general statements
7 about what could or could not be in an
8 abstract world, and I'm asking about your
9 analysis of KEYTRUDA.
10 What did you do to investigate the
11 impact of KEYTRUDA's brand recognition from
12 the time period before the first MSI-High
13 related indication, the impact of that on
14 sales associates with the MSI-High
15 indications?
16 MS. MCCORMICK: Object to form.
17 A So I've examined their sales and their
18 marketing efforts during this time. I've
19 examined the sales within the CRC indication,
20 in particular. I've compared it to other
21 drugs that were available at or even just
22 before for MSI-High CRC. So it -- I've

1 evaluated all of that in the context of their
2 marketing efforts.
3 And as I said in the declaration, I
4 don't see anything unusual that says there
5 they're touting a brand name or they're
6 touting anything other than the benefits of
7 KEYTRUDA for MSI-High CRC indication.
8 Q And you're basing all of this on the one
9 sentence from the earnings call; is that
10 right?
11 A In part, but also, I haven't seen any --
12 well, there's other discussion in that
13 section, too. I haven't seen any evidence of
14 sort of persuasive marking or advertising. I
15 have some discussion about even the
16 effectiveness of things like the direct to
17 consumer advertising for cancer drugs. And
18 I -- my review of the documents and data
19 available lead me to the conclusion that they
20 are marketing, to the extent they are
21 marketing and making efforts, it's about the
22 benefits to patient in the MSI-High CRC

1 population who are using KEYTRUDA.
2 Q Besides this one sentence from the
3 earnings call that you quote in your
4 declaration, can you please point me to a
5 single other piece of evidence relating to
6 Merck's brand recognition or marketing
7 efforts that you analyzed for your
8 declaration?
9 A Well, in that same paragraph, I also
10 point to Merck's website, where they have
11 information about KEYTRUDA. I noted that the
12 information on their website is talking about
13 MSI-High/dMMR and the results for patients
14 who use KEYTRUDA on those -- in this patient
15 population.
16 Q So it's your opinion that Merck's
17 website, with respect to the KEYTRUDA, all it
18 talks about is the MSI-High indication?
19 A No. That's not my opinion at all.
20 Q You agree that Merck also markets
21 KEYTRUDA more generally, correct?
22 A I agree.

1 Q And you agree that Merck also marketed
2 KEYTRUDA more generally before the MSI-High
3 indication was approved?
4 A Yes. I agree with that, too.
5 Q Those earlier marketing efforts from
6 before the '393 Patent was approved would
7 have impacted knowledge about KEYTRUDA in the
8 time period after the MSI-High indication was
9 approved, correct?
10 A It could to some extent, yes.
11 Q And Merck's marketing efforts relating
12 to KEYTRUDA, generally, even after the
13 MSI-High indication was approved, also would
14 have impacted sales of KEYTRUDA associated
15 with the MSI-High indications, correct?
16 A The -- I'm sorry. The advertising for
17 KEYTRUDA overall, sure, yes.
18 MR. ZEILBERGER: Why don't we take a
19 break.
20 (Whereupon, a recess was taken
21 from 2:54 PM until 3:30 PM.)
22 MR. ZEILBERGER: Let's go back on the

1 record.
2 Q Mr. Segers, do you still have your
3 declaration with you?
4 A I do.
5 Q Can you please turn to Paragraph 41 of
6 your declaration.
7 A Yes.
8 Q In Paragraph 41 you state that, "There
9 is evidence that direct-to-consumer
10 advertising is not particularly effective at
11 causing cancer patients to ultimately receive
12 the advertised drug," correct?
13 A That's right.
14 Q What evidence did you consider to arrive
15 at that conclusion?
16 A So I looked for papers in literature
17 about advertising to consumers who are cancer
18 patients, and I cite the article I've
19 reviewed there.
20 Q You're referring to Exhibit 2232?
21 A Yes.
22 Q You state that "it's not particularly

1 effective."
2 What do you mean?
3 A I think what's reflected in the last
4 sentence there, that only 3 percent received
5 the advertised medication.
6 Q So you agree that direct-to-consumer
7 advertising has an impact on sales?
8 A I don't think that concludes that. That
9 just noted that 3 percent of those received
10 the medication.
11 Q Paragraph 33, if you turn back, you
12 state that "The market share penetration that
13 KEYTRUDA had achieved so far since it's
14 approval to treat MSI-High or dMMR colorectal
15 cancer is further evidence of its commercial
16 success," correct?
17 A Yes.
18 Q Did you consider -- strike that.
19 When you refer to market share
20 penetration here, are you referring to
21 KEYTRUDA as a whole, or with respect to
22 MSI-High colorectal cancer?

1 A So the analysis that's reflected here in
2 this section refers to MSI-High colorectal
3 cancer, it refers to that -- that indication.
4 Q Please turn to Paragraph 26.
5 Do you recall we spoke earlier today
6 about what you refer to as an apparent
7 inflection point in KEYTRUDA's sales
8 trajectory?
9 A Yes.
10 Q And you are referring to the apparent
11 inflection point in Appendix 4, correct?
12 A Yes.
13 Q You also testified earlier today that
14 sales of KEYTRUDA associated with MSI-High
15 colorectal cancer make up [redacted]
16 of KEYTRUDA's sales, correct?
17 A Yes.
18 Q If you were to subtract out sales of
19 KEYTRUDA associated with the MSI-High
20 colorectal cancer, the apparent inflection
21 point in Appendix 4 would still be present,
22 correct?

1 A I think I agree with that, yes.
2 Q The apparent inflection point in
3 Appendix 4 is associated with things other
4 than the MSI-High colorectal cancer
5 indication for KEYTRUDA, correct?
6 MS. MCCORMICK: Object to form.
7 A Yes. I agree there are other factors
8 including the MSI-High agnostic indication.
9 Q [redacted] of the inflection point in
10 Appendix 4 relates to things other than the
11 MSI-High colorectal cancer indication for
12 KEYTRUDA, correct?
13 A I mean, that's kind of an odd way you've
14 worded it to say [redacted] of the inflexion
15 point. It certainly -- there are none really
16 before the inflection point and there are
17 some after, but in general, I think during
18 the period where the MSI-High CRC indication
19 is on the market, yes, it's fair to say that
20 [redacted] of those sales are other
21 indications.
22 Q The MSI-High indication did not cause

1 sales of KEYTRUDA for indications that are
2 not the MSI-High indication, correct?
3 A Yes. I have not made that claim.
4 Q And we talked earlier today about other
5 drugs that are approved for treating MSI-High
6 colorectal cancer such as OPDIVO and YERVOY,
7 correct?
8 A Yes.
9 Q And are you aware that OPDIVO and YERVOY
10 treat MSI-High colorectal cancer without
11 relying on the '393 Patent?
12 A Yes.
13 Q Is YERVOY a standalone treatment?
14 A One of them is prescribed with the
15 other, I believe it's YERVOY is prescribed
16 along with OPDIVO.
17 Q And both YERVOY and OPDIVO are sold by
18 Bristol Meyers Squibb, correct?
19 A That's right.
20 Q When YERVOY and OPDIVO were prescribed
21 together, they are more expensive than
22 KEYTRUDA, correct?

1 A Yes. That's my understanding. I think
2 my report discusses that a little bit, for
3 the period of time where a patient is taking
4 both of them, it may be more expensive. But
5 then, my understanding is, after that initial
6 period, they would be on OPDIVO only.
7 And to clarify, that answer is based on
8 the list prices.
9 Q And when you say it may be more
10 expensive. It would be more expensive,
11 correct, to --
12 A So this price would be. That's why I
13 said maybe, because it depends on what the
14 payer is ultimately paying.
15 Q And you say that because you did not
16 analyze insurance-related factors in your
17 declaration, correct?
18 A Well, I didn't have the net sales prices
19 that would be net of things like discounts
20 and rebates, that are paid to insurers.
21 Q And you didn't ask for that information?
22 A I think that would be reflected in the

1 P&L that I did ask for, at least from Merck.
2 Q When you say you asked for it from
3 Merck, do you mean you asked JHU to get it
4 from Merck?
5 A I believe I communicated the request
6 through counsel, that I would like to see a
7 P&L for KEYTRUDA, a profit and loss
8 statement.
9 Q And profit and loss statement would
10 provide information relating to the cost that
11 a consumer has for KEYTRUDA after discounts
12 and insurance?
13 A No. It would provide for information on
14 net sales or net revenue that are net of
15 things like discounts and rebates paid to
16 insurers.
17 Q And it's your opinion that there are no
18 public sources that provide typical costs of
19 KEYTRUDA that a patient will ultimately pay?
20 A No. I did review some data on the
21 patient payment.
22 Q Okay. Where, which exhibit is that

1 contained in, in your declaration?
2 A It's in the discussion about pricing at
3 the end of -- there is no exhibit for it.
4 Q Which discussion are you referring to?
5 A So it starts on Page 27, and goes
6 through Page 30. The discussion about
7 patient costs would be, for example, in
8 Paragraph 43.
9 43 would have most of the discussion
10 about patient costs.
11 Q Do you know whether KEYTRUDA, OPDIVO,
12 and YERVOY have similar levels of
13 authorization with insurance providers?
14 A I don't know as I sit here right now. I
15 don't know if I ever knew or I don't recall
16 if I didn't look at it. But I don't know.
17 Q Are patients typically the ones that
18 would pick between using KEYTRUDA, or OPDIVO
19 and YERVOY?
20 A As I said earlier, I'm not a physician.
21 I'm not, you know, that's not my area of
22 expertise. Again, is they're treating their

1 patients the best they know how. I'm sure
2 for a patient, price is a consideration.
3 Q Is price a consideration for a physician
4 describing KEYTRUDA, or OPDIVO and YERVOY?
5 A Again, I'm not a physician. I mean,
6 I -- my assumption is it could be. I assume
7 they also care about their patient's
8 concerns, but...
9 Q A few moments ago you rendered an
10 opinion that the direct-to-consumer marketing
11 isn't effective, correct?
12 A That's correct.
13 Q So why is it that pricing would impact a
14 consumer's decision on whether to use
15 KEYTRUDA or OPDIVO and YERVOY, in your
16 opinion?
17 A Well, I wanted to look to see things
18 like if there was any differences in the
19 extent in which patients were basically able
20 to obtain the treatments for zero copay, or
21 for free, or for a very low copay. Because
22 that would, obviously, I think for many

1 patients, they face financial constraints.
2 And that unfortunately would be a
3 consideration for them.
4 Q The overall market growth for drugs that
5 treat MSI-High colorectal cancer is not
6 solely attributable to the '393 Patent,
7 correct?
8 A Yes. There are other products out there
9 that we've been discussing, so yes, I agree
10 with that.
11 Q Did you attempt to isolate the impact of
12 the '393 Patent on the overall market growth
13 for the drug that is treating MSI-High
14 colorectal cancer?
15 A So I've looked at this success
16 specifically for KEYTRUDA within this
17 indication, I've measured it for KEYTRUDA
18 only excluding those other drugs, that's the
19 way I accounted for it.
20 Q It's the way you accounted for what?
21 A That's the way I accounted for the
22 measuring the sales attributable to the '393

1 Patent, as I look at the sales for which that
2 patent, in the indication that patent
3 enables.
4 Q Is it your opinion that if the '393
5 Patent didn't exist, you would just subtract
6 out those sales and that's what the market
7 would look like?
8 A No. Well, for KEYTRUDA, I think you
9 would subtract out those sales for KEYTRUDA.
10 Q I'm asking about the overall market for
11 MSI-High colorectal cancer drugs?
12 A No. That's not my opinion.
13 Q Did you perform an analysis of what the
14 market for MSI-High colorectal cancer drugs
15 would look like if KEYTRUDA was not
16 prescribed for MSI-High colorectal cancer?
17 A No. I don't believe that's necessary.
18 Q And you didn't perform that analysis,
19 correct?
20 A Yes. That's correct. I said no.
21 Q Let's go to Appendix 9 of your
22 declaration please.

1 Let me know when you're there.
2 A I have it.
3 Q Appendix 9 of your declaration is a bar
4 graph reflecting annual US market shares of
5 KEYTRUDA, OPDIVO, and YERVOY for MSI-High
6 dMMR CRC, correct?
7 A Yes.
8 Q When you say market share in Appendix 9,
9 you are referring to revenue market share,
10 correct?
11 A That's correct.
12 Q Appendix 9 is displaying the same
13 information you provide in Appendix 6, but in
14 the bar graph form instead of line graph
15 form, correct?
16 A Give me one second to look at
17 Appendix 6.
18 Yes. That's correct.
19 Q Are you familiar with the concept of but
20 for causation?
21 A Yes.
22 Q Did your analysis include a but for

1 assessment of what projected sales would have
2 been in a world without the patented
3 invention?
4 A For the MSI-High CRC indication, yes,
5 because that sort -- as I understand from my
6 conversations with Dr. Goldberg those sales
7 in that indication would not be possible
8 without the patent.
9 Q What about sales of KEYTRUDA overall?
10 A Overall would include the indications
11 within the patent. So they would be changed.
12 Q Is it your opinion that you would just
13 subtract out the MSI-High colorectal cancer
14 related sales in a but for world where you
15 don't have the '393 Patent?
16 A Potentially. I haven't done that
17 analysis. I focused on the MSI-High CRC
18 indication.
19 Q What would KEYTRUDA's price be in a
20 world without the '393 Patent?
21 A Well, it's overall net sales price,
22 again, which I don't have full data for, is a

1 function in part of their net sales price
2 within that indication. So I mean, as I sit
3 here today without having access to actually
4 their net sales price it's hard to say.
5 Q You then perform that analysis in your
6 declaration, correct?
7 A I don't have their net sales.
8 Q So you did not perform the analysis in
9 your declaration, correct?
10 A Yes. Because I didn't have it.
11 Q Did your analysis include a but for
12 assessment of what projected OPDIVO and
13 YERVOY sales would have been in a world
14 without the '393 Patent?
15 A No. It does not.
16 Q If you turn to Paragraph 14 of your
17 declaration. Please let me know when you're
18 there.
19 A I am here.
20 Q Paragraph 14 refers to a clinical study
21 that started in 2013, correct.
22 A That's correct.

1 Q And it's your understanding that that
2 clinical study led to the '393 Patent,
3 correct?
4 A Yes.
5 Q You understand that that clinical study
6 was conducted using what's today referred to
7 as KEYTRUDA?
8 A Yes. I understand that.
9 Q Were you aware that JHU initially wanted
10 to conduct the clinical study using OPDIVO?
11 A I am aware and my recollection is that
12 the request was rejected.
13 Q Is it your understanding that the
14 clinical study used KEYTRUDA because Bristol
15 Meyers Squibb declined to provide JHU with
16 OPDIVO?
17 A No. I don't think I would go -- I
18 understand there was a prior request and
19 there was decline, that's the extent of my
20 understanding.
21 Q If Merck had not provided KEYTRUDA for
22 the clinical study then the '393 Patent

1 wouldn't have existed, correct?
2 A I am not a patent attorney, but I would
3 think in its current form that that's
4 correct.
5 Q In what way did you account for JHU's
6 willingness to implement it's alleged
7 invention using OPDIVO instead of KEYTRUDA?
8 MS. MCCORMICK: Object to form.
9 A I think they had a willingness to use
10 KEYTRUDA because that's how they designed the
11 study and I don't know that I have an
12 understanding beyond that.
13 Q Well, a few minutes ago you said you did
14 have an understanding that they approached
15 Bristol Meyers Squibb to use OPDIVO for the
16 clinical study, did you not?
17 A I did, but I don't think that tells me
18 anything about their willingness to use or
19 not use KEYTRUDA. My understanding is they
20 had a willingness to use KEYTRUDA and that's
21 why they decided to study this way.
22 Q So my question is in what way did you

1 account in your commercial success analysis
2 for JHU's willingness to implement its
3 alleged invention using OPDIVO?
4 MS. MCCORMICK: Object to form.
5 A I don't think that I needed to.
6 Q Why not?
7 A Because ultimately the study was done
8 with KEYTRUDA not with OPDIVO for whatever
9 reasons Bristol Meyers had for rejecting the
10 claim, perhaps they didn't think it would
11 work or whatever reason they did not do the
12 study with that. All I know from the record
13 is they did do and intended to do the study
14 using KEYTRUDA.
15 Q Did your analysis factor the degree to
16 which brand recognition for KEYTRUDA led to
17 JHU choosing to use KEYTRUDA in the clinical
18 study?
19 A No.
20 Q If JHU chose KEYTRUDA for the clinical
21 study, due to its brand recognition, that
22 would be relevant to commercial success

1 analysis, correct?
2 A You mean as opposed to other features
3 like clinical results and that sort of thing?
4 Q Yes.
5 A Solely from the brand name?
6 Q If JHU chose KEYTRUDA for the clinical
7 study due to its brand recognition that would
8 be relevant to a commercial success analysis,
9 correct?
10 A No. I'm not sure I agree with that.
11 Q If JHU chose KEYTRUDA for the clinical
12 study due to its safety profile that would be
13 relevant to a commercial success analysis,
14 correct?
15 MS. MCCORMICK: Object to form.
16 A Again, I'm not sure. Those things are
17 before there was a commercial product
18 embodied in the invention, so I'm not sure
19 they would be relevant.
20 Q You don't think that would be an
21 acknowledgment by JHU that KEYTRUDA has
22 benefits apart from the claimed invention?

1 MS. MCCORMICK: Object to form.
2 A No. I don't have an opinion on that.
3 And I'm not aware of any acknowledgment like
4 you're talking about.
5 Q Do you have any understanding as to what
6 drugs were available to JHU to chose from
7 when it was choosing a drug for the clinical
8 study?
9 A At least KEYTRUDA and OPDIVO, I'm not
10 aware that there were any beyond that.
11 Q If you go to Paragraph 21 of your
12 declaration.
13 In Paragraph 21 you note how for adults
14 with MSI-High colorectal cancer KEYTRUDA is
15 administered either 200 milligrams every
16 three weeks or 400 milligrams every
17 six weeks, correct?
18 A Yes.
19 Q The '393 Patent does not refer to these
20 dosages, correct?
21 A Again, I'm not an attorney or a patent
22 attorney, but if you represented that to me,

1 I -- I'll take your word for it, but I don't
2 have an opinion to whether -- outside of just
3 reading it to see if it's in there, I don't
4 have an opinion on it.
5 Q You didn't investigate whether the '393
6 Patent had any discussion about the dosages
7 that you referred to in Paragraph 21,
8 correct?
9 A I've looked at the claims, like I said
10 earlier when we were talking, but I don't
11 recall whether I was looking to see if the
12 dosage information was in there or not.
13 Q Did you ask anybody whether the '393
14 Patent has any information directed to the
15 dosages you refer to in Paragraph 21?
16 A I don't recall.
17 Q Did you analyze the extent to which the
18 particular dosages recited in Paragraph 21 of
19 you declaration led to KEYTRUDA's commercial
20 success?
21 A No. I haven't looked at any dosage
22 specific information nor do I think I had

1 any, in terms of how many sales or how many
2 patients were on each dosage.
3 Q And it's possible if KEYTRUDA was
4 prescribed with a different dosage it would
5 have had a different degree of commercial
6 success, correct?
7 A I don't have an opinion on that.
8 Q It's not something you considered,
9 correct?
10 A That's correct.
11 Q Do you have any understanding as to who
12 determined the appropriate dosage for
13 KEYTRUDA?
14 A As I sit here right now, no, I don't
15 recall whether that's in the prescribing
16 information or not.
17 Q On Paragraph 21 you cite to KEYTRUDA's
18 prescribed information to support your
19 statement about the appropriate dosages,
20 correct?
21 A For these, yes, I'm sorry I thought you
22 were asking more broadly about every single

1 indication, but...
2 Q For the dosages you refer to in
3 Paragraph 21 with respect to MSI-High
4 colorectal cancer, do you have any
5 information as to who determined that those
6 are the appropriate dosages?
7 A Well, my assumption is if it's in the
8 prescribing information or on the label that
9 it's the FDA in conjunction with Merck were
10 involved in that process.
11 Q If the appropriate dosages for KEYTRUDA
12 for MSI-High colorectal cancer had not been
13 determined then KEYTRUDA could not have been
14 successful, correct?
15 MS. MCCORMICK: Object to form.
16 A I'm not sure I follow your question.
17 Q In order to have a successful drug, an
18 appropriate dosage for that drug has to be
19 determined, correct?
20 MS. MCCORMICK: Object to form.
21 A I think in order to be successful there
22 has to be an approval and an approved label,

1 I agree with that.
2 Q Part of an approval with an approved
3 label is an approved dosage, correct?
4 A That my general understanding, yes.
5 Q So a portion or even all of a drug's
6 commercial success can be tied to the dosage
7 for that drug, correct?
8 MS. MCCORMICK: Object to form.
9 A No. I don't think I agree that --
10 especially your statement about even all
11 would be merely to the dosage.
12 Q You would agree that a portion of a
13 drug's commercial success can be tied to the
14 dosage of that drug, correct?
15 MS. MCCORMICK: Objection to form.
16 A It could contribute to it.
17 Q And here you do not analyze whether the
18 '393 Patent has any relationship to the
19 dosage information for KEYTRUDA, correct?
20 MS. MCCORMICK: Object to form.
21 A I'm sorry, can you ask that one more
22 time?

1 Q You did not analyze whether the '393
2 Patent has any relationship to the dosage
3 information for KEYTRUDA, correct?
4 A That's right, I didn't do an analysis of
5 the claims to determine whether these
6 particular dosages are within the claim
7 limitations of the patent. That was beyond
8 my scope, I agree with that.
9 Q KEYTRUDA, OPDIVO, and YERVOY, have
10 different side effects, correct?
11 A I believe that's correct, yes.
12 Q Did you analyze the degree to which
13 KEYTRUDA's commercial success is attributed
14 to its side effects as compared to OPDIVO and
15 YERVOY?
16 A I did not. Nor did I feel that I needed
17 to.
18 Q Is it your opinion that the '393 Patent
19 covers the side effects of KEYTRUDA?
20 A I don't have an opinion on that.
21 Q If it's the case that KEYTRUDA is
22 prescribed more often than OPDIVO or YERVOY

1 because it has fewer side effects, that would
2 not relate to the '393 Patent, correct?
3 A Again, I don't have an opinion on that
4 as to whether side effects are within the
5 claim limitations or not.
6 Q It's not something you considered,
7 correct?
8 A That's right.
9 Q Did you consider whether KEYTRUDA OPDIVO
10 and YERVOY have a different safety profile?
11 A No.
12 Q Did you analyze the degree to which
13 KEYTRUDA's commercial success is attributed
14 to its safety profile as compared to OPDIVO
15 and YERVOY?
16 A No. What I did is analyzed whether
17 KEYTRUDA's commercial success within the
18 MSI-High CRC indication is attributable to
19 the patent.
20 Q In conducting that analysis, you did not
21 factor in whether some of KEYTRUDA's
22 commercial success for MSI-High colorectal

1 cancer is attributed to its safety profile or
2 its side effects as compared to OPDIVO and
3 YERVOY, correct?
4 A I did not calculate the portion of their
5 commercial success that's attributable to
6 those factors, I agree with that.
7 Q You didn't consider those factors
8 holistically either, correct?
9 A I think I did, but I also considered, as
10 I mentioned my discussions with Dr. Goldberg
11 and whether or not the sales of KEYTRUDA
12 within this indication are possible at all
13 without the patented -- without the '393
14 Patent.
15 Q So you said you think you did consider
16 the safety profile and side effects of
17 KEYTRUDA, can you please show me where you
18 analyzed that in your declaration?
19 A I don't think I did just say that. I
20 think I considered whether the '393 Patent is
21 necessary and a driver of sales for KEYTRUDA
22 within that indication. I had discussions

1 with Dr. Goldberg about that, that formed my
2 understanding and then I measured KEYTRUDA
3 sales within that indication.
4 Q Do you understand that the question of
5 whether something practices a patented
6 invention is different from the question of
7 whether the commercial success of that thing
8 are driven by the patented invention?
9 MS. MCCORMICK: Object to form.
10 A Yes, I think I agree that they are
11 different, but I also understand that they
12 can't make the sales at all without the
13 label, without the approval.
14 Q You don't know whether it is the dosage
15 information, the safety profile, the side
16 effects of KEYTRUDA that are driving its
17 commercial success as opposed to the mere
18 fact that it may or may not practice the '393
19 Patent, correct?
20 MS. MCCORMICK: Object to form.
21 A It's correct that I did not measure each
22 of those individually, that's correct.

1 Q You didn't measure dosage information,
2 safety profile, side effects, or rather
3 consider them in their affect on commercial
4 success at all in your declaration, correct?
5 MS. MCCORMICK: Object to form.
6 A I mean, the dosage information is
7 mentioned in the declaration. I don't
8 believe I have a discussion of the other two.
9 Q Can you please show me in your
10 declaration where you considered whether it
11 is the dosing information that is driving
12 KEYTRUDA's success?
13 A Well, I think it's in the paragraph in,
14 and I'm not saying that that's -- I
15 considered it the way you're talking about,
16 but in Paragraph 21 that we were just looking
17 at, it does note the dosage information on
18 the prescribing information.
19 Q Right. So when you prepared your
20 declaration you knew that KEYTRUDA had a
21 particular dosage that was recommended with
22 its prescribing information, correct?

1 A That's correct.
2 Q Wouldn't you then want to find out
3 whether the '393 Patent speaks at all to that
4 dosage information?
5 A I don't have any opinion of my own
6 whether it does or it doesn't.
7 Q I understand you don't have an opinion
8 on it, I'm asking you why you didn't want to
9 find out, ask somebody?
10 A I think what I wanted to find out and
11 it's reflected in my discussion with
12 Dr. Goldberg was the product itself as it
13 sold within that indication and it's
14 relationship to the patent.
15 Q I see. So you just didn't want to know
16 whether it was the dosing information that
17 was provided with KEYTRUDA's prescribing
18 information that might have played a factor
19 in KEYTRUDA's commercial success?
20 MS. MCCORMICK: Object to form.
21 A I think I haven't said that it plays no
22 factor or that there weren't other

1 contributing factors, what I have said is
2 there is a nexus between the success and the
3 patent.
4 Q Let's turn to Appendix 6 of your
5 declaration.
6 Are you there?
7 A Yes.
8 Q We touched on this a little earlier
9 today, in the notes section of Appendix 6 you
10 say that OPDIVO and YERVOY US sales for
11 MSI-High dMMR CRC are assumed to equal
12 5 percent of their respective total US sales,
13 correct?
14 A Yes.
15 Q What was the basis for this assumption?
16 A I think that's described in text. So
17 that comes from Paragraph 28. Where it says:
18 "According to Bristol Meyers
19 Squibb that the MSI-High or dMMR CRC
20 indications accounted for no more and
21 likely less than 5 percent."
22 So that comes from their earnings

1 calls where they list the indications
2 that they're in and sort of decreased
3 in order. Stating that, if you look at
4 that footnote, that 35 percent of their
5 mix is melanoma, the lung cancers in
6 line with that, 20 percent for renal,
7 5 percent for head and neck, little bit
8 of all the others, which would
9 presumably include this CRC indication.
10 So that's why I've used the upper bound
11 of 5 percent, because in his public
12 statement, he quit listing the
13 indications at 5 percent.
14 Q Well, the quote you just read, it goes
15 on and it says, in the bottom 5, 10 parts,
16 correct?
17 A Right.
18 Q What does in the bottom 5, 10 parts
19 mean?
20 A Well, I'm not sure exactly, but he is
21 categorizing indications. So I assume here
22 those counts refer to indications. So they

1 have five or ten more indications.
2 Q In the quotation that you're referring
3 to in your Footnote 37, it refers to an I-O
4 franchise, correct?
5 A That's right.
6 Q What is the I-O franchise?
7 A I'm not sure as I sit here right now.
8 Q Do you have any understanding as to
9 whether this quotation is even referring to
10 all of Bristol Meyers Squibb's sales in the
11 US for OPDIVO and YERVOY?
12 A Well, I mean, what he's saying here at
13 the part of the quote that I cite from, is
14 he's saying, when you look at OPDIVO and
15 YERVOY together. So, yes, my assumption is
16 he's talking about the sales in totality of
17 those two drugs.
18 Q He is not talking about OPDIVO alone in
19 this paragraph, correct?
20 A OPDIVO and YERVOY together, he says.
21 Q Right. He's talking about situations
22 when OPDIVO and YERVOY are prescribed

1 together, correct?
2 A I don't know that I interpret it that
3 way. He could just be talking about the
4 combined sales of the two products, which
5 would include instances where OPDIVO is
6 prescribed on its own.
7 Q The quotation in your Footnote 37
8 doesn't make any mention of colorectal
9 cancer, correct?
10 A That's right.
11 Q Did you investigate whether there was
12 any data that showed OPDIVO or YERVOY's
13 prescription frequency for MSI-High
14 colorectal cancer?
15 A I think I looked for data. As I said, I
16 requested data of this type from Merck when I
17 asked for the IQVIA data. I would have liked
18 to have seen market shares as well as just
19 KEYTRUDA's own prescriptions.
20 Q Is it -- go ahead. I didn't mean to cut
21 you off. Please go ahead.
22 A I don't know what else I would add to

1 that.
2 Q Is it your understanding that Merck is
3 in a better position to provide OPDIVO and
4 YERVOY data than JHU?
5 A I don't know if I have an understanding
6 about that. Merck is who we made the request
7 for IQVIA data from. I do have an
8 understanding that IQVIA data often has
9 estimates of market share that would show
10 competitive products.
11 Q Is it your understanding that JHU
12 requested OPDIVO and YERVOY IQVIA data from
13 Merck?
14 A I don't know how the request was made,
15 but, yes, it's my understanding that that
16 data, IQVIA data was requested. I ultimately
17 received some, but it contained patient
18 information and it was limited to just that.
19 Q But just to be clear here, you requested
20 from JHU's attorneys IQVIA data for OPDIVO
21 and YERVOY and you didn't receive it,
22 correct?

1 A I think I received some IQVIA data. It
2 was less than I believe I asked for or would
3 have liked. I think I would have liked to
4 have seen market shares as well.
5 Q So you received IQVIA data for OPDIVO
6 and YERVOY?
7 A No. No. For KEYTRUDA.
8 Q I'm asking you about IQVIA data for
9 OPDIVO and YERVOY, which you said you
10 requested.
11 Did you not request it?
12 A I requested data from Merck that would
13 show market shares within these indications.
14 Q You requested IQVIA data from Merck for
15 OPDIVO and YERVOY; is that right?
16 A Yes. That I hoped would include things
17 like their share in relation to OPDIVO and
18 YERVOY.
19 Q Do you have any understanding as to
20 whether JHU could have obtained IQVIA data
21 for OPDIVO and YERVOY for your analysis?
22 A I don't.

1 Q Did you ask JHU to get you IQVIA data
2 for OPDIVO and YERVOY?
3 A I assume I made a request, a broad
4 request for information pertaining to market
5 shares. So I don't know if I asked
6 specifically for one type of data or another,
7 but I did ask for data that would allow me to
8 calculate market shares, including OPDIVO and
9 YERVOY.
10 Q You don't have any data to suggest that
11 OPDIVO and YERVOY sales for use in colorectal
12 cancer patients remained under 5 percent of
13 total OPDIVO and YERVOY sales in 2020,
14 correct?
15 A Or that it was even lower, no, I don't
16 have data one way or the other.
17 Q You don't have any data to suggest that
18 OPDIVO and YERVOY sales for colorectal cancer
19 patients remained under 5 percent of total
20 OPDIVO and YERVOY in 2021, correct?
21 A That's correct. Other than that I've
22 noted prior to that period it was -- appears

1 to be under 5 percent. And so I think at
2 least for that time period it's conservative
3 to use 5 percent.
4 Q You have any data to suggest that OPDIVO
5 and YERVOY sales for colorectal cancer
6 patients remained under 5 percent of total
7 OPDIVO and YERVOY sales in 2022, correct?
8 A Again, or that percentage didn't go
9 down. Either way, I agree with that.
10 Q You don't have any data to suggest that
11 OPDIVO and YERVOY sales for colorectal cancer
12 patients remains under 5 percent of total
13 OPDIVO and YERVOY sales in 2023, correct?
14 A I've answered. Or that it didn't go
15 down, yes.
16 Q If OPDIVO and YERVOY sales for
17 colorectal cancer patients became 10 percent
18 of total OPDIVO and YERVOY sales in 2023,
19 then they would have a larger market share
20 than KEYTRUDA, correct?
21 A Which year, '23?
22 Q Right.

1 A Combined, that's correct. You'd have to
2 combine the two of them.
3 Q If OPDIVO and YERVOY sales for
4 colorectal cancer patients became 15 percent
5 of total OPDIVO and YERVOY sales in 2023,
6 then [redacted]
7 [redacted] than KEYTRUDA, correct?
8 A I think in that hypothetical, yes, yeah.
9 Q And with the data you had available to
10 you in preparing your declaration, you don't
11 know one way or the other whether that
12 hypothetical is true or not true, correct?
13 A Or whether it went the other way, and
14 that KEYTRUDA shares are even larger than
15 they appear here.
16 I do have information that at least in
17 2017, '18 and '19, KEYTRUDA shares likely are
18 larger than they appear on this graph,
19 because I believe the information suggests
20 that OPDIVO and YERVOY CRC accounts for less
21 than 5 percent of their sales.
22 Q For 2020, 2021, 2022 and 2023, OPDIVO

1 and YERVOY sales for colorectal cancer, they
2 could be 1 percent, 5 percent, 10 percent,
3 15 percent, it could be anything, with
4 respect to total OPDIVO and YERVOY sales,
5 correct?
6 A I don't know that they could be
7 anything. I haven't seen any evidence that
8 there's been a dramatic shift in the
9 composition. So I've used this data point
10 from 2019 to do this estimation, but I
11 haven't seen anything that suggests they've
12 moved incrementally up or down as a portion
13 of their overall sales.
14 Q You haven't seen anything to suggest
15 they stayed the same either, correct?
16 A That's correct.
17 Q Do you know how many indications OPDIVO
18 is approved for?
19 A Not as I sit here right now. I haven't
20 looked at that information.
21 Q Do you know how many indications YERVOY
22 is approved for?

1 A The same thing. I've looked at that, I
2 can't recall as I sit here right.
3 Q Do you know how many indications
4 KEYTRUDA is approved for?
5 A Again, I've looked at that information,
6 but as I sit here today, I don't know how
7 many it is at present.
8 Q Did you analyze the proportion of
9 indications tied to MSI-High colorectal
10 cancer for which KEYTRUDA was approved in
11 2017 versus the total number of indications
12 for which KEYTRUDA was approved in 2017?
13 A Sorry. I think you said 2017 twice.
14 You're saying what percent of
15 indications was -- I'm not sure I follow your
16 question.
17 Q I can rephrase it as a percentage.
18 A Number of indications.
19 Q I can rephrase it as a percentage, if
20 that's easier for you.
21 A Sure.
22 Q Did you analyze the percentage -- well,

1 strike that.
2 What percentage of approved indications
3 in 2017 of KEYTRUDA were MSI-High colorectal
4 cancer indications?
5 A I'm sorry. I'm still a little -- are we
6 asking about counts of indication?
7 So, in other words, one indication
8 counts as one. So MSI-High CRC is one
9 indication. And then how many indications
10 did they have, is that what you're asking me?
11 Q The ratio of MSI-High colorectal cancer
12 indications to total indications that are
13 approved.
14 Do you understand that concept?
15 A Yes. But you're talking about counts of
16 indications, not counts of products or
17 anything like that. Is that correct?
18 Q Well, within KEYTRUDA. There's only
19 KEYTRUDA.
20 A No. I understand. But I'm talking
21 about units of products that are sold.
22 We're not talking about sales,

1 percentage of sales or anything like that,
2 you're just talking about indications?
3 Q Correct.
4 A I mean, I am aware there was one
5 MSI-High CRC indication. There's an MSI-High
6 agnostic indication. And, as we discussed
7 earlier, there were several more, I think you
8 had discussed two or three in 2014, basically
9 a few each year up until 2017, where there
10 might have been five. I don't remember if
11 the five includes the other MSI-High
12 indication or not.
13 Q Did you look at the ratio of MSI-High
14 colorectal cancer indications to total
15 indications over time for KEYTRUDA?
16 A No. What I did was I looked at the
17 ratio of patients in that indication to the
18 total patients for KEYTRUDA.
19 Q Did you look at the ratio of MSI-High
20 colorectal cancer indications to total
21 approved indications over time for OPDIVO?
22 A No. And I don't know that would be

1 relevant to the analysis on Appendix 6.
2 Q Wouldn't that be relevant to the portion
3 of total OPDIVO sales that colorectal cancer
4 can be attributed to?
5 A No. That's simply just, you're talking
6 about a portion of indication, not a portion
7 of sales or patients, as we just clarified.
8 Q Earlier today you agreed with me that
9 additional indications that are approved
10 would lead to additional sales, did you not?
11 A I did. But they're not all equal, of
12 course.
13 Q They're not equal, and I didn't ask you
14 for an exact number.
15 My question was whether the proportion
16 of MSI-High colorectal cancer indications to
17 total approved indications would impact the
18 proportion of sales that can be attributed to
19 colorectal cancer for OPDIVO?
20 A You're asking if it would impact it. I
21 don't disagree that there would be some
22 impact. I just think that's not the most

1 appropriate measure. The most appropriate
2 measure would be some proportion of either
3 directly measured of sales within an
4 indication or of patients.
5 Q Right. The most appropriate way to know
6 how frequently OPDIVO is prescribed for
7 MSI-High colorectal cancer or how much money
8 it makes would be to look at actual data,
9 correct?
10 A Agree.
11 Q And for 2020, 2021, 2022 and 2023, you
12 don't have any of that data, correct?
13 A Right. I did not have it available,
14 that's correct.
15 Q Did you consider whether use of KEYTRUDA
16 is covered by Merck patents?
17 A Yes. I understand that there may be
18 other Merck patents, so I've considered it.
19 Q When you say you understand there may be
20 other Merck patents, what do you mean?
21 A I understand there are patents, for
22 example, I think if you looked in the orange

1 book, you would find patents for Merck for
2 KEYTRUDA.
3 Q Can you turn to Paragraph 30 of your
4 declaration.
5 A Okay.
6 Q In Paragraph 30, you say:
7 "KEYTRUDA's large profits are a
8 clear indication that the '393 Patent
9 has created economic value. And if the
10 invention were obvious, others would
11 have had an incentive to undertake the
12 same research as the patent owner."
13 Correct?
14 A Yes.
15 Q Others could not have undertaken the
16 same research as JHU without Merck's
17 approval, correct?
18 MS. MCCORMICK: Object to form.
19 A Without Merck's -- yeah, in the same way
20 that JHU had it, I agree with it. Or
21 similar, same or similar way.
22 Q So even if someone else had an incentive

1 to undertake the same research as JHU, they
2 couldn't have independently done it, correct?
3 A Well, I think they could have
4 independently approached Merck with the same
5 proposal, had they had the idea first.
6 Q And is it your opinion that Merck would
7 have an equal reason to say yes to anybody?
8 MS. MCCORMICK: Object to form.
9 A I don't know about -- that seems like a
10 very broad question. I don't know that they
11 would have equal reason to say yes to any
12 other possible person in the entire world,
13 but I believe there are others who could do
14 the same research.
15 Q Is it your opinion that JHU believed
16 there was something special about KEYTRUDA
17 over OPDIVO when it filed patent applications
18 that lead to the '393 Patent?
19 MS. MCCORMICK: Object to form.
20 A I don't think I have an opinion about
21 what they believed about their invention.
22 Q You understand that JHU did not develop

1 KEYTRUDA in any manner, correct?
2 A Yes. I understand that.
3 Q What portion of KEYTRUDA's commercial
4 success did you attribute to Merck's patents?
5 A So, again, when I've looked to assess
6 commercial success here, I've looked within
7 the MSI-High CRC indication. I talked to
8 Dr. Goldberg about whether the '393 Patent is
9 attributable for those sales and whether
10 there was a causal connection between that
11 patent and the sales that were made through
12 that indication. And my understanding is
13 that there was.
14 I did not seek to sort of factor out
15 from that success the portion of that success
16 to each of these other things like Merck's
17 patent.
18 MR. ZEILBERGER: Let's go off the
19 record.
20 (Whereupon, a recess was taken
21 from 4:46 PM until 5:02 PM.)
22 MR. ZEILBERGER: Back on the record.

1 Q Mr. Segers, during today's deposition,
2 did you speak to anyone or receive any
3 information from anyone regarding today's
4 deposition?
5 A No. I did not.
6 MR. ZEILBERGER: Thank you for your
7 time today, Mr. Segers. We have no
8 further questions.
9 THE WITNESS: All right. Thank you.
10 MS. MCCORMICK: No questions from me
11 either. Thank you.
12 MR. ZEILBERGER: Let's go off the
13 record.
14 MS. MCCORMICK: Is Paul Hastings
15 getting a rough transcript?
16 We'll take one, too, please.
17 (Whereupon, this examination was
18 concluded at 5:03 PM.)
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5 BRIAN J. SEGERS

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7 Subscribed and sworn to
before me on this ____ day
8 of _____, _____.

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10 _____
Notary Public
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1 I N D E X

2 WITNESS: BRIAN J. SEGERS

3 EXAMINATION BY PAGE

4 MR. ZEILBERGER 5

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7 E X H I B I T S

8 EXHIBITS DESCRIPTION PAGE

9 Exhibit 2188 Document 12, 14 pages (Bates No. 31
10 IPR2024-00240)

11 Exhibit 2223 Cancer Statistics, 2017 (Bates No. 70
12 IPR2024-00240)

13 Exhibit 2224 Cancer Statistics, 2019 (Bates No. 71
14 IPR2024-00240)

15 Exhibit 2225 Cancer Statistics, 2019 (Bates No. 71
16 IPR2024-00240)

17 Exhibit 2226 Cancer Statistics, 2020 (Bates No. 71
18 IPR2024-00240)

19 Exhibit 2227 Cancer Statistics, 2022 (Bates No. 71
20 IPR2024-00240)

21 Exhibit 2228 Cancer Statistics, 2022 (Bates No. 72
22 IPR2024-00240)

1 Exhibit 2229	Cancer Statistics, 2023 (Bates No. IPR2024-00240)	72
2		
3 Exhibit 2231	Merck & Co. Inc. NYSE:MRK FQ2 2017 Earnings Call Transcripts, Friday, July 28, 2017 (Bates No. IPR2024-00240)	94
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1 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC
2 I, KIARA MILLER, Certified Reporter and
3 Notary Public within and for the State of New York
4 do hereby certify:
5 That BRIAN J. SEGERS, the witness whose
6 deposition is hereinbefore set forth, was duly sworn
7 by me before the commencement of such deposition and
8 that such deposition was taken before me and is a true
9 record of the testimony given by such witness.
10 I further certify that the adverse party,
11 THE JOHN HOPKINS UNIVERSITY, was represented by
12 counsel at the deposition.
13 I further certify that the deposition of
14 BRIAN J. SEGERS, occurred virtually via Zoom on
15 Tuesday, December 17, 2024, commencing at 12:02 p.m.
16 to 5:03 p.m.
17 I further certify that I am not related to
18 any of the parties to this action by blood or
19 marriage, I am not employed by or an attorney to any
20 of the parties to this action, and that I am in no way
21 interested, financially or otherwise, in the outcome
22 of this matter.

1 IN WITNESS WHEREOF, I have hereunto set my
2 hand this 20th day of December, 2024.
3
4
5 Kiara Miller
6 _____
7 NOTARY PUBLIC IN AND FOR THE
8 STATE OF NEW YORK
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