

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

SAMSUNG BIOEPIS CO LTD,)
)
 Petitioner,)
) Case No.
 vs.) IPR2023-00933
) Patent: 9,732,149
 ALEXION PHARMACEUTICALS,) B2
 INC.,)
)
)
 Patent Owner.)
 _____)

VIDEO-RECORDED DEPOSITION OF CINDY IPPOLITI

New York, New York

Tuesday, February 20, 2024

Reported Stenographically By:
PATRICIA A. BIDONDE
Registered Professional Reporter
Realtime Certified Reporter
JOB#: SY008732

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February 20, 2024
9:07 a.m.

Video-Recorded Deposition of
CINDY IPPOLITI, held at the offices of
Cooley LLP, 55 Hudson Yards, New York,
New York, before Patricia A. Bidonde,
Stenographer, Registered Professional
Reporter, Realtime Certified Reporter,
Certified eDepoze Court Reporter, Notary
Public of the States of New York, New
Jersey, and Connecticut.

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

2

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19 BY: CHRISTINE HLAVKA, ESQ.

20 (Via Videoconference)

21

22

23

24

25

1 A P P E A R A N C E S (CONTINUED)

2

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14 ALSO PRESENT:

15 CHRISTIAN BIDONDE, Legal Video Specialist

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2 P R O C E E D I N G S

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4 THE VIDEOGRAPHER: We are now on
5 the record. The time is 9:06 a.m. on
6 February 20, 2024. Audio and video
7 recording will continue to take place
8 until all parties agree to go off the
9 record. Please note that microphones
10 are sensitive and may pick up whispering
11 and private conversations.

12 This is the video-recorded
13 deposition of Cindy Ippoliti in the
14 matter of Samsung Bioepis Co., LTD.,
15 plaintiff, versus Alexion
16 Pharmaceuticals, Inc. This deposition
17 is being held at Cooley LLP, New York,
18 New York.

19 My name is Christian Bidonde. I
20 am the legal video specialist. The
21 certified stenographer is Patricia
22 Bidonde on behalf of TransPerfect Legal
23 Solutions.

24 Counsel will state their
25 appearances for the record. All those

1 appearing remotely will be noted for the
2 record. Then the certified stenographer
3 will swear in the witness.

4 MR. SOLOMON: Andrew Solomon with
5 Cahill Gordon for Alexion, and with me
6 is Andy Cochran also with Cahill Gordon,
7 and we're also joined on the line with
8 Christine Hlavka who is in-house counsel
9 at Alexion.

10 MR. KNAUSS: Good morning. Dan
11 Knauss from Cooley for petitioner,
12 Samsung Bioepis.

13 C I N D Y I P P O L I T I, called as a
14 witness, having been duly sworn by a
15 Notary Public, was examined and
16 testified as follows:

17 EXAMINATION BY

18 MR. SOLOMON:

19 Q. Good morning, Dr. Ippoliti.
20 Would you please state your full name for the
21 record.

22 A. Cindy Ippoliti.

23 Q. Great. And where do you live?

24 A. West New York, New Jersey.

25 Q. And where are you currently

1 employed?

2 A. NewYork-Presbyterian Hospital at
3 this time.

4 Q. Have you had your deposition
5 taken before?

6 A. Yes. Twice before.

7 Q. Twice before. What kind of cases
8 were those?

9 A. One was -- very similar type of
10 cases where --

11 Q. Patent cases?

12 A. -- patent cases.

13 Q. And were you on the brand or
14 generic side of those cases?

15 A. Well, the first one, which was
16 over -- close to ten years ago, it was the
17 branded product. And then the last one, I
18 guess, was going to be a generic product.
19 Well, it was a new drug coming to market they
20 were challenging. But it's a little bit
21 different.

22 Q. And you submitted expert
23 declarations in those cases as well?

24 A. Yes.

25 Q. Generally, what's your

1 understanding of the technology at issue in
2 this case?

3 MR. KNAUSS: Objection to the
4 form.

5 You may answer, Dr. Ippoliti.

6 A. The way that I understand it is
7 that Samsung is contesting or petitioning for
8 saying that the patents in question,
9 specifically the ones that I'm addressing,
10 were obvious at the time.

11 Q. And what's your understanding of
12 the underlying technology of the patents?

13 A. That they -- I'm not quite sure I
14 understand the question.

15 Q. Just in terms of broad strokes,
16 subject matter of what the patents contain.

17 A. Right. They're talking about the
18 sequencing of --

19 Q. Right.

20 A. -- the monoclonal antibody.

21 Q. And in the context of these
22 proceedings involving Alexion and Samsung,
23 you've offered opinions from the perspective
24 of a person of ordinary skill in the art.
25 Right?

1 A. Yes.

2 Q. And you've considered what a
3 person of ordinary skill in the art would have
4 understood regarding the patents at issue and
5 the technology at issue in the proceedings
6 prior to a certain date, which is March 15,
7 2007. Right?

8 A. Yes.

9 Q. So you've had your deposition
10 taken before, so you understand this, but I'd
11 like to walk you through a few ground rules.

12 First, I'll be asking questions,
13 and you'll be giving me answers. Do you
14 understand that?

15 A. Yes.

16 Q. And the court reporter is taking
17 a record of what we say, and the videographer
18 is also recording. So please give me verbal
19 answers only, no head nods, no mm-hmms. Got
20 it?

21 A. Yes.

22 Q. And as we've already seen, your
23 counsel may object, but that's just for the
24 record. You're to answer my questions unless
25 your counsel specifically instructs you not

1 to. Okay?

2 A. Yes.

3 Q. And if you don't understand any
4 of my questions or you need me to clarify,
5 just please let me know. Sound good?

6 A. Yes.

7 Q. And if you answer, I'll assume
8 that you understand the question. Is that
9 fair?

10 A. Yes.

11 Q. And you also understand that you
12 took an oath to tell the truth as if you were
13 testifying live in court or before the patent
14 office. Right?

15 A. Yes.

16 Q. Is there any reason that you
17 can't give me any true and accurate testimony
18 today?

19 A. No.

20 Q. And if you need a break at any
21 point, please let me know. All I ask is that,
22 if I ask you a question and you're answering,
23 that we just finish your answer before we take
24 the break. Sound good?

25 A. Yes.

1 Q. So you're here today on behalf of
2 Samsung. Right?

3 A. Yes.

4 Q. And as you already alluded to,
5 you understand that Samsung has filed five
6 inter partes review petitions with the patent
7 office, challenging the patentability of five
8 of Alexion's patents covering the drug
9 Soliris. Right?

10 A. Yes, eculizumab, yes.

11 Q. And you understand if I refer to
12 these inter partes reviews as IPRs. Right?

13 A. Yes.

14 Q. And you're testifying today
15 because you submitted four declarations to
16 support Samsung's unpatentability positions in
17 these IPR proceedings. Right?

18 A. Yes.

19 Q. So I'd like to introduce your
20 declarations.

21 MR. SOLOMON: Yeah, we can mark
22 this Ippoliti Exhibit 1.

23 (Ippoliti Exhibit 1, Declaration
24 of Cindy Ippoliti regarding US Patent
25 9,718,880, submitted in Case

1 IPR2023-00998, marked for
2 identification, as of this date.)

3 Q. And if you could just confirm
4 that this document is your declaration
5 regarding US Patent 9,718,880, and this was
6 submitted in Case IPR2023-00998. Correct?

7 A. Yes.

8 Q. Okay.

9 (Ippoliti Exhibit 2, Declaration
10 of Cindy Ippoliti regarding US Patent
11 9,725,504, submitted in Case
12 IPR2023-00999, marked for
13 identification, as of this date.)

14 Q. And this is Ippoliti Exhibit 2.
15 Bear with me for a second while I get
16 organized here. And this is regarding
17 US Patent 9,725,504, submitted in Case
18 IPR2023-00999. Right?

19 A. Yes.

20 (Ippoliti Exhibit 3, Declaration
21 of Cindy Ippoliti regarding US Patent
22 10,703,809, submitted in Case
23 IPR2023-01070, marked for
24 identification, as of this date.)

25 Q. And then Exhibit 3 is your

1 declaration regarding US Patent 10,703,809,
2 submitted in Case IPR2023-01070?

3 A. Yes.

4 (Ippoliti Exhibit 4, Declaration
5 of Cindy Ippoliti regarding US Patent
6 10,703,809, submitted in Case
7 IPR2023-01070, marked for
8 identification, as of this date.)

9 Q. And finally, we have your
10 declaration regarding US Patent 10,703,809,
11 submitted in Case IPR2023-01070. Correct?

12 A. Yes.

13 Q. Great. And just for simplicity
14 sake, you'll understand if I refer to a
15 declaration by its associated patent. Right?

16 For instance, your declaration
17 regarding US Patent 10,703,809, if I refer to
18 it as the '809 declaration, that'll make
19 sense?

20 A. Yes.

21 Q. Great.

22 MR. KNAUSS: Just a procedural
23 point, Andrew, before you launch in, I
24 noticed that the sticker versions are
25 with the reporter.

1 (Discussion off the record.)

2 MR. KNAUSS: Sorry for the
3 interruption.

4 MR. SOLOMON: All good.

5 Q. So who drafted your declarations?

6 A. You mean who actually typed the
7 complete thing up or who drafted it?

8 Q. Yes, exactly.

9 A. So I did not type up the full
10 thing. I put together a draft of it, and then
11 that was taken and turned into the legalese
12 that you guys all use, so that was inserted.
13 And then I, you know, asked Cooley for
14 additional resources and references, and then
15 I was given a draft, and then reviewed the
16 draft, made my revisions, comments, and then
17 got the final version.

18 Q. Do you know how many
19 conversations you had with counsel regarding
20 the proceedings before the first draft?

21 A. I don't recollect exactly how
22 many personal conversations we had, but I can
23 tell you how many hours I spent doing that.

24 Q. And about how many hours did you
25 spend?

1 A. About 12, 13 hours.

2 Q. Okay. And is everything in your
3 declarations true and correct?

4 A. Yes.

5 Q. And you signed those declarations
6 under penalty of perjury. Right?

7 A. Yes.

8 Q. Okay. And one more quick
9 housekeeping tip. I'd like to introduce the
10 underlying patents associated with each
11 declaration. So bear with me for one more
12 second.

13 (Ippoliti Exhibit 5, US Patent
14 9,718,880, marked for identification, as
15 of this date.)

16 Q. So this is Exhibit 5, and it's
17 US Patent 9,718,880. Correct?

18 A. Yes.

19 (Ippoliti Exhibit 6, US Patent
20 9,725,504, marked for identification, as
21 of this date.)

22 Q. And then this is Exhibit 6, and
23 it's the US Patent 9,725,504. Is that
24 correct?

25 A. Yes.

1 (Ippoliti Exhibit 7, US Patent
2 10,703,809, marked for identification,
3 as of this date.)

4 Q. Exhibit 7 is US Patent Number
5 10,703,809. Correct?

6 A. Correct.

7 (Ippoliti Exhibit 8, US Patent
8 10,590,189, marked for identification,
9 as of this date.)

10 Q. And last, Exhibit 8 is Patent
11 Number 10,590,189. Correct?

12 A. Correct.

13 Q. So you understand that these are
14 the four patents at issue in the IPR
15 proceedings where you've submitted
16 declarations on Samsung's behalf. Correct?

17 A. Correct.

18 Q. And, again, you'll understand if
19 I refer to these patents by the last three
20 digits. So the '189 patent, for instance?

21 A. Yes.

22 Q. And if I refer to them
23 collectively as the challenged patents, you'll
24 understand that as well?

25 A. Yes.

1 Q. So when did you first see the
2 challenged patents?

3 A. I actually don't remember. Many
4 months ago. I honestly don't remember the
5 exact date when I was contacted.

6 Q. But you received the patents
7 prior to receiving the first draft of your
8 declaration --

9 A. Yes.

10 Q. -- from Samsung?

11 A. Yes, I did.

12 Q. Okay. And starting with the '189
13 declaration, did you do your best to include
14 all of the opinions you had regarding the
15 patent ability of the '189 patent in your '189
16 declaration?

17 A. So can you clarify? I did not
18 address all of the claims. I just addressed
19 the ones that were in scope for me.

20 Q. Sure. But you did your best to
21 include all of your opinions within the scope
22 of those claims that you were asked to address
23 within your '189 declaration. Correct?

24 A. Yes.

25 Q. And likewise, with regards to the

1 other three declarations, you did your best to
2 include all of the opinions you had regarding
3 the scope of those claims that you were asked
4 to provide opinions on. Correct?

5 A. Correct.

6 Q. So you didn't hold any opinions
7 back to be used at a later date. Correct?

8 A. Correct.

9 Q. And you're not planning on
10 raising any new arguments or evidence later on
11 in these proceedings that you could have
12 presented in your declarations?

13 A. No.

14 Q. So I'd like to walk through your
15 CV. So let's turn to your '809 declaration.
16 And starting on page 45 of -- and I'll be
17 referring generally to the stamped numbers on
18 the bottom right corner of the various
19 exhibits.

20 So starting on page 45, your CV
21 is attached to your declaration as Exhibit A.
22 Right?

23 A. Yes.

24 Q. And this version of your CV is
25 current and accurate?

1 A. Yes.

2 Q. Are there any omissions that
3 you'd like to add or anything that needs to be
4 addressed?

5 A. The only thing that is very, very
6 recent was my title changed from enterprise to
7 senior enterprise director.

8 Q. Congratulations. Is your
9 employment history otherwise accurately
10 described in your CV?

11 A. Yes, it is.

12 Q. And is your education accurately
13 described in your CV?

14 A. Yes, it is.

15 Q. So as you mentioned before, and
16 as you were just eluding to, you are currently
17 employed by NewYork-Presbyterian Hospital.
18 Right?

19 A. Yes.

20 Q. And what are your current
21 responsibilities in your senior position at
22 NewYork-Presbyterian?

23 A. The same as they were in the
24 other one.

25 Q. Okay.

1 A. But it was just a title change.
2 So I currently oversee all clinical pharmacy
3 services across all 11 sites. So we have 11
4 hospitals, and these are -- when I say
5 "clinical pharmacy services," I mean
6 overseeing the clinical pharmacists, not
7 directly, but indirectly. They all have a
8 dotted line to me. These are highly trained
9 experts in their field who provide direct
10 patient care.

11 But it also encompasses other
12 clinical services that we provide,
13 pharmacokinetic monitoring and the like, drug
14 management. I oversee our drug information
15 services. I oversee our subcommittees, which
16 report up to F&T, so new drugs that are being
17 brought into the formulary.

18 I oversee the ambulatory care
19 network. And I also oversee the residency
20 program, where we have 22 residents, pharmacy
21 residents.

22 Q. So you're wearing many hats. And
23 I see that you've been employed, and correct
24 me if I'm wrong, at NewYork-Presbyterian back
25 to at least to 2006. Is that correct?

1 A. Yeah. January 2006.

2 Q. And in your previous positions in
3 NewYork-Presbyterian, did your
4 responsibilities differ significantly than
5 they do now?

6 A. They did. I have -- when I first
7 started at NewYork-Presbyterian, so prior to
8 that, I was at MD Anderson. And when I came
9 to NewYork-Presbyterian, I started rounding on
10 the bone marrow transplant service and then
11 the leukemia service.

12 We have a robust service,
13 actually. It's actually larger than Memorial.
14 So I was providing direct patient care to the
15 patients on the leukemia service. Then I took
16 on additional roles of overseeing while still
17 providing direct patient care of overseeing
18 our oncology infusion sites. So two very
19 large ambulatory infusion centers.

20 I've always overseen oncology
21 services, but my boss doesn't like me to refer
22 to that because she says that clinical falls
23 under oncology, so I still continue to oversee
24 the oncology pharmacy services across our
25 enterprise.

1 Q. In your professional capacity,
2 have you worked directly with eculizumab or
3 Soliris?

4 A. Yes, I have.

5 Q. And is that administering it to
6 patients? What, I guess, were the -- was your
7 involvement?

8 A. So my involvement is -- so, like
9 I said, I would provide direct patient care
10 to -- so we would be considered mid-level
11 providers --

12 (Stenographer clarification.)

13 -- which means that we make
14 rounds and provide direct patient care to the
15 patients. Clinical pharmacists routinely write
16 the orders for the patients. So that was one
17 of the hats I would wear when I was actually
18 directly taking care of patients. And so we
19 would pen the orders, basically, for the
20 patients.

21 Drugs like Soliris don't need a
22 co-signature by an attending. Only those that
23 are considered cytotoxic chemo. So we would
24 have occasion to order it.

25 And then the other side of it was

1 as overseeing the infusion center, which is
2 where Soliris is often given. We, sort of -- I
3 would help with, you know, developing the work
4 flow. So we don't directly administer
5 medications, IV medications, we are not
6 credentialed to do that. But we can, you know,
7 take it everywhere.

8 So I would oversee the staff
9 compounding the drug, deal with purchasing if
10 needed, compounding the drug, and then
11 obviously take it through that entire process,
12 and then a technician usually delivers the drug
13 to the nurse to administer it to the patient.

14 Q. Thank you.

15 Flipping back into your
16 declaration now. If you could turn to
17 paragraph 7 for me. And that's on page 5.
18 Can you describe your role as a study chairman
19 or principal investigator in those 19 clinical
20 trials that you referenced in this paragraph?

21 A. Yeah, so most of my role in the
22 clinical trials was oftentimes either doing --
23 following the patients and recording adverse
24 events that we would see, all the way to data
25 analysis for a few studies, like the IVIG

1 study that I did back then. That was my own
2 idea, and I wrote the protocol and put it
3 through the IRB.

4 Other times, one trial I was
5 involved in I actually was drawing blood on
6 the patients, checking for drug levels. But
7 again, that was in Texas where they were a
8 little bit more lenient with what clinical
9 pharmacists can do. New York is very
10 different.

11 So my involvement was usually
12 around either helping with the development of
13 the protocol, collecting the data, observing
14 the patients, and recording their adverse
15 events.

16 I did have a focus on that and an
17 interest in that, and then helping with the
18 data analysis and the publication.

19 Q. Great. Were any of those
20 clinical trials related to Soliris?

21 A. No, they were not.

22 Q. And do your responsibilities as a
23 co-investigator differ significantly from what
24 you just described?

25 A. Not really.

1 Q. Okay. Would you consider
2 yourself an expert in pharmacology?

3 MR. KNAUSS: Object to the form.

4 You may answer.

5 A. I would not say it's my area of
6 expertise, but do I understand basic
7 pharmacology? Yes.

8 Q. How would you describe your area
9 of expertise?

10 A. I'm more of a clinician. So,
11 sort of, at the bedside helping make decisions
12 on patients.

13 Q. Sure. Do you consider yourself
14 an expert in antibody-based drug development?

15 MR. KNAUSS: Object to the form.

16 You may answer.

17 A. I am not a drug developer, no.

18 Q. Okay. And what about formulation
19 or commercialization of an antibody-based
20 drug?

21 MR. KNAUSS: Object to the form.

22 You may answer.

23 A. But I consider myself expert.
24 I'm sure there are people that are actually
25 paid to do that work. But do I understand the

1 general concepts and understand what place it
2 plays in a pharmacy in drug delivery to the
3 patient? Yes.

4 Q. Sure. So have you ever been
5 directly involved in the development of a drug
6 before?

7 MR. KNAUSS: Objection to the
8 form.

9 You may answer.

10 A. I have never been directly
11 involved. I do not work for pharma.

12 Q. Okay. So sticking with your '809
13 declaration. In reviewing your four
14 declarations, it seems, to me, that the '809
15 declaration is generally encompassing of your
16 opinions across those four declarations.

17 Is that a fair assessment?

18 MR. KNAUSS: Object to the form.

19 Answer if you are able to.

20 A. I think I understand the question
21 that you're asking, which is am I opining on
22 the four?

23 Q. Right. And the limitations that
24 exist in the '809 declaration exist elsewhere.
25 It's also the longest declaration, so I think

1 it's, sort of, encompassing of the limitations
2 that we see in the other three. Right?

3 A. Yes.

4 Q. And just for simplicity sake,
5 because of that, I'll be referring to the '809
6 declaration today to guide our discussions.

7 And in each of your declarations,
8 you state that your opinions pertain
9 specifically to the underlying limitations of
10 the relevant claims. Right?

11 A. Yes.

12 Q. So as stated in paragraph 30 in
13 the '809 declaration -- I'll give you time to
14 get there. Now I have to find it. So the top
15 of page 20.

16 A. Where is paragraph 30?

17 Q. Paragraph 30, top of page 24. So
18 in that paragraph, you state that your
19 opinions are limited to claims 1 through 5, 7,
20 and 20. Right?

21 A. Yes.

22 MR. KNAUSS: Object to the form.

23 But it's fine.

24 Q. So from those claims, your
25 opinions are related to the following

1 limitations: From claim 1, "intravenously
2 administering." Right?

3 A. Right.

4 Q. From claim 2, "wherein the
5 antibody is formulated in a pharmaceutical
6 composition comprising a single unit dosage
7 form." Right?

8 A. Yes.

9 Q. From claim 3, "wherein the single
10 unit dosage form is a 300 milligram single
11 unit dosage form"?

12 A. Yes.

13 Q. From claim 4, "wherein the
14 pharmaceutical composition comprises a 300
15 milligram single-use formulation of
16 30 milliliters of a 10 milligram per
17 milliliter sterile, preservative-free
18 solution." Right?

19 A. Yes.

20 Q. From claim 5, "wherein the
21 antibody is diluted to a concentration of 5
22 milligrams per milliliter prior to
23 administration." Right?

24 A. Yes.

25 Q. From claim 7, "wherein the

1 antibody is administered to the patient at a
2 dosage level of between 5 milligrams per
3 kilogram and 50 milligrams per kilogram per
4 patient per treatment." Right?

5 A. Yes.

6 Q. And from claim 20, "wherein the
7 antibody is administered to the patient at a
8 dosage level of between 5 milligrams per
9 kilogram and 50 milligrams per kilogram per
10 patient per treatment." Right?

11 A. Yes.

12 Q. And you haven't provided any of
13 your own opinions that specifically pertain to
14 the limitations, a heavy chain consisting of
15 Sequence ID Number 2 and a light chain
16 consisting of Sequence ID Number 4, as stated
17 in claim 1. Right?

18 A. Correct, I am not opining on
19 those.

20 Q. So if we turn to paragraph 35 of
21 your '809 declaration, and that is at the
22 bottom of page 27. Are you there?

23 You provide brief summaries of
24 the prior art that's to be discussed in your
25 declaration. Right?

1 A. Correct.

2 Q. And these are the core documents
3 that you rely on in support of your opinions.
4 Right?

5 MR. KNAUSS: Object to the form.

6 You may answer.

7 A. I use them as references, for
8 sure.

9 MR. SOLOMON: I'd like to
10 introduce Exhibit 9.

11 Q. And this is the Bell publication.

12 (Ippoliti Exhibit 9, Patent
13 application published by Leonard Bell
14 dated September 1, 2005, marked for
15 identification, as of this date.)

16 Q. And you're familiar with this
17 document. Right?

18 A. I have reviewed it.

19 Q. Can you briefly explain your
20 understanding of the document?

21 A. And where it pertains to me, I
22 mean, that's a document about its patent of --
23 looking at eculizumab. But where it pertains
24 to me specifically is a review of the dosing
25 specifically.

1 Q. And this is a US patent
2 application that was published on September 1,
3 2005. Right?

4 A. Yes, 2005.

5 Q. So a POSA, as of March 15, 2007,
6 would have had no reason to doubt the truth
7 and accuracy of Bell. Right?

8 A. Correct.

9 Q. And as you said before, you rely
10 on Bell in your declarations to support a
11 number of your opinions. Right?

12 A. Yes.

13 Q. If you could turn to paragraph 51
14 of your declaration, and that's on page 34.
15 And this paragraph discusses the 300 milligram
16 single unit dosage form limitation that's
17 found in claim 3 of the '809 patent. Right?

18 A. Yes.

19 Q. And at the end of this paragraph,
20 your conclusion regarding this limitation is
21 that a POSA would have been motivated to
22 choose a single-use dosage form of 300
23 milligrams. Correct?

24 A. Correct.

25 Q. And in reaching that conclusion,

1 you rely in part on the teachings of Bell.

2 Right?

3 A. Yes.

4 Q. Because Bell expressly taught a
5 600 milligram dose of eculizumab. Right?

6 A. That was used in the Phase II
7 trial, yes.

8 Q. And Bell also expressly taught a
9 900 milligram dose of eculizumab. Correct?

10 A. Correct, for maintenance.

11 Q. Does Bell expressly disclose a
12 300 milligram dose of eculizumab?

13 A. No, he does not. He was merely
14 stating the doses for the patients.

15 Q. Okay. So returning to paragraph
16 51 of your declaration, in the third sentence,
17 you state that a 300 milligram dose would
18 "best support convenience and scaling as
19 necessary to the needed 600 or 900 milligram
20 dose amounts." Right?

21 A. Correct.

22 Q. And you don't cite to any
23 documents as support for this statement in
24 your declaration. Right?

25 A. I used my experience of 15 years

1 at that point, that most drug products that
2 are released are in some mathematical equation
3 equaling that dose. And from a pharmacy
4 stand- -- both IV and oral meds are always in
5 some, you know, either two of this or
6 whatever.

7 And so it would not make sense to
8 have created a 6- or a 900 milligram vial from
9 a pharmacy stand- -- from a manufacturing
10 standpoint. As I said, I'm not an expert in
11 manufacturing, but there are plenty of cases
12 over the years where you choose one size
13 because why would you have two separate sizes
14 from a manufacturing standpoint? We've seen
15 some examples of that.

16 And -- but from a pharmacy
17 standpoint, you always want a vial size that
18 can make multiple if there are multiple doses
19 available, or dosing schedules available, you
20 would want to be able just to have one product
21 on the shelf, just from an inventory
22 standpoint and also simple math.

23 Q. Sure. But Bell doesn't contain
24 any discussion of convenience or scaling or
25 pharmacy stocking. Correct?

1 MR. KNAUSS: Object to the form.

2 Answer if you know.

3 A. No.

4 Q. And would Bell have guided a POSA
5 to determine the optimal amount of vials to be
6 used to administer this treatment to a
7 patient?

8 MR. KNAUSS: Object to the form.

9 You may answer.

10 A. I mean, researchers don't usually
11 opine on the final dosage form that the
12 manufacturer is going to make. That is done
13 oftentimes by pharmacists who sit in pharma
14 companies.

15 Q. And in that same paragraph 51 in
16 your declaration, you go on to say that a
17 larger single-size vial "would unnecessarily
18 create a situation causing waste" or costly --
19 or "waste of costly antibody treatments." Is
20 that right?

21 A. Correct.

22 Q. And again, do you cite to any
23 document in your declaration to support that
24 statement?

25 A. No. I think my 15 years of

1 experience at that point.

2 Q. And again, Bell is not concerned
3 with waste or the cost of antibody treatments.
4 Right?

5 MR. KNAUSS: Object to the form.

6 You may answer.

7 A. No, they're not but hospitals
8 certainly are.

9 Q. On page 35, same paragraph, you
10 then go on to say:

11 "A pharmacy also would not prefer
12 to stock (nor, presumably, would a drug
13 company prefer to make) two different
14 vial amounts of 600 and 900 milligrams
15 each. This would unnecessarily
16 complicate antibody supply services,
17 inventory tracking, and also
18 unnecessarily create the risk of an
19 incorrect dose."

20 Right?

21 A. Correct.

22 Q. And again, same questions: Do
23 you cite to any documents to support these
24 statements?

25 A. No. Just the common practice,

1 accepted practices in medicine and
2 pharmaceutical products.

3 Q. Elsewhere in your declarations,
4 you cite the Avastin 2004 package insert in
5 your declarations. Is that correct?

6 A. That's correct.

7 MR. SOLOMON: I'd like to
8 introduce that label as Exhibit 10.

9 (Ippoliti Exhibit 10, Avastin
10 2004 package insert, marked for
11 identification, as of this date.)

12 Q. And before I discuss the label,
13 if -- the common practices in the
14 pharmaceutical industry you speak of, or from
15 pharmacists' perspective you speak of, were
16 common practices, they would be in the
17 literature. Right?

18 MR. KNAUSS: Objection, calls for
19 speculation.

20 A. I highly doubt it. Nobody would
21 publish a paper on what size of a vial is
22 best.

23 Q. But you think minimizing waste
24 would --

25 MR. KNAUSS: Hold on a second,

1 Andrew.

2 Were you done with your answer?

3 THE WITNESS: I guess.

4 MR. KNAUSS: Okay. And maybe if
5 you just speak a little louder --

6 THE WITNESS: Okay.

7 MR. KNAUSS: -- Dr. Ippoliti.

8 Thanks.

9 Go ahead.

10 BY MR. SOLOMON:

11 Q. But minimizing waste in a
12 hospital or pharmacy setting seems like an,
13 you know, something worth writing about.
14 Correct?

15 MR. KNAUSS: Object to the form.

16 A. Does it add to the body of the
17 science? Probably not. Either probably --
18 possibly publications and throwaway nonpeer
19 review journals like Hospital Pharmacy talking
20 about waste? I'm sure there are.

21 Q. Have you sought out any such
22 articles?

23 A. No. This is common knowledge
24 amongst any high-performing organization, any
25 organization, frankly.

1 Q. Fair enough. Turning our
2 attention back to the Avastin label that you
3 cite in your declarations. You say in your
4 declarations that Avastin is an antibody that
5 you were personally familiar with before 2007.
6 Is that right?

7 A. Yes. I worked with Avastin.

8 Q. Okay. So on page 2 of the label
9 under the heading "Description," halfway down
10 about at line 44, it reads:

11 "Avastin is supplied in 100
12 milligram and 400 milligram
13 preservative-free, single-use vials to
14 deliver 4 milliliters or 16 milliliters
15 of Avastin."

16 Do you see that?

17 A. Mm-hmm.

18 Q. So Avastin was manufactured and
19 supplied in two different dosage forms.
20 Correct?

21 A. Mm-hmm.

22 Q. Okay. You also cite the Rituxan
23 label in your declaration. Is that correct?

24 A. Yes.

25 Q. And Rituxan is also an antibody

1 that you were personally familiar with before
2 2007. Right?

3 A. Yes.

4 (Ippoliti Exhibit 11, Rituxan
5 label description dated November 1997,
6 marked for identification, as of this
7 date.)

8 Q. This is Exhibit 11 and it's the
9 Rituxan label as cited in Dr. Ippoliti's
10 declaration.

11 And on page 1 -- and I apologize
12 for the size of this text here, but this is
13 how the exhibit was given -- in the third
14 paragraph, it states that:

15 "Rituxan is supplied at a
16 concentration of 10 milligrams per
17 milliliter in either 100 milligrams
18 (10 milliliter) or 500 milligrams
19 (50 milliliter)."

20 Do you see that?

21 A. Yes.

22 Q. And so Rituxan is another
23 example, prior to 2007, that was supplied and
24 manufactured in two different dosage amounts.
25 Right?

1 A. Yeah. And there's a reason for
2 that. So --

3 Q. But that was a limited question.

4 A. One dose is a flat dosing and --
5 which Soliris is -- and one is a milligram per
6 kilo or a metered squared dosing. So you have
7 to be able to account for differences in body
8 weight amongst people and then create
9 strengths that you know will hit the majority
10 of the population so as to minimize waste.

11 Q. Are you aware of any other
12 antibody-based products, prior to 2007, that
13 would have been manufactured and supplied in
14 multiple dosage forms?

15 A. You mean multiple package sizes?

16 Q. Correct.

17 MR. KNAUSS: Sorry. Did your
18 question say drugs or antibody drugs? I
19 just didn't hear you.

20 MR. SOLOMON: Antibody-based
21 drugs.

22 MR. KNAUSS: Is the question
23 clear to you, Dr. Ippoliti?

24 THE WITNESS: Yeah. But I'm
25 trying to recollect the size of some of

1 the others at the time.

2 A. But, again, most of the agents,
3 most antibody agents/chemotherapy agents are
4 all either weight-based on some level, where
5 this was the difference with Soliris, it was
6 flat dosing.

7 Q. Sure. Dr. Ippoliti, do you
8 mention flat dosing at all in your
9 declaration?

10 A. No, I don't.

11 Q. You don't. And why is that?

12 MR. KNAUSS: Object to the form.
13 You may answer.

14 A. Because it's obvious that it was
15 flat dosing.

16 MR. SOLOMON: I'd next like to
17 introduce the Wang reference, which you
18 also cite to in your declarations. And
19 this is Exhibit Number 12.

20 (Ippoliti Exhibit 12, Wang Patent
21 Application Publication dated
22 December 8, 2005, marked for
23 identification, as of this date.)

24 Q. And again, you're familiar with
25 this document. Correct?

1 A. Correct.

2 Q. And this is a US patent
3 application that was published on December 8,
4 2005. Correct?

5 A. Correct.

6 Q. And it's titled:
7 "Nebulization of Monoclonal
8 Antibodies For Treating Pulmonary
9 Diseases." Right?

10 A. Correct.

11 Q. And a POSA, as of March 15, 2007,
12 you would have had no reason to doubt the
13 truth and accuracy of Wang. Right?

14 A. Correct.

15 Q. And you rely on Wang in your
16 declarations to support a number of your
17 opinions. Right?

18 A. Correct.

19 Q. In part, you rely on Wang for
20 teaching the 10 milligram per milliliter
21 concentration limitation. Is that right?

22 A. Correct.

23 Q. And if we turn to Wang on page
24 25, right before paragraph 68, Wang discloses
25 here that:

1 "The antibody may be stable in a
2 formulation at a concentration ranging
3 from 1 microgram per milliliter to 200
4 micrograms per milliliter."

5 Do you see that?

6 A. Yes.

7 MR. KNAUSS: He meant to say
8 milligram.

9 MR. SOLOMON: Yes, correct.
10 Thank you.

11 Q. And if we turn to page 11 of
12 Wang, and we look at Figure 10. This
13 Figure is titled "Example of Suitable
14 Formulations." And Formulation 1 references a
15 monoclonal antibody from 1 to 30 milligrams
16 per milliliter. Right?

17 A. Correct.

18 Q. And according to paragraph 25 on
19 page 20, which references Figure 10 --

20 MR. KNAUSS: We're in the
21 declaration now?

22 MR. SOLOMON: Still in Wang,
23 paragraph 25.

24 MR. KNAUSS: Thank you.

25 (Discussion off the record.)

1 Q. So according to this paragraph,
2 Figure 10 shows "exemplary formulations
3 suitable for nebulization of an antibody."
4 Right?

5 A. Correct.

6 Q. So if we turn back to Figure 10,
7 does Figure 10 expressly use the term
8 "eculizumab" anywhere?

9 A. No, it does not.

10 Q. And Formulation 1, listed on the
11 left-hand side of Figure 10, simply describes
12 a monoclonal antibody with no name or
13 indication of any specific monoclonal
14 antibody. Is that right?

15 A. Correct.

16 Q. And on the right-hand side,
17 Formulation 2 doesn't even list a monoclonal
18 antibody, let alone a generic one like the
19 left-hand side. Right?

20 A. Correct.

21 Q. And if we turn to paragraph 170
22 on page 33. About halfway down, in reference
23 to Figure 10, this paragraph simply says
24 "anti-C5 antibody." Right? Without any
25 reference to eculizumab specifically?

1 A. Correct. Although eculizumab is
2 an anti-C5 antibody.

3 Q. Sure. If we go down to the next
4 paragraph, 171, Wang discloses that
5 eculizumab:

6 "At 30 milligrams per milliliter
7 can be effectively and efficiently
8 nebulized by a conventional nebulizer."

9 Is that right?

10 A. Correct.

11 Q. Does Wang ever specifically
12 discuss a concentration of 10 milligrams per
13 milliliter?

14 A. It does not. What was 30
15 milligrams per ml, I mean, was within the
16 range of the Figure 10, which was 1 to 30.

17 Q. Sure. But it's never expressly
18 listed? The words "10 milligram per
19 milliliter" don't appear anywhere in Wang?

20 A. No, it's not.

21 Q. Okay. Simple math question: 900
22 and 600 are both divisible by 150 as well.
23 Correct?

24 A. Correct.

25 Q. And then if we follow that down,

1 they're both divisible by 100?

2 A. Yes.

3 Q. And they're both divisible by 75,
4 and they're both divisible by 50. Right?

5 A. Correct.

6 Q. And does any of the prior art
7 that you rely on tell a POSA the proper amount
8 of vials to divide the total dosage form --
9 total dosage amount?

10 MR. KNAUSS: Object to the form.
11 You may answer, if you may.

12 A. If your question is: Is there
13 anything that states that I would prefer to
14 use two vials versus ten vials? No. But if
15 you're the person compounding in the satellite
16 under sterile conditions, it takes a very long
17 time to open and withdraw using ten vials --
18 which in current practice, would actually be a
19 red flag that the dose was inappropriate --
20 versus just using two vials.

21 Also putting ten vials on my
22 shelf for every single dose would be obscene
23 and very costly.

24 Q. Sure. So if Bell recently
25 teaches 150 milligrams as a divisible amount

1 of 600 and 900, and we assume a 30 milliliter
2 volume, that would put us at a concentration
3 of 5 milligrams per milliliter, which is
4 taught by Wang. Correct?

5 A. Can you rephrase the question? I
6 wasn't really following it.

7 Q. Sure.

8 You agree that 5 milligrams per
9 milliliter concentration falls within the
10 range that was taught by Wang. Right?

11 A. Yes.

12 MR. SOLOMON: Ten-minute break
13 sound good?

14 MR. KNAUSS: That's fine.

15 THE VIDEOGRAPHER: The time now
16 is 10:00 a.m. This concludes Media 1.
17 Off the record.

18 (Recess taken from 10:00 a.m. to
19 10:19 a.m.)

20 THE VIDEOGRAPHER: The time now
21 is 10:19 a.m. This begins Media 2. On
22 the record.

23 BY MR. SOLOMON:

24 Q. Great. Let's take a look at
25 another document that you cited in your

1 declaration. This is the Daugherty reference,
2 2006.

3 (Ippoliti Exhibit 13,
4 "Formulation and Delivery Issues for
5 Monoclonal Antibody Therapeutics" by Ann
6 L. Daugherty and Randall J. Mrsny,
7 marked for identification, as of this
8 date.)

9 Q. This is Exhibit 13. And you're
10 familiar with this paper?

11 A. Yes.

12 Q. It's titled "Formulation and
13 delivery issues for monoclonal antibody
14 therapeutics," and it's by Ann L. Daugherty
15 and Randall J. Mrsny, and I'll refer to this
16 as Daugherty.

17 And you rely on Daugherty in
18 support of some of your opinions in your
19 declarations. Right?

20 A. Yes.

21 Q. Are you familiar with either of
22 the authors of this paper?

23 A. No, I'm not.

24 Q. But from the abstract page, these
25 are folks in the industry from Genentech and

1 the center for drug delivery biology at
2 Cardiff University.

3 Do you see that?

4 A. Yes.

5 Q. And would you say those are
6 reputable organizations within the industry?

7 A. Yes.

8 Q. So a POSA, as of March 15, 2007,
9 would have had no reason to doubt the truth
10 and accuracy of Daugherty. Right?

11 A. Correct.

12 Q. If we start at the abstract, in
13 the second-to-last sentence, which is
14 exhibit -- page 3, the authors state:

15 "With this success, however, has
16 come a series of technical challenges in
17 the formulation of antibody-based
18 materials to maintain sufficient
19 stability in a variety of configurations
20 and sometimes at particularly high
21 concentrations. This review focuses on
22 issues related to identifying and
23 verifying stable antibody-based
24 formulations."

25 Do you see that?

1 A. Yes.

2 Q. If we turn to page 5 of this
3 exhibit, the top left-hand column, sentence
4 beginning with the word "Novel," the authors
5 state:

6 "Novel concerns then related to
7 the development of stable formulations
8 and delivery strategies for such large
9 amounts of a complex molecule.
10 Understanding product instability with
11 regard to physiochemical and
12 thermodynamic events becomes more and
13 more critical to ensure market success."

14 Do you see that?

15 A. Yes.

16 Q. Then on the next page, the
17 beginning of Section 3 titled "General
18 concerns for antibody formulations," the
19 authors state:

20 "Due to their proteinaceous
21 nature, antibodies present generic
22 formulation issues that are similar for
23 most protein therapeutics. Proteins, in
24 general, can be degraded under
25 conditions when they are exposed to

1 heat, freezing, light, pH extremes,
2 agitation, sheer stress, some metals,
3 and organic solvents."

4 Do you see that?

5 A. Yes.

6 Q. And on the next page, page 7, the
7 sentence starting with "A priori."

8 A. With -- starting with what?

9 Q. "A priori," kind of, middle, top
10 right hand on page 7, right-hand column.

11 A. Oh, right-hand column.

12 Q. It's further up.

13 A. (Document review.)

14 Okay. I see it.

15 Q. Got it? Okay. And the authors
16 say:

17 "A priori, one might assume that
18 by finding a stable formulation for one
19 of these antibody drugs, that such a
20 formulation would be good for most if
21 not all similar antibodies. If this
22 were borne out by experience, there
23 would be no need for a review such as
24 this. Instead, each antibody seems to
25 have a unique personality related to its

1 requirement for stability; a phenomenon
2 derived from the fact that the small
3 differences between these antibodies are
4 focused on surface-exposed amino acid
5 differences that stipulate antigen
6 specificity. Thus, the interfacial
7 surface of each antibody drug is unique,
8 and thus requires specific formulation
9 components to provide maximal stability
10 and retention of activity."

11 Do you see that?

12 A. Yes.

13 Q. Do you agree generally with the
14 authors of Daugherty, that each antibody has
15 its own requirements for stability?

16 A. Yes.

17 Q. So a person of ordinary skill in
18 the art wouldn't just assume that a known
19 formulation would work for a new antibody.
20 Right?

21 A. Correct.

22 Q. And again, on page 7, right-hand
23 column, the second full sentence of that
24 middle paragraph, the authors say in that
25 sentence:

1 "It is the recognition of a
2 stability indicating parameter (or
3 several parameters) that allows the
4 formulation scientist to focus in on
5 what is critical to development of a
6 successful product."

7 Do you see that?

8 A. Yes.

9 Q. And after outlining stability
10 issues for antibody formulations in Section 4,
11 which begins on page 7, the authors then go on
12 to discuss strategies to stabilize antibody
13 formulations in Section 5, which is on page
14 11. Right?

15 A. Correct.

16 Q. Is it fair to say that the
17 authors of Daugherty viewed maintaining
18 stability as one of the key challenges in
19 formulating an antibody-based drug product?

20 A. Yes.

21 Q. And you agree that maintaining
22 stability is one of the key challenges that
23 needs to be addressed in a drug -- or
24 antibody-based formulation?

25 A. Yes.

1 Q. And at the beginning of
2 Section 5, the bottom left-hand corner of page
3 11, the authors state:

4 "While liquid antibody
5 formulations are less expensive, faster
6 to develop, and generally easier to
7 prepare for administration than
8 alternative formulation approaches,
9 liquid antibody formulations are prone
10 to oxidation, deamidation, aggregation,
11 and fragmentation as discussed above."

12 Do you see that?

13 A. Yes.

14 Q. And then a few lines later in
15 that same paragraph, the authors conclude
16 "Thus, water is a big problem for stabilizing
17 antibody-based drugs."

18 Do you see that?

19 A. Yes.

20 Q. If we turn to Table 1 on page 14.
21 This table shows formulations of approved
22 products. Right?

23 A. Yes.

24 Q. And in the "formulation
25 concentration" column, we see two products.

1 Rituxan and Remicade are listed with
2 10 milligram per milliliter concentrations.
3 Right?

4 A. Yes.

5 Q. And the other concentrations
6 listed a range from a minimum of 1 milligram
7 per milliliter to a maximum of 125 milligrams
8 per milliliter. Right?

9 A. Correct.

10 Q. If we could flip back to your
11 declaration, the '809 declaration at paragraph
12 53. And near the beginning of that paragraph,
13 you state "it was commonplace by 2007 for" --
14 strike that.

15 From the beginning of the
16 paragraph, you say:

17 "Regarding the 30 milliliters at
18 10 milligrams per milliliter limitation,
19 it was commonplace, by 2007, for
20 antibody therapies to be supplied in a
21 liquid solution that could easily be
22 drawn into a syringe and added to IV
23 bags for infusions."

24 Do you see that?

25 A. Yes.

1 Q. Do you think the ease of drawing
2 into a syringe and adding to IV bags is a
3 serious consideration for a POSA who
4 formulates an antibody-based product?

5 MR. KNAUSS: Object to the form.

6 You can answer.

7 A. Does volume make a difference
8 when you're compounding? Yes. Is it better
9 to have a smaller volume or reasonable volume?
10 Well, the syringes that we use to draw
11 medications out are maximum of 60 ml syringes,
12 which you never want to have anything close to
13 60 because, your plunger falls out, drug falls
14 all over the table.

15 But -- so if you could optimize
16 that and make things easier, of course.

17 Q. But do you think the POSA who
18 formulates an antibody-based product would be
19 more concerned with establishing the stability
20 of the product or the ease of administration
21 of the product?

22 A. Stability of the product is
23 always the driver.

24 Q. In paragraph 54 of your
25 declaration, you, sort of, expound on what you

1 were just talking about. And you say that:

2 "30 milliliters is neither such a
3 small volume that there would be concern
4 about successfully drawing all the drug
5 substance into a syringe, nor such a
6 large volume as to be impractical to
7 draw using a standard syringe or
8 impractical to dilute into an
9 IV solution for infusion into the
10 patient."

11 Right?

12 A. Correct.

13 Q. Again, do you think a POSA, when
14 formulating an antibody-based drug product, is
15 concerned with the practicalities of drawing
16 the product into a syringe?

17 MR. KNAUSS: Asked and answered.

18 You may answer.

19 A. Yeah, I do think so, because if
20 the volume is too small, it gets stuck in your
21 syringe. So that's a problem. Right?
22 There's always loss in the bevel of a syringe,
23 so if it's a very small volume, like a couple
24 of cc's, there is a large error in that.

25 And if it's too large, it

1 actually is difficult. And when deciding on
2 adding drugs to formulary, these things are
3 taken into serious consideration, whether you
4 can actually do it in a reasonable amount of
5 time and deliver it to the patient safely,
6 maintaining all the quality and safety
7 features. So, yes, it is under -- it should
8 be under consideration.

9 Q. Do the authors of the Daugherty
10 paper, when discussing generally the
11 formulation and delivery issues for monoclonal
12 antibody therapeutics, take syringe draw into
13 account as one of the challenges that needs to
14 be overcome?

15 A. No, this paper was addressing how
16 to formulate these, you know, and the
17 complexities of that, of monoclonal
18 antibodies.

19 Q. But you don't cite anything in
20 your declaration as of 2007 that shows that a
21 POSA would have been concerned of the
22 constraints of a syringe. Right?

23 A. No, I don't. That, again, is
24 based on years of experience and working in
25 and delivering drugs to patients. And to take

1 that further, there are drugs that we have not
2 added to formulary because they are too
3 complex and they cannot be operationalized.

4 Q. When you talk about 30
5 milliliters as being a particularly practical
6 volume to work with, what would you consider
7 the limits on that practicality?

8 MR. KNAUSS: Objection to the
9 form.

10 You may answer.

11 A. Anything too small, like I've
12 already alluded to, 5 cc's or less, is
13 actually quite difficult to draw up without
14 significant dilution. And anything going over
15 50 mls would be -- but again, if we were
16 already saying that the concentration was
17 30 milligrams per ml, then the 30 mls was
18 obvious if we were targeting a 300 milligram
19 vial.

20 Q. Do either Bell or Wang make
21 express reference to a 30 milliliter volume?

22 A. No, they don't. Though, Wang
23 does state that albeit a nebulized solution,
24 still a solution, an aqueous solution, that
25 the drug was stable. It's in the diagram,

1 looking at the HPLC, specifically around
2 eculizumab, that it maintained its
3 concentration or its stability.

4 Q. If we could go back to Bell. Can
5 you walk me through specifically what made you
6 choose a 300 milligram dose as it relates to
7 Bell's disclosure of 600 and 900 milliliter
8 doses?

9 A. Again, I think I've already
10 addressed that but we knew the doses were 600
11 and 900 milligrams. Induction was 600,
12 maintenance was 900. And just doing easy
13 simple math and what would be a good dosage
14 form to have where I could treat all patients
15 with just having one product on my shelf.

16 Q. Right. But you didn't pull that
17 300 milligram value from the patents. Right?

18 MR. KNAUSS: Object to the form.

19 A. I'm not sure I understand "from
20 the patent."

21 Q. In other words, you weren't
22 operating with hindsight of what the patent
23 had disclosed and then applying that to Bell's
24 600 and 900 milligram disclosures, were you?

25 A. And I just think it's simple math

1 and obvious that 300 makes the most sense if
2 dealing with a 600 and 900 milligram dosing
3 regimen.

4 Q. You agree that Bell discloses a
5 potential range of dosages. Right?

6 A. The Phase II specifically use 600
7 and 900.

8 Q. But as we discussed earlier, you
9 can divide 600 and 900 into multiple ways?

10 A. True.

11 Q. You'd have to supply an
12 additional step that 300 is the most logical
13 because of your experience. Correct?

14 A. Correct.

15 Q. But 600 and 900 can be
16 subdivided, as we discussed earlier, into a
17 number of different values?

18 MR. KNAUSS: Asked and answered.

19 A. Correct. But that doesn't make
20 any sense if I can get at it with fewer vials,
21 fewer inventory, fewer workload. It takes
22 time to do these things.

23 And you have a patient sitting
24 there with a horrible disease, and I don't
25 want to sit there all day waiting for me to

1 compound a drug. So it's about patient's
2 quality of life. And you try to make things
3 as easy as possible at the end of the day.
4 And as efficient as possible.

5 Q. Understood.

6 And similarly, you didn't take 10
7 milligrams per milliliter from the patents and
8 apply that retroactively to the disclosure of
9 Wang, which also teaches a range from 1 to 30
10 milligrams per milliliter. Right?

11 A. Correct. It's within the range
12 of 1 to 30. And remember, you're talking
13 about 2007, before we had electronic medical
14 records that did smart math. Everything was a
15 manual calculation.

16 And so if you could pick
17 something that was easily divisible and, you
18 know, we can all divide by ten or multiply by
19 ten. Right? So -- but, again, you're driven
20 by the stability, as Daugherty said. But if I
21 have a range, just picking within the range.

22 Q. Do you know how changes in
23 concentration impact the stability of a drug
24 product?

25 MR. KNAUSS: Object to the form.

1 A. I'm not an expert but I do know
2 that changes in concentration can affect
3 stability, and that's why most agents have a
4 specific range of when you dilute them and how
5 long they're stable for, yes.

6 When compounding, we have a
7 range. 250, 300, whatever.

8 Q. Do you know if decreasing
9 concentration generally improves stability of
10 an antibody drug product?

11 A. It can go either way.

12 Q. It can go either way. Would a
13 25 milliliter volume be a practical amount for
14 you to work with?

15 A. Sure.

16 Q. You'd have no problems with that?

17 A. No, I would not.

18 Q. So because Bell and Wang both
19 each -- both teach a potential range of values
20 that could be pulled from them, I'm curious if
21 a few examples would have been taught by Bell
22 and Wang according to the same logic that you
23 applied to get to 300 and 10.

24 Do you agree that 100 milligrams
25 could have flowed reasonably from the

1 disclosure of Bell since it's
2 divisible -- since 600 and 900 are both
3 divisible by 100?

4 A. Sure.

5 Q. Sure. And if we assume a
6 25 milliliter volume, which you just said
7 would be practical to work with, that would
8 put us at a 4 milligram per milliliter
9 concentration.

10 And 4 milligrams per milliliter
11 would flow reasonably from the disclosure of
12 Wang. Right?

13 A. Yes. But still within the range,
14 still 1 to 30.

15 Q. Sure. And by that same logic,
16 150 milligrams, as we discussed, would flow
17 reasonably from the disclosure of Bell.
18 Right?

19 A. It would.

20 Q. And if we use your same 30
21 milliliters of volume, that would give us
22 5 milligrams per milliliter of concentration,
23 which is also within the range disclosed by
24 Wang. Right?

25 A. Correct. But again, I go back to

1 why would I have multiple vials if I can just
2 have a few on my shelf, like two to three at
3 any given moment?

4 Q. But if presented with overriding
5 stability concerns, a POSA could have
6 reasonably followed any one of those paths to
7 get at the final product that we have in the
8 patents. Is that fair?

9 MR. KNAUSS: Hypothetical.

10 But you may answer.

11 A. Yes.

12 MR. SOLOMON: We'll take another
13 ten-minute break.

14 MR. KNAUSS: Okay.

15 MR. SOLOMON: Thank you.

16 THE VIDEOGRAPHER: The time now
17 is 10:44 a.m. This concludes Media 2.
18 Off the record.

19 (Recess taken from 10:44 a.m. to
20 11:02 a.m.)

21 THE VIDEOGRAPHER: The time now
22 is 11:02 a.m. This begins Media 3. On
23 the record.

24 BY MR. SOLOMON:

25 Q. If we could turn to page 12 of

1 your '809 declaration, paragraph 17. And at
2 the top of this paragraph, you state that
3 you've "reviewed Dr. Ravetch's statement of
4 the level of ordinary skill in the field," and
5 you "agree with it and have applied it in
6 reaching the opinions expressed in this
7 declaration."

8 Is that correct?

9 A. Correct.

10 Q. And it goes on to state that:

11 "Specifically, Dr. Ravetch opines
12 (and I agree) that a POSA, as of March
13 2007, would have knowledge of the
14 scientific literature and have skills
15 relating to the design and generation of
16 antibodies."

17 Do you believe that you have the
18 requisite skills relating to the design and
19 generation of antibodies that this definition
20 envisions?

21 A. No, I don't. That was left up to
22 Dr. Ravetch.

23 Q. Okay. Next, it references the
24 complement system. Do you believe that you
25 have the requisite knowledge of the complement

1 system as described in this definition of a
2 POSA?

3 A. Not in drug development or drug
4 sequencing.

5 Q. Okay. But then references the
6 application of antibodies as therapeutics
7 before March 15, 2007. Do you have the skills
8 in the application of antibodies as
9 therapeutics that this POSA definition
10 describes?

11 A. In the application of antibodies
12 as therapeutic in the treatment of patients,
13 yes, I have experience in that.

14 Q. So do you believe that you're a
15 POSA according to this definition?

16 A. I think if you go down further
17 where it says a POSA would have worked as
18 "part of a multidisciplinary team and drawn
19 upon," so, you know, by 2007, I had been in
20 clinical pharmacy for 15 years, plus my
21 education, worked at the number one cancer
22 hospital in the country, if not the world, and
23 it has been that way for a lot of years.

24 And, you know, MD Anderson, up
25 until I moved to New York, where we did

1 provide these drug therapies to patients, I
2 also, at that time, or prior to that time, had
3 done a significant amount of research in drugs
4 that were in, you know, in clinical trials.

5 But I was well aware of the
6 treatment of patients and the use of
7 antibodies in treating patients.

8 Q. And you beat me to this portion
9 of the definition. I was about to get there.
10 And you might have just stated some of this.
11 In the context of a multidisciplinary team,
12 can you described the skills that you would
13 contribute as a team member?

14 A. Yeah, so, as I said, clinical
15 pharmacists are seen as mid-level providers,
16 and so my role on the medical team, both when
17 I was at MD Anderson and also at
18 NewYork-Presbyterian, was that I would round
19 with the medical team, and the medical team
20 was made up of an attending physician, myself
21 or another clinical pharmacist, and a nurse
22 practitioner. We rarely had medical fellows.

23 So my responsibility on the team
24 was to help provide information to the
25 physician on the drug dosing, whether there

1 needed to be dose modifications based on end
2 organ function, dysfunction, age, the like.

3 And we actually wrote the orders.
4 So it was my responsibility to hand write all
5 the orders for the patients, to include their
6 chemotherapy or bio therapy.

7 I also created the order sets
8 that were used, again, long before the
9 electronic medical record existed. I took it
10 upon myself to, in a Word document, create the
11 order sets, which, sort of, made it safer
12 because somebody could actually read them
13 because they were typed, and then we would
14 just input the specific data for the patient,
15 and it would default to, similar to what we
16 currently do, with the electronic medical
17 records, just not quite as smart.

18 Q. Sure. And you touched on -- you
19 started to touch on the last portion of this
20 definition, which states that, as part of a
21 team, you may help solve a given problem.

22 Can you describe the source of
23 problems that you would help to solve in a
24 team of this nature?

25 A. So at the time, I was doing bone

1 marrow transplantation.

2 (Stenographer clarification.)

3 A. And so because my training is all
4 clinical or predominantly clinical, I would
5 identify the patients newly diagnosed with
6 graft-versus-host disease, help drive the
7 therapies for that, ensure standardization of
8 therapies.

9 You practice almost on the level
10 of being a physician without the physical exam
11 skills.

12 Q. And the problems that you just
13 described, do you think these were taken into
14 consideration when the inventors were
15 formulating eculizumab?

16 MR. KNAUSS: Calls for
17 speculation.

18 You may answer.

19 A. Likely not.

20 (Continued on the next page.)

21

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1 MR. SOLOMON: No further
2 questions.

3 THE VIDEOGRAPHER: The time now
4 is 11:09 a.m. This concludes Media 3 of
5 3 of today's deposition. Off the
6 record.

7 (Time noted: 11:09 a.m.)

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A C K N O W L E D G M E N T

STATE OF)
: ss
COUNTY OF)

I, CINDY IPPOLITI, hereby certify
that I have read the transcript of my
testimony taken under oath in my
deposition of February 20, 2024; that
the transcript is a true, complete, and
correct record of my testimony, and that
the answers on the record as given by me
are true and correct.

CINDY IPPOLITI

Signed and subscribed to
before me this _____
day of _____, 2024.

Notary Public

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C E R T I F I C A T E
STATE OF NEW YORK)
 : ss.
COUNTY OF NASSAU)

I, PATRICIA A. BIDONDE, a Notary
Public within and for the State of New
York, do hereby certify:

That CINDY IPPOLITI, the witness
whose deposition is hereinbefore set
forth, was duly sworn by me, and that
such deposition is a true record of the
testimony given by the witness.

I further certify that I am not
related to any of the parties to this
action by blood or marriage, and that I
am in no way interested in the outcome
of this matter.

IN WITNESS WHEREOF, I have
hereunto set my hand this day,
February 20, 2024.

PATRICIA A. BIDONDE
Stenographer
Registered Professional Reporter
Realtime Certified Reporter

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1 E R R A T A
2 INSTRUCTIONS TO WITNESS
3

4 Please read your deposition over
5 carefully and make any necessary corrections. You
6 should state the reason in the appropriate space
7 on the errata sheet for any corrections that are
8 made.

9 After doing so, please sign the errata
10 sheet and date it.

11 You are signing same subject to the
12 changes you have noted on the errata sheet, which
13 will be attached to your deposition.

14 It is imperative that you return the
15 original errata sheet to the deposing attorney
16 within thirty (30) days of receipt of the
17 deposition transcript by you. If you fail to do
18 so, the deposition transcript may be deemed to be
19 accurate and may be used in court.
20
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22
23
24
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1 E R R A T A

2 ERRATA SHEET FOR THE TRANSCRIPT OF:

3 Case Name: Samsung v Alexion

4 Dep Date: February 20, 2024

5 Deponent: Cindy Ippoliti

6	Pg.	Ln.	Now Reads	Should Read	Reason
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1 E R R A T A (Continued)

2	Pg.	Ln.	Now Reads	Should Read	Reason
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Cindy Ippoliti

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Signed and subscribed to before me

22

this ____ day of _____, 2024

23

24

Notary Public

25

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