IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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HERON THERAPEUTICS, INC., :
Plaintiff, :
Civil Action No.:
v. :
22-cv-00985-WCB
FRESENIUS KABI USA, LLC, :
Defendant. :
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DAY 4 - AM
BEFORE JUDGE WILLIAM CURTIS BRYSON
Washington, D.C.
Thursday, June 27, 2024
8:15 a.m.

Reported by: Matthew Goldstein, RMR, CRR

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PGR Petition – USP 12,115,255

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1 C O N T E N T S

2 EXAMINATION OF MICHAEL EDWARD TATE PAGE

3

4 By MR. HILL - DIRECT 1137

5 By MR. NELSON - CROSS 1178

6 By MR. HILL - REDIRECT 1208

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8 EXAMINATION OF STEVEN LITTLE, PH.D. PAGE

9 By MR. ASHKENAZI - DIRECT 1212

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1 JUDGE BRYSON: We have the next witness
2 for plaintiffs.
3 MR. HILL: Your Honor, plaintiffs are
4 going to put on their commercial success witness,
5 which will be the other witness Mr. Nelson
6 referred to yesterday who will be talking about
7 confidential information.
8 JUDGE BRYSON: So we need to close the
9 courtroom again today?
10 MR. HILL: Yes.
11 JUDGE BRYSON: Is there anybody here who
12 is not aligned with either of the parties?
13 MR. ASHKENAZI: Your Honor, just for
14 timing, I think we'll be about 45 minutes on
15 direct.
16 JUDGE BRYSON: Forty-five minutes on
17 direct. Okay. And some time for cross, I
18 imagine.
19 I don't know if you were able to find a
20 place. The library is available, and if you want
21 to hang out there, you're certainly welcome to.
22 I'm sorry we don't have a better common room for
23 you or a lunchroom, which would be convenient, but
24 we don't. But we'll go find you, if you're
25 someplace nearby, when we are ready.

1 So, again, my apologies for having to
2 close the courtroom but it does happen and it's, I
3 suppose, a good reason. Okay.
4 MR. HILL: And plaintiffs are going to
5 call Michael Tate.
6 JUDGE BRYSON: The witness' name is?
7 MR. HILL: Michael Tate.
8 JUDGE BRYSON: Tate?
9 MR. HILL: T-A-T-E.
10 JUDGE BRYSON: All right. And that's
11 Dr. Tate; am I right?
12 MR. HILL: Mr.
13 JUDGE BRYSON: Oh, Mr. Tate, okay.
14 Good morning.
15 (Witness duly sworn.)
16 MR. HILL: May I approach, Your Honor.
17 JUDGE BRYSON: You may.
18 MR. HILL: May we begin?
19 JUDGE BRYSON: You may.
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1 Whereupon,
2 MICHAEL EDWARD TATE,
3 being first duly sworn or affirmed to testify to the
4 truth, the whole truth, and nothing but the truth, was
5 examined and testified as follows:
6 DIRECT EXAMINATION BY COUNSEL FOR THE PLAINTIFF
7 BY MR. HILL:
8 Q. Good morning, Mr. Tate.
9 A. Good morning.
10 Q. Would you please state your full name
11 for the record?
12 A. Sure. My name is Michael Edward Tate,
13 T-A-T-E.
14 Q. And by whom are you employed?
15 A. I am a vice president at a consulting
16 firm by the name of Charles River Associates, and
17 I sit within the intellectual property practice of
18 Charles River.
19 Q. And, Mr. Tate, what is the business of
20 Charles River?
21 A. So CRA is an international business
22 consulting firm that focuses on, among other types
23 of consulting projects, projects involving patents
24 in the context of valuation, licensing, and
25 litigation support, including quantification of

1 economic damages and the assessment of commercial
2 success.
3 Q. And what kind of consulting expertise do
4 you provide to clients in the litigation arena?
5 A. You know, over the course of my career,
6 most of the work that I've done involves the
7 preparation of financial and economic analyses for
8 the purpose of determining damages and assessing
9 commercial success.
10 Q. And about how long have you worked at
11 Charles River Associates?
12 A. So I've been at Charles River now about
13 20 years. And then prior to that, I was at
14 several other consulting firms, including
15 AT Carney, which is another international business
16 consulting firm, and the accounting firm of
17 PriceWaterhouse. And I was at those firms another
18 17 years.
19 Q. So for the approximately 37-year period
20 that you've been a consultant, have you worked on
21 projects involving pharmaceutical companies?
22 A. Yes, at this point in my career, I've
23 probably worked on three to four hundred
24 consulting assignments, and a significant portion
25 of those have been in the pharmaceutical area or

1 medical device area.
2 Q. And have you ever testified at trial as
3 an expert on the subject of patent infringement
4 damages and commercial success?
5 A. Yeah, today marks the 39th time that
6 I've testified as an expert either in a trial
7 setting like this or an arbitration proceeding.
8 Q. And how many times have you analyzed the
9 issue of commercial success in lawsuits like this
10 one?
11 A. You know, I don't have an exact number,
12 but it's been in access of 30 times at this point
13 in my career.
14 Q. And did any of those commercial success
15 cases involve pharmaceutical companies and
16 products?
17 A. Most of them did, yes.
18 Q. And have you worked for both branded and
19 generic companies?
20 A. Yes.
21 Q. Have you testified at trial as an expert
22 on the subject of commercial success?
23 A. I have, on numerous occasions, yes.
24 MR. HILL: Mr. Campos, can we please
25 pull up JTX-157.

1 BY MR. HILL:
2 Q. And, Mr. Tate, what is this document?
3 A. This is the current version of my CV.
4 MR. HILL: And, Your Honor, Heron offers
5 Mr. Tate as an expert in the field of economic
6 analysis as it pertains to commercial success.
7 MR. NELSON: No objection, Your Honor.
8 JUDGE BRYSON: He will be so accepted.
9 BY MR. HILL:
10 Q. Mr. Tate, what were you asked to do with
11 respect to this case?
12 A. So I was asked to assess whether or not
13 the Cinvanti product is a commercial success.
14 Q. What is your understanding of commercial
15 success?
16 A. So the way I approach these types of
17 projects is it's a two-step approach. The first
18 step is to determining how the product performed
19 in the marketplace; in other words, was there
20 demand for the product. If the answer to that is
21 yes, then you go to the second step, and you
22 determine whether or not that success is
23 attributable to the patents at issue in the case.
24 Q. And what is the first thing that you did
25 in your analysis of commercial success here?

1 A. So the first thing that I always do is I
2 understand what product is at issue and whether or
3 not that product is covered by the patents that
4 are asserted in the case.
5 Q. And what did you determine?
6 A. So here, it's the Cinvanti product that
7 is the product that's at issue in the case. And I
8 understand that it's covered by the patents that
9 are asserted in the case.
10 Q. And what's the source of that
11 understanding that Cinvanti is covered by the
12 patents-in-suit in this case?
13 A. So I'm relying on Dr. Little for that
14 understanding.
15 Q. Mr. Tate, what was the next step of your
16 analysis of commercial success here?
17 A. So next, what I undertook is to
18 understand and analyze how Cinvanti performed in
19 the marketplace.
20 Q. And how did you make that determination?
21 A. Based on review of various books and
22 records, financial records of Heron, as well as a
23 focus of my analysis was on the revenue and unit
24 sales of Cinvanti over the course of time, as well
25 as its relative market share in the market that it

1 participates in.
2 Q. And what did you find regarding the
3 amount of revenue that Heron generated from the
4 sales of Cinvanti?
5 A. So I have a slide. If we could pull
6 that slide up, please. This is PDX-3-3.
7 And what you see reflected on this slide
8 is the result of my analyses of the amount of
9 annual net sales, so net revenue that Heron
10 generated from the sale of Cinvanti. And so what
11 you see graphed here is beginning in 2018 --
12 remember that's the launch year for Cinvanti. It
13 launched in January of 2018 -- Heron generated
14 $56 million of net revenue from the sale of
15 Cinvanti.
16 Now, that revenue increased year over
17 year, in 2019, to $132 million. Now, in 2019,
18 that revenue was impacted by the launch of the
19 generic fosaprepitant product. That's the Emend
20 IV generic form product. And that launched in
21 September of 2019.
22 And so what we see in 2020 is a decline
23 in net revenue to 87, almost $88 million, and
24 that's as a result of Cinvanti having to compete
25 with the lower priced generic. And we heard

1 Mr. Sullivan testify to this in his deposition
2 that was played yesterday.
3 The decrease continued into 2021, where
4 there were $73 million of net revenue generated
5 from the sale of Cinvanti. And then it began to
6 increase in 2022 at $87 million. And then when we
7 get out to 2023, we see a decline, but that's only
8 because at the time I submitted my expert report,
9 Your Honor, I only had six months of data. And so
10 we see --
11 JUDGE BRYSON: So you extrapolated.
12 THE WITNESS: No, it's not extrapolated.
13 It's actual sales for the first six months.
14 JUDGE BRYSON: Oh, this is actual sales?
15 THE WITNESS: That's correct, yes.
16 JUDGE BRYSON: Ah, okay.
17 THE WITNESS: Yes. And so you see
18 $47 million of revenue for the first six months.
19 Now, subsequent to the time I submitted
20 my report, Heron has filed its annual financial
21 filings, and in those filings, they --
22 JUDGE BRYSON: Yes.
23 MR. NELSON: Your Honor, I object if
24 he's going to go into information that wasn't in
25 his expert report that we haven't had a chance to

1 comment on.
2 JUDGE BRYSON: Well, I may have provoked
3 the departure from the expert report. So why
4 don't I withdraw my question --
5 MR. NELSON: Thank you.
6 JUDGE BRYSON: -- and let counsel --
7 THE WITNESS: Sure, understood.
8 JUDGE BRYSON: -- question you, and we
9 can solve that problem.
10 MR. NELSON: Thank you.
11 THE WITNESS: Understood.
12 BY MR. HILL:
13 Q. Mr. Tate, what did you find regarding
14 Cinvanti's level of unit sales over time?
15 A. So over the course of time launched
16 through June of 2023, there were about 3.1 million
17 unit sales. And then the total revenue during
18 that period, net revenue, was $484 million.
19 Q. And, Mr. Tate, what was the source
20 document that you relied on for this analysis?
21 A. So I relied on a financial document
22 produced by Heron in this case that reflected
23 Cinvanti's unit dollar -- unit sales and net
24 revenues. And that's JTX-181.
25 Q. Mr. Tate, are you aware of Fresenius'

1 personnel communicating regarding Cinvanti's
2 performance in the market?
3 A. I am, yes.
4 MR. HILL: Can we please pull up DTX-304
5 at page 3.
6 BY MR. HILL:
7 Q. And, Mr. Tate, what do you see reflected
8 on this page?
9 A. So this is an e-mail string between
10 internal employees at Fresenius.
11 THE WITNESS: And if we can blow up the
12 top of the chart. There you go.
13 So this happens to be an e-mail that was
14 sent by Ms. Divya Katre on February 20, 2019.
15 JUDGE BRYSON: Excuse me, what is the --
16 again, what is the exhibit number?
17 MR. HILL: DTX-304.
18 JUDGE BRYSON: 304.
19 Go ahead, thank you.
20 THE WITNESS: So this is at a time
21 period where Fresenius was evaluating whether or
22 not the Cinvanti product would be a good generic
23 product to develop at Fresenius. And what we see
24 in this e-mail is Ms. Katre is telling others at
25 Fresenius that -- if we could highlight this,

1 Mr. Campos, please -- that the product is doing
2 exceedingly well in the market, and that this is a
3 product that should be expedited with the highest
4 priority.
5 BY MR. HILL:
6 Q. And, Mr. Tate, turning back to Heron, is
7 it your understanding that Heron has been a
8 profitable company?
9 A. No, my understanding is consistent with
10 what we heard from Mr. Masztak yesterday.
11 Cumulatively, Heron has lost about $1.8 billion to
12 date.
13 Q. And what is your understanding as to why
14 Heron has not been a profitable company?
15 A. Well, there are two main reasons. The
16 first is Heron has invested a significant amount
17 of money in research and development activity,
18 including the research and development as it
19 relates to Cinvanti.
20 However, in addition to that, they have
21 spent during that period about a billion dollars
22 on research and development activity for
23 non-Cinvanti-related products. So these are
24 products that are in the pipeline or were in the
25 pipeline, some have been launched commercially

1 more recently.
2 Secondly, during that time frame,
3 Cinvanti was building an organization. They were
4 building infrastructure. They were building a
5 management organization and a sales and marketing
6 organization. And they were building this
7 organization in order to sell not only Cinvanti,
8 but also the other products that were in its
9 pipeline and hopefully -- and anticipated that
10 they would be launched at some point in time.
11 So there were two significant
12 investments made during this period, and that's
13 the genesis of the large loss.
14 Q. And is it your opinion that Cinvanti is
15 a profitable product for Heron?
16 A. So Heron does not track product line
17 profitability. So they don't have a product line
18 P&L. But what I was able to is do is get it on a
19 contribution margin basis. And at a contribution
20 margin basis it is profitable, yes.
21 Q. And can you explain what you mean by
22 that term, "contribution margin"?
23 A. Sure. So when you measure contribution
24 margin, you start out with the net revenue of the
25 product, and you subtract from that product

1 specific cost and variable cost. And what you're
2 left with is a pool of profits, it's called
3 contribution margin or contribution profit, that
4 can then be used to pay for nonspecific
5 product-related costs, so the sales and marketing
6 organization, the R&D for the entity. And so
7 that's what contribution margin is.
8 JUDGE BRYSON: Do you -- going back to
9 the question of what net profit is -- or net
10 revenue, not net profit -- net revenue, what
11 components do you typically have in there? You're
12 not -- I take it from what you just testified to
13 that you don't add in at that point
14 product-specific costs.
15 How about something like, is there an
16 attributable overhead that goes into that, or does
17 that come into variable costs?
18 THE WITNESS: Sure. So I think you
19 asked about net revenue. So let me start there,
20 and then I'll talk about profits, if that's okay.
21 JUDGE BRYSON: Right.
22 THE WITNESS: So net revenue is -- it's
23 the revenue that the company receives after
24 various discounts are taken. So that's the --
25 JUDGE BRYSON: Okay. So you're just

1 talking the dollars and cents coming into the --
2 THE WITNESS: That's now revenue.
3 JUDGE BRYSON: -- company from sales.
4 THE WITNESS: Yes.
5 JUDGE BRYSON: So you're not talking
6 about -- when you say "net revenue," it's net,
7 which is the total price minus all rebates,
8 et cetera.
9 THE WITNESS: That's correct.
10 JUDGE BRYSON: It's actual money coming
11 in.
12 THE WITNESS: Yes.
13 JUDGE BRYSON: It doesn't take any costs
14 into account.
15 THE WITNESS: Net revenue does not,
16 that's correct.
17 JUDGE BRYSON: Okay. All right.
18 THE WITNESS: Yes. And so net profit,
19 to get to profit, you start with your net revenue,
20 you subtract out what are called cost of goods
21 sold, those include materials that go into a
22 product, labor that goes into a product, and then
23 something called manufacturing overhead, which
24 would include all the supervisory time and --
25 JUDGE BRYSON: But all attached to

1 manufacturing, not overhead of the home office --
2 THE WITNESS: That's correct.
3 JUDGE BRYSON: -- and marketing and --
4 THE WITNESS: Yes, you're absolutely
5 right, Your Honor.
6 There is a fixed component to that and a
7 variable component. Then that's called gross
8 profits, once you deduct those from net revenue.
9 And then you deduct those costs that you're
10 talking about, the operating expenses, so that
11 would include selling, marketing, R&D, the general
12 administrative organization, it's where the
13 lawyers would sit, the accountants, the CFO and
14 the CEO, those sorts of things.
15 And once you subtract those out, that
16 gives you operating profit. So you go from
17 revenue less cost of goods, gives you gross
18 profit, minus operating expenses gives you
19 operating profit.
20 JUDGE BRYSON: All right. And the
21 operating profit is actually the -- I take it, the
22 bottom line that would be distributed, for
23 example, to shareholders?
24 THE WITNESS: If there was profit to be
25 distributed, yes.

1 JUDGE BRYSON: Right.
2 THE WITNESS: Yes, that's correct.
3 JUDGE BRYSON: Okay. So then you've
4 cleared all the costs at that point.
5 THE WITNESS: There might be some other
6 miscellaneous costs, like interests and those
7 types of things and taxes, but, yes, essentially,
8 you're right.
9 JUDGE BRYSON: And you call that
10 operating profit?
11 THE WITNESS: Well, that's miscellaneous
12 cost, but it would be net income at the bottom
13 line, yes. Yes, Your Honor.
14 JUDGE BRYSON: Okay. Thank you.
15 BY MR. HILL:
16 Q. Mr. Tate, were you here for
17 Mr. Masztak's testimony yesterday?
18 A. I was, yes.
19 Q. And Mr. Masztak testified that the
20 70 percent gross profit figure you used in your
21 contribution profit analysis is higher than
22 Heron's gross profit percentages reflected in its
23 10-Ks.
24 Why is that?
25 A. So there are several reasons. The

1 70 percent gross profit margin that I had used in
2 my assessment of contribution margin is meant to
3 be a variable gross profit margin. It's not what
4 what's called a fully burden gross profit margin.
5 And the difference between those two
6 things, a fully burdened gross profit margin,
7 which is what you saw on Mr. Masztak's chart
8 yesterday, includes a deduction from net revenue
9 of all fixed and variable cost of goods sold.
10 A variable gross profit margin would
11 exclude that fixed component. It would only
12 deduct a variable cost. And so that's the
13 distinction between what Mr. Masztak showed and
14 what I'm using in my analyses of contribution
15 margin.
16 Q. And do you agree with Mr. Masztak that
17 because Cinvanti represented a significant portion
18 of Heron's overall company revenue that it
19 follows, that a large percentage of Heron's
20 overall costs should be attributable to Cinvanti?
21 A. No, I don't agree with that. In the
22 Heron organization, there are a lot of what are
23 called common costs, in other words, costs that
24 aren't specific to any one product.
25 And so, for example, the sales and

1 marketing organization, throughout the course of
2 time, Cinvanti wasn't the only product that was
3 sold by the Heron entity. There were other
4 products, Sustol, for example, early on, and then
5 several other products, Zynrelef and Aponvie,
6 later in the period that were also sold.
7 In addition to that, there were
8 activities in the sales and marketing organization
9 getting ready for the launch of some of these
10 products. So in advance of launching products
11 that are in the pipeline, there was work done and
12 people hired in that function.
13 And so there is no sales force, for
14 example, dedicated to Cinvanti. And so that's why
15 it's not necessarily the case that just because
16 Cinvanti has, you know, a large percentage of the
17 revenue, that it would also get a large percentage
18 of the costs. There are many costs that are not
19 specific or related to Cinvanti.
20 Q. And, Mr. Tate, turning back to the
21 previous discussion of the fully burdened versus
22 the variable gross margin -- gross profit margin,
23 why did you use the variable gross profit margin?
24 A. Well, I think it's similar to what I
25 just said, and that is, there are many costs in

1 the organization that are not specific to any one
2 product. So what I tried to do is identify those
3 costs with the data that I had that were specific
4 to the product, deduct those, and then I'm left
5 with a pool of profits, and then that profit goes
6 to pay the bills of the organization. It doesn't
7 pay all of the bills, but it pays some of the
8 bills of the organization, including the R&D
9 associated with the Cinvanti product.
10 Q. And, Mr. Tate, did you consider research
11 and development expenses related to Cinvanti in
12 your analysis of contribution margin?
13 A. I did, yes.
14 Q. And I think we have PDX-34 up, can you
15 please explain what's shown on the slide?
16 A. Sure. If we focus on the right-hand
17 side of the slide, what this reflects is the
18 amount of R&D that was spent on the Cinvanti
19 product through 2022. So it's essentially through
20 the life of the product. And Heron spent about
21 $102 million on research and development activity
22 relating to the Cinvanti product.
23 The contribution profits that I
24 determined in my analyses during the period 2018
25 to 2021, and I limit it to that time frame because

1 that's what I had data for, is sufficient to cover
2 that total amount of R&D, as well as there's some
3 left over after that to pay for some of the other
4 company overhead, a portion of the other company
5 overhead. So I considered all of the R&D in my
6 assessment of contribution margin.
7 Q. And, Mr. Tate, what source documents did
8 you rely on in preparing this analyses?
9 A. So I relied on Heron's 10-Ks, and I'll
10 just list those for the record. JTX-159, JTX-160,
11 JTX-162, JTX-172, JTX-173, JTX-194, JTX-195, and
12 JTX-196.
13 Q. And, Mr. Tate, did you prepare an
14 analysis of Cinvanti's share of the U.S. market?
15 A. I did, yes.
16 Q. What market does Cinvanti compete in?
17 A. So Cinvanti competes in the IV NK-1 RA
18 marketplace.
19 Q. What is the basis for the definition of
20 the market that you use in your market share
21 analysis?
22 A. So this is how Heron describes or
23 defines its market and how it manages the product,
24 it's the IV NK-1 RA marketplace. And I based
25 reliance on that definition of "market" on a

1 discussion I had with Mr. Sullivan, as well as we
2 heard Mr. Sullivan's deposition testimony
3 yesterday, he defined the market in this fashion.
4 And then I relied on various internal Heron
5 documents that also described the market as such.
6 MR. HILL: And can we please pull up
7 JTX-169.
8 BY MR. HILL:
9 Q. And, Mr. Tate, what is this document?
10 A. So this is what's called a 2022 CINV
11 brand plan. And CINV is the name of the franchise
12 at Heron that includes products that treat the
13 CINV issue. And Cinvanti is part of that
14 franchise.
15 Q. And this is one of the documents that
16 you relied on in support of your market definition
17 that you used?
18 A. It is, yes.
19 MR. HILL: Can we please turn to
20 page 12?
21 BY MR. HILL:
22 Q. And, Mr. Tate, what does this page
23 reflect?
24 A. So here Heron is defining the market
25 that Cinvanti participants in. And you can see in

1 the top of the chart, it defines it as IV NK-1 RA
2 market. And you see that the market participants,
3 in addition to Cinvanti, are the branded IV Emend
4 product and then the generic version of that
5 product, the generic IV fosaprepitant. And then,
6 lastly, they include IV Akynzeo, which as we've
7 heard is a combination product.
8 MR. NELSON: Your Honor, just objection.
9 This may not be a big -- we were not provided this
10 demonstrative ahead of time in accordance with the
11 party's agreement on exchange of demonstratives.
12 So -- oh, I'm sorry, I apologize. It's from the
13 slide. I apologize. My apologies.
14 JUDGE BRYSON: Okay. Very well.
15 BY MR. HILL:
16 Q. Mr. Tate, is this definition of the
17 market that Cinvanti competes in consistent with
18 the definition reflected in other Heron documents
19 that you reviewed and relied on?
20 A. It is, yes.
21 Q. And, Mr. Tate, what are the results of
22 your analysis of the Cinvanti's share of the U.S.
23 markets?
24 A. If we can go to the next slide, please.
25 So what this slide reflects is the

1 results of my analyses of the market share for
2 each of the participants in the IV NK-1 RA market
3 in the U.S. And you see in green reflects the
4 IV Akynzeo market share. The red line affects the
5 branded Emend IV market share. The purple line
6 represents the generic fosaprepitant market share.
7 And, lastly, the Cinvanti's market share is
8 reflected by the dark blue line.
9 And so if we focus on the Cinvanti line,
10 what we see is from its launch in 2018, through
11 about the end of quarter 3, 2019, Cinvanti's share
12 grew period over period and peaked at about
13 43 percent. And it did so at the cost of the
14 Emend IV product. You can see Emend declines as
15 Cinvanti increases.
16 Now, in September of 2019, as I
17 mentioned previously, the generic fosaprepitant
18 product entered the market. And so at this point
19 in time, as we heard from Mr. Sullivan, Heron was
20 faced with Cinvanti having to compete with a
21 significantly lower priced generic product. And
22 so through about quarter 2 or quarter 3, 2020,
23 Cinvanti's share declined, and then it stabilized
24 between quarter 2, 2020, and quarter 4, 2023, it
25 stabilized in the range of 25 to 28 percent.

1 Q. And what was the source document you
2 relied on in preparing your analysis of market
3 share?
4 A. This is based on what is called IQVIA
5 data, and this is data that is commonly relied
6 upon in pharmaceutical industry for market share
7 type data. And it is marked as PTX-25.
8 Q. Mr. Tate, you heard Mr. Masztak
9 yesterday discuss the price of Cinvanti.
10 Did you consider the price of Cinvanti
11 in your analysis?
12 A. I did, yes.
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8 BY MR. HILL:
9 Q. And, Mr. Tate, can you please identify
10 the sources that you relied on in comparing -- in
11 this net price comparison?
12 A. Sure. There are two sets of sources.
13 The first are two CINV brand plans, and those are
14 designated as JTX-169 and JTX-175. And then in
15 addition to that, with respect to the Heron
16 Cinvanti selling price, I relied on JTX-181.
17 Q. And, Mr. Tate, if we could go back to
18 the previous slide.
19 What happened to the Emend IV market
20 share once generic fosaprepitant came into the
21 market?
22 A. Sure. It's a very good point. So let
23 me respond to that.
24 As you see in September of 2019, once
25 the generic product comes on the market, there is

1 automatic substitution for the Emend IV product,
2 the branded product. And you can see from the red
3 line that it pretty quickly declines to very
4 negligible market share. It doesn't quite hit
5 zero, but it's in the 1 percent range, I think, by
6 the time we get on to 2023. So the generic
7 fosaprepitant product has entirely eroded the
8 Emend IV market share.
9 Q. Mr. Tate, are you familiar with the
10 concept of net cost recovery?
11 A. I am, yes.
12 Q. What is net cost recovery?
13 A. So, formulaically, it's the difference
14 between the reimbursed amount for a particular
15 product, so it's the amount of reimbursement that
16 a customer would receive, less the actual price
17 that the customer paid for the product.
18 So, for example, if the actual price the
19 customer paid was $10 and they were reimbursed
20 $15, there's a positive net cost recovery of $5.
21 Now, it can also work the other way, where the
22 actual price is $10, but they're only reimbursed
23 $5. So there's a negative net cost recovery of $5
24 in that example.
25 Q. And how did the net cost recovery for

1 Cinvanti compare with the net cost recovery for
2 the generic IV fosaprepitant?
3 A. So --
4 MR. NELSON: Your Honor, I object. I
5 don't think this was in his expert report, a
6 comparison of the generic fosaprepitant product.
7 MR. HILL: This was discussed in his
8 deposition transcript. It's not in his report.
9 MR. NELSON: I don't believe in his
10 deposition you asked about a comparison of the net
11 cost recovery.
12 MR. HILL: Can we --
13 JUDGE BRYSON: Mr. Hill.
14 MR. HILL: Can we display page 216 of
15 Mr. Tate's deposition?
16 JUDGE BRYSON: Okay.
17 MR. HILL: I'm sorry, can we go to
18 page 214, line 14. If you scroll down a little
19 bit.
20 So he's talking about the concept here.
21 The words "net cost recovery" don't appear. So we
22 can withdraw the question.
23 JUDGE BRYSON: Okay.
24 MR. NELSON: Thank you.
25 JUDGE BRYSON: Withdrawn.

1 BY MR. HILL:
2 Q. Mr. Tate, did you also analyze Heron's
3 marketing efforts related to Cinvanti?
4 A. I did, yes.
5 Q. What is the purpose of Heron's marketing
6 activity as it relates to Cinvanti?
7 A. So, just generally, pharmaceutical
8 companies, as well as Heron specifically, they use
9 sales and marketing efforts to educate the
10 marketplace on the clinical benefits of the
11 products that they're marketing.
12 So in the case of Cinvanti, the sales
13 and marketing organization would educate health
14 care providers, whether it would be doctors,
15 nurses, or some other professional in the health
16 care industry, on the benefits of the Cinvanti
17 product, you know, how does it treat the patients,
18 what are the clinical benefits of the patient.
19 And so that's the kind of things that they would
20 highlight in the marketplace.
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19 BY MR. HILL:
20 Q. And, Mr. Tate, can we please turn to
21 another document, DTX-265?
22 And what is this document?
23 A. So at this point we've looked at
24 internal Heron documents discussing drivers of
25 demand, product differentiation. Now what this

1 document is, it's a customer facing document.
2 This is a marketing brochure that Cinvanti
3 provides to health care providers and it is an
4 informational package relating to -- I said
5 Cinvanti. I meant Heron provides to customers.
6 And this is an informational package relating to
7 the Cinvanti product.
8 And so what we see here on the first
9 page is they highlight at the very top of the
10 document the two product differentiators that we
11 see in the internal documents.
12 And that is the first and only synthetic
13 surfactant-free IV NK-1 RA product approved for
14 prevention of acute and delayed CINV due to both
15 HEC and MEC. So that was the first differentiator
16 that we looked at in the product positioning
17 document.
18 And then the second thing they highlight
19 on the front page is the fact that this is the
20 only IV NK RA with the operational flexibility of
21 a two-minute IV push.
22 Q. And Mr. Tate, is it your understanding
23 that these marketed benefits are attribute to the
24 patents-in-suit?
25 A. That is my understanding, yes.

1 Q. And what's the basis for that
2 conclusion?
3 A. So I'm relying on Dr. Little for that.
4 Q. And, Mr. Tate, let's talk a little bit
5 more about the two-minute IV push.
6 MR. HILL: Can we please pull up JTX-169
7 at page 59?
8 THE WITNESS: Can we go -- before we do
9 that, I'd like to go through this document and go
10 to -- there's a two-minute IV push page in this
11 document, if we could.
12 BY MR. HILL:
13 Q. Sure.
14 MR. HILL: Can we turn to page 10 of
15 this document?
16 BY MR. HILL:
17 Q. And what do you see on this slide,
18 Mr. Tate?
19 A. So what we see on this slide is Heron is
20 highlighting the two-minute IV push benefit. But
21 in addition to that, we see that there are several
22 other benefits, and I think we've heard a little
23 bit about these other benefits during the course
24 of the trial.
25 One is that there's no dilution

1 necessary with the two-minute IV push product, and
2 there's no constitution required.
3 And then the third --
4 JUDGE BRYSON: We have an objection.
5 MR. NELSON: Yeah, this was never
6 testified about with any other witness that the
7 product doesn't have any dilution or any
8 constitution. No other expert has laid that
9 foundation. And certainly no technical expert for
10 this expert to rely upon.
11 JUDGE BRYSON: Well, the document says
12 it, do not --
13 MR. NELSON: That is true, but this
14 witness is relying on the technical expertise to
15 establish that these are actually things that were
16 done in the clinic, not that just promoted, and I
17 don't think he can provide that testimony.
18 JUDGE BRYSON: Well, I suppose he can't
19 testify that that was what was done at the clinic,
20 but he can certainly testify that that is what
21 they were alleging.
22 MR. NELSON: Okay.
23 JUDGE BRYSON: For what it's worth.
24 MR. NELSON: I suppose that's true. For
25 what it's worth, I think you're right. Thank you.

1 JUDGE BRYSON: I'll allow it, but I do
2 think -- if I recall, I don't think we've had
3 testimony to the effect that there was a
4 non-dilution protocol that was used. Maybe we'll
5 hear it from other witnesses, but I don't think
6 we've heard it yet.
7 Have we, or is my recollection wrong?
8 MR. HILL: I think mine is consistent
9 with yours. I certainly couldn't point to a line
10 or a page regarding that. So we can move on from
11 this, Your Honor.
12 MR. ASHKENAZI: Your Honor, if I may,
13 just to remind the Court, yesterday Dr. Roeland
14 discussed what a two-minute IV push is.
15 JUDGE BRYSON: Right.
16 MR. ASHKENAZI: It's the very nature of
17 a two-minute IV push is you just inject it.
18 JUDGE BRYSON: Well, fine, but I don't
19 think there was any focus -- the term "dilution,"
20 I don't recall having been brought up.
21 MR. ASHKENAZI: That's fair, Your Honor.
22 I'm just saying that's the nature of what a
23 two-minute IV push is as opposed to an IV
24 infusion.
25 MR. NELSON: Your Honor, I would

1 disagree with counsel testifying about that,
2 because my expert could come up and say things
3 quite different.
4 JUDGE BRYSON: Yeah, I think we probably
5 want to --
6 MR. ASHKENAZI: Okay.
7 JUDGE BRYSON: It's helpful for me to
8 understand where the dispute lies, but I think
9 resolution of the dispute we're going to have to
10 hear it from an expert. Maybe we will, but to the
11 extent that we don't, you can question on this
12 point. But I think all Mr. Tate can say is that
13 this was in the document.
14 Now, whether it's true, whether it has
15 any consequence, whether it's something that
16 somebody else could testify to, we'll have to find
17 out.
18 MR. HILL: Understood, Your Honor.
19 Thank you.
20 BY MR. HILL:
21 Q. So, Mr. Tate, is it your understanding
22 that Heron markets its product as not requiring
23 dilution for the two-minute IV push and no
24 reconstitution required for either administration
25 option?

1 A. That's correct.
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13 Q. Mr. Tate, can we please turn back to
14 slide PDX-5 for a minute?
15 Does maintaining a 25 to 28 percent
16 market share with the competition from the
17 generic -- IV generic fosaprepitant represent a
18 successful drug product?
19 MR. NELSON: Your Honor, that's a
20 leading question. We've been pretty liberal here,
21 but that's pretty --
22 JUDGE BRYSON: That is a --
23 MR. HILL: Withdrawn.
24 JUDGE BRYSON: I am pretty liberal, but
25 I think you probably crossed the tripwire.

1 Let me ask a -- well, while I've
2 interrupted --
3 THE WITNESS: Go ahead, Your Honor.
4 JUDGE BRYSON: Well, I mean, I don't
5 have a question for the witness.
6 THE WITNESS: Okay.
7 JUDGE BRYSON: Do you happen to have a
8 hard copy of the demonstratives for this witness?
9 Because it would be helpful to me if I can follow
10 along.
11 MR. HILL: I apologize, Your Honor. I
12 thought they were in your binder.
13 JUDGE BRYSON: No, that's fine. Thank
14 you.
15 So objection will be sustained. You can
16 reformulate the question.
17 BY MR. HILL:
18 Q. Mr. Tate, what is your opinion regarding
19 Cinvanti's market share after the launch of
20 generic fosaprepitant?
21 A. So after the launch of generic
22 fosaprepitant, you see that Cinvanti's market
23 share stabilized over a four-year period between
24 25 and 28 percent. And during that time period,
25 there was economic advantage both -- you know, it

1 worked both ways, to find the fosaprepitant
2 product for the customer, and economic advantage,
3 sometimes we'll get the Cinvanti product. Yet,
4 the market share stayed stable.
5 And so you didn't see the market share
6 going up and down with price changes in the
7 marketplace. And so I believe that in competition
8 with the generic product, that is an indicator of
9 success.
10 MR. HILL: And could we please turn to
11 slide PDX-3-7?
12 BY MR. HILL:
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3 MR. HILL: I have no further questions
4 for Mr. Tate.
5 JUDGE BRYSON: Very good.
6 Cross-examination.
7 MR. NELSON: Your Honor, may I approach
8 the witness with some binders?
9 JUDGE BRYSON: You may, yes.
10 MR. NELSON: And, Your Honor, may I
11 approach the bench?
12 JUDGE BRYSON: Yes. Thank you.
13 MR. NELSON: They're heavy ones, sorry.
14 JUDGE BRYSON: At the close of the case,
15 we will be having a sale on reduced prices for
16 binders.
17 MR. NELSON: I was thinking a nice
18 bonfire, Your Honor.
19 May it please the Court, Your Honor.
20 Kevin Nelson on behalf of Fresenius.
21 JUDGE BRYSON: Proceed.
22 MR. NELSON: Thank you.
23 CROSS-EXAMINATION BY COUNSEL FOR THE DEFENDANT
24 BY MR. NELSON:
25 Q. Mr. Tate, good morning.

1 A. Good morning.
2 Q. Mr. Tate, on your direct examination,
3 you talked about Heron building an organization.
4 Do you recall that testimony?
5 A. I do, yes.
6 Q. And you read the deposition of
7 Mr. Sullivan in preparing your opinions; correct?
8 A. I did.
9 Q. And you recall Mr. Sullivan said that
10 Heron has been an existing entity -- existing
11 before its AP Pharma for about 30 years; right?
12 A. It was in a different form, I believe,
13 yes, not in the form that you see during the
14 period that we're focused on, but a predecessor
15 company existed, yes.
16 Q. As AP Pharma; correct?
17 A. I believe that was the name of the
18 company, yes.
19 Q. And you provided an opinion to the Court
20 about $484.3 million of total net revenue from
21 2018 to 2023; correct?
22 A. Through June of 2023, yes, correct.
23 Q. And you agree by itself the fact that
24 Cinvanti made that 484.3 million in net revenue in
25 about six years does not make it a commercial

1 success by itself; correct?
2 A. No, I think you have to look at that in
3 context of the other things that I looked at. But
4 I would agree with you, just that alone wouldn't
5 necessarily lead somebody to believe that it was a
6 commercial successful product, but in context it
7 is, yes.
8 Q. There's no specific dollar figure that
9 constitutes commercial success; correct?
10 A. No, as you and I discussed at my
11 deposition, you often get asked that question.
12 I'm not aware of any threshold that a product has
13 to achieve in order for it to be a commercial
14 success. I've been involved in cases where the
15 revenue was quite small, and then involved in
16 cases where, you know, it's a blockbuster drug
17 where it's billions of dollars of sales.
18 Q. And you didn't compare the net revenue
19 of this product to any other branded on patent
20 product over that six-year period?
21 A. I didn't compare the net revenues, but I
22 did make a relative comparison with respect to
23 market share. So I did compare the market share
24 of the Cinvanti product relative to the revenue --
25 or excuse me, the sales of other manufacturers'

1 products.
2 Q. But not branded on patent product;
3 correct?
4 A. Well, I compared Emend IV's market share
5 to Cinvanti's market share, yes.
6 Q. Which was not on patent at the time;
7 correct?
8 A. Emend IV was -- yes, prior to the launch
9 of the generic product, it was a patented product,
10 I believe. There was no generic in the market
11 anyhow. I'm not quite -- I don't understand your
12 question, I guess.
13 Q. Well, let me move on to this.
14 The branded and generic fosaprepitant
15 products, since you bring them up, both contain
16 polysorbate 80; correct?
17 A. Say that again.
18 Q. Both the branded and generic Emend IV
19 product, fosaprepitant products, those both
20 contain polysorbate 80; correct?
21 A. They do, that's my understanding, yes.
22 Q. And both those branded and generic
23 fosaprepitant products are not approved for a
24 two-minute administration; correct?
25 A. That's my understanding, yes.

1 Q. And you agree that the net revenue for
2 Cinvanti decreased when generic fosaprepitant came
3 on the market in Q3, 2019; correct?
4 A. Yeah, it did decrease at that point,
5 yes.
6 Q. And you agree the number of units sold
7 for Cinvanti decreased when generic fosaprepitant
8 entered the market in Q3, 2019; correct?
9 A. It did. As a result of the low price
10 competition, it did decrease, yes.
11 Q. If you could turn to your DTX-150, your
12 schedule.
13 A. Is that in your binder or --
14 Q. Either binder. You can probably use my
15 binder, since I'll use that one.
16 A. Sure. Will it be on the screen or --
17 Q. 150, and it will be on the screen.
18 A. Okay.
19 Q. And if you turn to Schedule I .1, which
20 is at page 4.
21 Now, here you have the unit sales data
22 for the products that are listed on the left-hand
23 side; correct?
24 A. One second, let me just get oriented to
25 the schedule.

1 Yes, that's correct.
2 Q. You agree Cinvanti never achieved the
3 unit sales in a single quarter that's equal to or
4 higher than the highest monthly unit sales for
5 Emend IV; correct?
6 A. The monthly or quarterly, I can't tell
7 you monthly from this data. I can tell you on a
8 quarterly basis that's true, but I don't know
9 about a monthly basis.
10 Q. Generic fosaprepitant, however, has
11 exceeded the highest quarterly sales for a unit of
12 Emend IV on several occasions; correct?
13 A. In some quarters, yes. Other quarters,
14 the answer would be no. But on some occasions,
15 yes.
16 Q. Let's turn to Schedule 3.1 at page 21.
17 And I want to focus on 2022 for a second, the
18 gross sales.
19 In 2022, Cinvanti achieved the highest
20 gross sales of any single year that you have
21 listed there; correct?
22 A. On a gross sales basis, that is correct,
23 yes.
24 Q. And 2022 also had the highest total
25 amount of discounts and rebates that Heron

1 provided; correct?
2 A. In terms of absolute dollar amount, that
3 appears to be correct, yes.
4 Q. And the highest total amount of expenses
5 of any of those years; correct?
6 A. I'm not sure what you mean by
7 "expenses."
8 Q. Well, you have a "total expenses" line
9 there, do you see?
10 A. Oh, the sum of the discounts, yes. In
11 my answer to your prior question, that's what I
12 was answering.
13 Q. Okay. That's fair. Thank you.
14 A. Sure.
15 Q. We're on the same page.
16 A. Sure.
17 Q. And if we look at the 2019, that's the
18 second highest gross sales of any of the years you
19 report; correct?
20 A. That is correct, yes.
21 Q. And it's also the second highest total
22 expenses, discounts, rebates, et cetera, that
23 you're reporting; correct?
24 A. I don't think so.
25 Q. I'm sorry, you're right. But if we look

1 at just the rebate, not the total expenses, I
2 apologize. I withdraw, you're right.
3 But if we look at the discounts and the
4 distributor fees, off-invoice discounts, rebates,
5 those are the second highest than what we're
6 seeing throughout; correct?
7 A. I don't think so. The expense line
8 reflects -- it's a total of all those discounts
9 above it. Those aren't expenses as I think you --
10 we might be saying two different things here.
11 Q. Okay. Let me -- I'll alleviate that
12 confusion.
13 A. Okay.
14 Q. We can go back to 2022. We're on the
15 same page at least that when gross sales were the
16 highest, the total expenses and discounts were
17 also the highest; correct?
18 JUDGE BRYSON: I'm sorry, you said the
19 total expenses what?
20 MR. NELSON: The total expenses and
21 discounts were the highest.
22 JUDGE BRYSON: Yeah.
23 THE WITNESS: Yeah, total expenses is a
24 sum of the discounts above it. So that's correct.
25

1 BY MR. NELSON:
2 Q. I'd like to look at your PDX-3-6,
3 please.
4 When Heron launched its Cinvanti
5 product, it actually priced it lower than the
6 fosaprepitant products that were available at the
7 time; correct?
8 A. At launch or at --
9 Q. At launch, correct, yes.
10 A. At launch, on a net selling price basis,
11 it was at times -- not always, but at times lower
12 than the Emend IV product, for the reasons that I
13 stated in my direct testimony.
14 Q. And for this source data, you didn't
15 review your original source data for the generic
16 fosaprepitant price that you provide there;
17 correct?
18 A. No, this is based on the internal
19 analyses prepared by Heron, and I did not see the
20 underlying source data that they relied upon for
21 this particular -- those particular numbers.
22 Q. And typically, source information -- or
23 I'm sorry. Typically, price information, net
24 price information, for a competitor is not readily
25 available to another competitor; right?

1 JUDGE BRYSON: If I could interrupt.
2 MR. NELSON: Sure.
3 JUDGE BRYSON: I think you said PDX-3-6.
4 MR. NELSON: 6, yes.
5 JUDGE BRYSON: Right. And I did not
6 understand -- you were starting questioning about
7 the comparison of what was it again?
8 MR. NELSON: Of the Cinvanti price at
9 launch to the fosaprepitant product at launch --
10 or when the launch of Cinvanti occurred. So it's
11 at the far left.
12 THE WITNESS: No, no. I have to
13 interrupt, Mr. Nelson, but this chart wouldn't
14 reflect that.
15 JUDGE BRYSON: Yeah.
16 THE WITNESS: This chart is in
17 quarter 3, 2019.
18 JUDGE BRYSON: 3.3-6. Do you mean 3-5?
19 MR. NELSON: I may have misspoke.
20 Well, no, that's market share. Well,
21 let me try to get this back if there's confusion.
22 JUDGE BRYSON: Well, because you're
23 dealing with Q3 of 2019 as the first number in
24 3-6.
25 MR. NELSON: That's fair.

1 BY MR. NELSON:
2 Q. So let me rephrase my question.
3 A. Sure.
4 Q. And I think we're on the same page
5 without this slide.
6 A. When I responded, I was not focused on
7 the slide.
8 MR. NELSON: And, yeah, I started out
9 with the slide, I asked him a question. So I
10 apologize.
11 JUDGE BRYSON: Okay.
12 BY MR. NELSON:
13 Q. Without context of the slide, I
14 appreciate it, thank you.
15 At launch Cinvanti was launched at a
16 price that was lower than fosaprepitant that was
17 available on the market at the time?
18 A. As I said, for certain customers, it was
19 at a lower price at launch. And the reason for
20 that was the two reasons I gave during my direct
21 testimony; and that is, the pricing strategy that
22 was employed found it necessary to compete with
23 Emend IV, which was a product that had been on the
24 marketplace for ten years. It was the standard of
25 care. And then Heron also knew that the eminent

1 launch -- or the launch of the generic version of
2 the product was eminent. So it had to price
3 accordingly.
4 Q. And now we can bring up PDX-3-6. And
5 this is where I caused the confusion, I apologize.
6 At Q3, 2019, that's when generic
7 fosaprepitant launched; correct?
8 A. In September of that quarter, yes.
9 Q. And at that time, the price was higher
10 for generic fosaprepitant than Cinvanti,
11 Cinvanti's price was lower; correct?
12 A. The net selling price at that point was
13 higher, and then there's also a net recovery issue
14 and generic arbitrage that goes on here that also
15 impacted this, yes.
16 Q. Okay. And we were talking about the
17 generic pricing that's provided here. That's not
18 readily available to a competitor; correct?
19 A. It would not be readily available, but
20 based on various industry sources, they have
21 surveys that, you know, you can purchase, as well
22 as market intelligence from your sales and
23 marketing folks, is how they compile this type of
24 information.
25 Q. And at the time of generic entry,

1 Cinvanti had about two years of contracting
2 experience and relationships that it had built on;
3 correct?
4 A. A year and a half, yes.
5 Q. You agree that at launch of Cinvanti,
6 Heron attempted to leverage the known, trusted,
7 and safety and efficacy of Emend and aprepitant by
8 informing payers that it had a bioequivalent
9 version of those products; correct?
10 A. That was one of the things that they
11 highlighted to payers and to health care
12 providers, in addition to the benefits and the
13 differentiation that I spoke about during my
14 direct exam.
15 Q. I'd like to focus now on your
16 contribution margin testimony.
17 A. Okay.
18 Q. There's no criteria or benchmark or
19 threshold for a product's contribution profit that
20 constitutes a commercial success product; correct?
21 A. No, similar to what we talked about with
22 respect to revenue, there is no threshold for
23 profitability. And I think as I explained in my
24 deposition, oftentimes in cases like this, we
25 don't even present profit information, primarily

1 because the patent owner, the plaintiff, doesn't
2 want that disclosed in a public setting.
3 And so oftentimes we rely on demand for
4 the product, in other words, the net revenue and
5 the sales, as well as market share. And so
6 oftentimes -- you know, there is no threshold to
7 answer your specific questions, but oftentimes we
8 don't even consider profitability.
9 Q. Now, your contribution margin analysis,
10 that 70 percent number, was based on your
11 discussion with Mr. Sullivan; correct?
12 A. It was, yes.
13 Q. You didn't review any underlying
14 documents for that?
15 A. I did not. I relied on Mr. Sullivan.
16 He received that information from the accounting
17 department. And, again, not to dispute your
18 question, but it's a variable gross profit margin.
19 Q. And your analysis cut off at 2022; is
20 that right?
21 A. 2021.
22 Q. 2021. Thank you.
23 A. I looked at 2018 to 2021.
24 Q. Let's look at DTX-221. DTX-221.
25 And this is the earning call transcript

1 that you reviewed and Mr. Masztak talked about;
2 correct?
3 A. I believe he talked about it, yes. I
4 have reviewed it, yes.
5 Q. And if we could turn to DTX.0008. Okay.
6 And if we look at what Heron was telling
7 the public down at the bottom where it says
8 "Finally"?
9 A. I see that, yes.
10 Q. Finally, large scale Cinvanti
11 manufacturing is now online with product in the
12 distribution channel, resulting in a gross margin
13 increasing from about 50, moving toward
14 75 percent.
15 Do you see that?
16 A. I do.
17 Q. So Heron had calculated a gross margin,
18 reported it, and that was about 50 percent, which
19 is consistent with what Mr. Masztak had testified;
20 correct?
21 A. It's consistent with what you see in the
22 Form 10-Ks. But, again, what I testified to on
23 direct is that I am looking at this from a
24 variable contribution margin perspective. This is
25 what's called a fully burdened margin. So in

1 other words, it started with the net revenue,
2 subtracts out cost of goods and subtracts out, as
3 it relates to manufacturing overhead, both fixed
4 and variable costs.
5 The focus of the 70 percent is only on
6 variable costs. And so there would be a fixed
7 component that you would have to add back to this
8 number to get from 50 to 70 percent. And based on
9 my experience, that's a reasonable assumption with
10 regard to that particular metric.
11 Q. Okay. But you agree that Heron is
12 reporting to the public much lower gross margin
13 percentages than you were; correct?
14 A. On a fully burdened basis, I agree with
15 what they're reporting to the public, yes.
16 Q. In your market definition, you relied on
17 IQVIA data; is that correct? For your market
18 definition, your market analysis?
19 A. Not for the definition.
20 Q. No, no, for the data that you provided,
21 I'm sorry.
22 A. When I did the market share slide, the
23 underlying data is IQVIA data, yes.
24 Q. And IQVIA provides data in a therapeutic
25 class, if requested.

1 A. If you wanted to get that, you could,
2 yes.
3 Q. You got the data from Heron. You didn't
4 request it directly from IQVIA?
5 A. I did not. It came from Heron, that's
6 correct.
7 Q. Now, your market -- the actual market
8 itself that you looked at, includes IV Akynzeo; is
9 that correct?
10 A. Yes.
11 Q. And that is not a NK-1 receptor
12 antagonist; correct?
13 A. It's a combination product that includes
14 two components.
15 Q. And you did not include an oral -- any
16 oral NK-1 receptor antagonists; correct?
17 A. I did not. As we heard from
18 Mr. Sullivan, that they don't consider oral to be
19 a competing product.
20 Q. But you agree neither Heron nor
21 Fresenius Kabi nor any of us in this courtroom
22 make the decision on how to treat a patient with
23 an antiemetic.
24 That's the doctor's decision; correct?
25 A. I would agree that that's the doctors.

1 It would be Dr. Markman or Dr. Roeland that would
2 do that, or other doctors, health care providers,
3 that's correct.
4 Q. And doctors have a choice in the
5 antiemetic space, as we've seen, to either use an
6 oral product NK-1 or to use a regimen that doesn't
7 even include an NK-1; correct?
8 A. They could do that. I think the
9 preferred method that we heard about is using an
10 NK-1 in a regime with three or four other drugs,
11 but the option would be there to use oral, if they
12 so chose.
13 Q. And can we go to JTX-169, which you
14 looked at in your direct? And if we could go to
15 page 91, please.
16 MR. NELSON: If you can pull up that.
17 It's all right. Take that down, please.
18 BY MR. NELSON:
19 Q. Let me ask you, you reviewed a chart
20 with your counsel on direct that provided --
21 apologies, withdrawn.
22 MR. NELSON: Please pull that back up,
23 JTX-169 at 91.
24 BY MR. NELSON:
25 Q. This is providing data on the

1 prophylaxis of CINV in the first cycle of chemo.
2 Do you see that?
3 A. One second, let me just get my bearings
4 here. I see the title, yes.
5 Q. And you can see the administration --
6 the regimens that are on the right-hand side with
7 those various colors; is that right?
8 A. You mean the key of the graph?
9 Q. Correct.
10 A. Yes.
11 Q. There's an A that says, 5-HT3 + dex, for
12 example?
13 A. I see that.
14 Q. Okay. And that does not include an NK-1
15 receptor antagonist; correct?
16 A. Which one?
17 Q. The A that I just mentioned.
18 A. On the bottom. I don't believe so. It
19 doesn't appear to.
20 Q. And this is doctors' actual use;
21 correct?
22 A. This is a survey. So it's based on a
23 limited number of doctors. I think it says they
24 surveyed 133 clinics and 87 hospitals. So on a
25 given day, that's what they reported.

1 Q. I'd like to look at DTX-150 now, please,
2 at Schedule 1.1. And --
3 MR. NELSON: Schedule 1.1, please.
4 BY MR. NELSON:
5 Q. There's no indication in this data how
6 many or what percentage of units that Cinvanti has
7 sold because it does not contain polysorbate 80;
8 correct?
9 A. Not in this data, no.
10 Q. And at Cinvanti's launch, IV Varubi was
11 on the market, and it did not contain
12 polysorbate 80; correct?
13 A. I believe that's correct, if my
14 recollection is correct.
15 Q. And you've become aware of a generic
16 fosaprepitant product by Teva that does not
17 contain polysorbate 80; correct?
18 A. Again, I believe that's correct, without
19 knowing all the inner workings of that product. I
20 believe it doesn't include polysorbate 80.
21 Q. And that was launched in Q3, September
22 of 2019; correct?
23 A. I don't know for sure that it was
24 launched at that initial date. I think it's on
25 the market, but that's all I know.

1 MR. NELSON: Can we go to DTX-187,
2 please? And page 16 of DTX-187.
3 JUDGE BRYSON: We have an objection.
4 MR. HILL: Yeah, I don't believe this
5 was discussed on direct.
6 MR. NELSON: Your Honor, this all goes
7 to the polysorbate 80 marketing message that he
8 went to. He doesn't have to discuss the same -- I
9 don't have to discuss the same documents on
10 cross-examination.
11 JUDGE BRYSON: I'm going to allow it.
12 This is on -- I think it's relevant to the
13 polysorbate 80 issue.
14 BY MR. NELSON:
15 Q. Yeah, I apologize, if we can go back to
16 the first page, just so I can --
17 A. I was going to ask you that, yeah.
18 Q. -- give you context, I apologize.
19 This is a Heron company update they
20 provided at the J.P. Morgan conference in
21 January 2018; correct?
22 A. I see that.
23 Q. And you actually reviewed this document
24 in preparing your opinions?
25 A. I did, yes.

1 Q. Thank you.
2 MR. NELSON: Let's go to page 16.
3 BY MR. NELSON:
4 Q. Now, it says here, Cinvanti is now
5 launched.
6 So Cinvanti is launched, according to
7 this document; right?
8 A. What was the date again on the front
9 page? Sorry, go back.
10 Q. January 2018.
11 A. Okay. So it had just launched, yes.
12 MR. NELSON: Back to 16, please.
13 BY MR. NELSON:
14 Q. And it says, Cinvanti is the first and
15 only polysorbate 80-free IV 1 -- IV NK-1 receptor
16 antagonist approved for the prevention of "both"
17 acute and delayed CINV.
18 Do you see the emphasis of "both"?
19 A. I do.
20 Q. And we agreed that IV Akynzeo at this
21 time already was polysorbate 80-free; correct?
22 A. That's my understanding. Again, I've
23 only discussed that with somebody of the technical
24 nature, but that's my understanding, yes.
25 Q. And from that understanding, plus the

1 emphasis of "both," what Heron was really
2 promoting was that its product had two
3 indications, the acute and the delayed CINV;
4 correct?
5 A. No, I think it was promoting the entire
6 statement here, including "both."
7 Q. And do you recall giving a deposition in
8 this case?
9 A. I do. And that's basically what I said,
10 is that it was the "both," it was emphasizing
11 "both."
12 Q. Thank you.
13 A. But it's clear that they're discussing
14 the polysorbate 80-free nature of the product.
15 Q. And you testified on direct with respect
16 to JTX-169, their statement about being
17 surfactant-free.
18 And that was in 2021; correct?
19 A. Correct. At some point I think they
20 switched the positioning to surfactant-free.
21 Polysorbate is a surfactant, but they switched it
22 to surfactant-free as opposed to
23 polysorbate 80-free, yes.
24 MR. NELSON: Turn to DTX-184.
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3 MR. NELSON: Thank you. No further
4 questions, Your Honor.
5 JUDGE BRYSON: Very well.
6 Redirect.
7 MR. HILL: No further questions.
8 JUDGE BRYSON: Okay.
9 MR. HILL: Just one moment, please.
10 THE WITNESS: Yes, sir, you have -- oh,
11 you want a moment? Yes, of course.
12 MR. HILL: I'll just ask a couple of
13 questions, Your Honor.
14 JUDGE BRYSON: All right.
15 REDIRECT EXAMINATION BY COUNSEL FOR THE PLAINTIFF
16 BY MR. HILL:
17 Q. Good afternoon, again, Mr. Tate -- or
18 good morning, again, Mr. Tate.
19 A. Good morning.
20 Q. The Akynzeo product, that includes the
21 NK-1 receptor antagonist; right?
22 A. That's one --
23 Q. Or does that include an NK-1 receptor
24 antagonist?
25 A. That's one of the components of the

1 combination, yes. That's my understanding.
2 Q. And why was that included in the market
3 share?
4 A. Because it's an IV product that competes
5 with the products that are in the market
6 definition.
7 Q. And did -- are you aware of Mr. Masztak
8 disagreeing with your definition of the relevant
9 market share for commercial success?
10 A. I don't believe he disagreed with it.
11 MR. HILL: No further questions.
12 JUDGE BRYSON: Very well.
13 Mr. Tate, thank you for your testimony.
14 THE WITNESS: Thank you, Your Honor.
15 JUDGE BRYSON: You're excused.
16 MR. HILL: And, Your Honor, may I
17 introduce the exhibits?
18 JUDGE BRYSON: Yes, we can do that
19 while -- if someone can go fetch -- I assume that
20 this is the end of the closed courtroom period?
21 MR. ASHKENAZI: Yes, Your Honor.
22 JUDGE BRYSON: Okay. If someone -- if
23 counsel can appoint someone to go fetch the folks
24 that are waiting outside while we're doing the
25 exhibits. Thank you.

1 MR. HILL: Your Honor, Heron would like
2 to move into evidence the following exhibits:
3 JTX-157, JTX-159, JTX-160, JTX-162, JTX-169 --
4 MR. ALBANO: Hold on, I'm so sorry. Can
5 you start over again? I'm on the wrong document.
6 MR. HILL: No problem.
7 Are you ready?
8 MR. ALBANO: Yeah.
9 MR. HILL: JTX-157, JTX-159, JTX-160,
10 JTX-162, JTX-169, JTX-172, JTX-173, JTX-175,
11 JTX-181, JTX-194, JTX-195, JTX-196, DTX-265,
12 DTX-304, and PTX-025.
13 JUDGE BRYSON: All right. And --
14 MR. ALY: And a couple of
15 cross-exhibits, Your Honor.
16 JUDGE BRYSON: Yes.
17 MR. NELSON: DTX-150, DTX-221, DTX-187,
18 DTX-184, JTX-177, and JTX-158.
19 JUDGE BRYSON: Very well. I assume no
20 objections?
21 MR. HILL: No objection.
22 JUDGE BRYSON: No objection. They'll
23 all be admitted. Thank you.
24 (Exhibit Nos. JTX-157, JTX-159, JTX-160,
25 JTX-162, JTX-169, JTX-172, JTX-173, JTX-175,

1 JTX-181, JTX-194, JTX-195, JTX-196, DTX-265,
2 DTX-304, PTX-025, DTX-150, DTX-221, DTX-187,
3 DTX-184, JTX-177, and JTX-158 were offered and
4 admitted.)
5 JUDGE BRYSON: Next witness.
6 MR. ASHKENAZI: Yes, next witness. The
7 plaintiff would like to call Dr. Steven Little to
8 the stand.
9 JUDGE BRYSON: Dr. Little, welcome back.
10 You understand that you are still under oath.
11 THE WITNESS: Yes, Your Honor.
12 JUDGE BRYSON: You may proceed.
13 MR. ASHKENAZI: Your Honor, if I could
14 have a moment just to get some binders
15 distributed.
16 JUDGE BRYSON: Yes.
17 MR. ASHKENAZI: Thank you.
18 (Pause in the proceedings.)
19 JUDGE BRYSON: Go ahead.
20 Whereupon,
21 STEVEN LITTLE, PH.D.,
22 being previously duly sworn or affirmed to testify to
23 the truth, the whole truth, and nothing but the truth,
24 was examined and testified as follows:
25

1 DIRECT EXAMINATION BY COUNSEL FOR THE PLAINTIFF
2 BY MR. ASHKENAZI:
3 Q. Good morning, Dr. Little. Welcome back.
4 I'd like to start off by discussing the
5 definition of a person of ordinary skill in the
6 art, or a POSA, in this case.
7 Dr. Little, did you prepare any slides
8 for your testimony today?
9 A. I did.
10 MR. ASHKENAZI: If we could please bring
11 up PDX-4-1.
12 BY MR. ASHKENAZI:
13 Q. Are those the slides you prepared for
14 today?
15 A. This is the cover slide.
16 Q. And if we could turn to PTX-4-2.
17 BY MR. ASHKENAZI:
18 Q. And can you please explain to us what
19 you're showing on this slide?
20 A. Yeah, so these are the two definitions.
21 There's not -- there's not significant difference
22 between the two, but there's two things I wanted
23 to point out.
24 When Dr. Rabinow was here, he mentioned
25 that I allowed for the individual to have a

1 bachelor's degree in something like pharmaceutics,
2 for instance. What wasn't mentioned, though, that
3 I just want to make sure is clear is that although
4 I do allow for an individual to have a bachelor's
5 degree in pharmaceutics, I have that individual
6 have some commensurate degree of experience in the
7 real world.
8 So if there is an issue, it's really
9 just whether that individual needed to have that
10 experience in a classroom or needed to have that
11 experience in the real world. And just from my
12 personal experience for the issues here, I felt
13 like the experience in the real world was
14 sufficient for that.
15 In addition to that, the other real
16 difference between these two is that given the
17 problem that a person of ordinary skill in the art
18 would be facing in the field at the time of
19 invention, I felt like that person should have
20 experience in parenteral drug products or
21 injectable drug products.
22 And Dr. Rabinow's definition, what you
23 can see is that he focuses in specifically in the
24 person of ordinary skill in the art already
25 assuming that it would be intravenous emulsion

1 formulations. So his person of ordinary skill in
2 the art is very focused already on the claim
3 elements in the claim.
4 JUDGE BRYSON: Thank you.
5 BY MR. ASHKENAZI:
6 Q. Dr. Little, how, if at all, would your
7 opinions change under Dr. Rabinow's definition of
8 a POSA in this case?
9 A. It wouldn't. I still include a
10 consideration of parenteral drug products as a
11 whole, but even if I were to say, I mean, that
12 person that I'm describing would have experience
13 with emulsion formulations. So I don't think it
14 would change.
15 Q. And just so we're clear, what is the
16 priority date or date of invention you used for
17 this case?
18 A. It's listed here. It's September 19th,
19 2014.
20 Q. And is that the same date Dr. Rabinow
21 applied?
22 A. That's my understanding, yes.
23 Q. Dr. Little, given Dr. Rabinow's focus on
24 CN '845, I want to just start off with that, if we
25 can.

1 MR. ASHKENAZI: Can we please bring up
2 JTX-71, which is the CN '845 reference we've been
3 discussing?
4 BY MR. ASHKENAZI:
5 Q. Well, at least would you agree with
6 that?
7 A. Yes.
8 Q. Okay.
9 MR. ASHKENAZI: And if we could please
10 pull up DDX-1-5 for a moment.
11 BY MR. ASHKENAZI:
12 Q. Dr. Little, do you recall Dr. Rabinow
13 discussing -- Dr. Rabinow's testimony on this
14 slide?
15 A. I do.
16 Q. And do you recall Dr. Rabinow
17 testifying, with reference to this slide, that
18 CN '845 accommodates or provides a range that
19 includes the levels stipulated in the claims?
20 A. Yes.
21 Q. And do you have an opinion on -- do you
22 agree with that opinion?
23 A. I don't.
24 Q. And why not?
25 A. Well, so I created a slide that I think

1 better -- I think it's a correction to this, but
2 it's a better representation of it, if we can pull
3 it up.
4 MR. ASHKENAZI: Can we please pull up
5 PDX-4-3?
6 BY MR. ASHKENAZI:
7 Q. And, Dr. Little, could you please
8 explain what you're trying to illustrate here?
9 A. Sure. So I think that it's appropriate
10 here to add a correction in the sodium oleate
11 line, specifically, and then I'll describe some
12 other information that I've put on here.
13 So, specifically, CN '845 does not have
14 sodium oleate in it. The claims require really
15 any amount of a substance as a pH modifier as
16 sodium oleate. Here in this case, it's not in
17 CN '845.
18 In addition to that, what I've done is
19 I've just pointed out something that's probably
20 apparent when you just read the claims, but just
21 so it's clear, when you go down through the claim
22 elements, those are specific items. So, for
23 instance, you have egg yolk lecithin or soybean
24 oil. Okay. But in the claims, it's a percent
25 range, but it's a genus.

1 So it doesn't specifically specify in
2 the CN '845 here what you would use. Like, it
3 doesn't say you would use egg yolk lecithin. And,
4 in fact, there's other examples of things beyond
5 that that are different emulsifiers that are used
6 in CN '845 throughout.
7 So I'm just pointing out that in the
8 CN '845, the listings of ranges are genuses, and
9 in the claims they're specific excipients.
10 Q. I'd like to look a little bit further
11 into CN '845, if we can.
12 MR. ASHKENAZI: Will you please turn to
13 JTX-71.13? And I want to focus in on paragraphs 8
14 to 11, if we can.
15 BY MR. ASHKENAZI:
16 Q. And, Dr. Little, can you please walk us
17 through these paragraphs and your understanding of
18 them?
19 A. Sure. So in paragraph 8, what you're
20 seeing is the disclosure in CN '845 of these
21 genuses, as I described in the last slide. And
22 these are the broadest disclosures from my review
23 of the CN '845 of these general genuses.
24 Then when you get down to paragraph 9,
25 it says the preferred mass percentage of each

1 component. So what you can see is -- in most
2 cases a narrow range here for those preferred
3 masses.
4 Then whenever you go down to the next
5 paragraph, what you see is a disclosure of the
6 types of excipients that would fit within the
7 genus above. And you see a large listing of
8 different types of excipients in each of those.
9 Then, finally, at the end here in
10 paragraph 11, it says the pH value of the
11 aprepitant microemulsion for injection is 6.0 to
12 8.0.
13 MR. ASHKENAZI: Now, if we could please
14 turn to JTX-71.14. It's the next page. I want to
15 focus in on paragraph 16 for a moment.
16 BY MR. ASHKENAZI:
17 Q. And, Dr. Little, can you please explain
18 whether the disclosure in paragraph 16 affects
19 your opinions regarding the pH disclosure of
20 CN '845?
21 A. Sure. So in paragraph 16, you have the
22 method for preparing. Okay. And if you go down,
23 oh, I'd say like three quarters of the way down,
24 it's after the water for injection is added, you
25 see adjusting the pH to 6 to 8 is the disclosure

1 here as to what one part of the method is.
2 Q. So what pH modifier does CN '845 say can
3 be used?
4 A. It doesn't say the pH modifier here.
5 Q. And what is the most common types of pH
6 modifiers you used at this time?
7 A. Yeah, so -- well, they're the same
8 common type of pH modifiers that are used today.
9 You would use something that is -- most commonly
10 used is something like sodium hydroxide. It gives
11 you a lot of bang for the buck. When it goes in,
12 it just associates. So you're putting it in, and
13 that's what it does, it adjusts the pH.
14 JUDGE BRYSON: It drives the pH up.
15 THE WITNESS: If you added sodium
16 hydroxide, it would dissociate, and it would drive
17 the pH. That would be its function. That's what
18 it would do.
19 JUDGE BRYSON: Drive it up.
20 THE WITNESS: Yeah, correct. And then
21 if you wanted to drive down in some of the
22 context --
23 JUDGE BRYSON: Yeah. Right.
24 THE WITNESS: Right. Correct.
25

1 BY MR. ASHKENAZI:
2 Q. So I'd like to understand your opinion
3 on how the claimed formulations compare to the
4 examples in CN '845.
5 MR. ASHKENAZI: Can we please turn to
6 PDX-4-4?
7 BY MR. ASHKENAZI:
8 Q. And, Dr. Little, could you please
9 explain to us what you're trying to list on this
10 slide?
11 A. Yeah, so what I'm doing here is I'm just
12 listing each of the examples. So we saw the
13 disclosures in the specification. Now what I want
14 to do is show you what was done in each of these
15 examples. You can see the amounts for each of the
16 ingredients. And I'll just point out a few
17 things.
18 So as I described earlier, in the
19 emulsifier row here that goes across all of the
20 examples, the first thing I'll point out is that
21 egg yolk lecithin is not the only emulsifier
22 that's used. You see an application of poloxamer,
23 you see an application of polysorbate, and then
24 others, as well.
25 You also see a spanning of the range of

1 emulsifiers that's discussed in the specification.
2 So you see it go down to .5 percent, for instance,
3 in egg lecithin, you see another instance of
4 5.6 percent, and then you see an instance of
5 10 percent.
6 So you see the span of that range
7 throughout these examples, as well. And then when
8 you go down to oil, it's kind of a similar
9 situation. Different oils span of the range of
10 oils throughout there, too. And the same for
11 protective agent and co-emulsifier.
12 I labeled this slide with colors in the
13 exact same way as I've done for the prior slide
14 that I showed the Court that talked about what
15 meets a claim, what doesn't meet the claim, just
16 so that you can see here that there are a couple
17 of claim elements throughout Zhou where that one
18 claim element would meet the claim.
19 So, for instance, I count here six claim
20 elements spread throughout. But if you look at
21 the columns, each one of these columns, there is
22 no single example that meets the elements of the
23 claim. And, in fact, there's a number of them
24 that don't meet any of them. And for the most
25 part, most of the claim elements are not met by

1 any of the examples.
2 Q. Dr. Little, just to clarify here, on the
3 right-hand side, what's the last column you're
4 showing?
5 A. Those are the claims.
6 Q. Okay. So if we exclude the claims, how
7 many claim elements --
8 A. Oh, sorry, yeah, four. Sorry, four. I
9 was counting the claims as a different example,
10 that's not correct. The claims are on the
11 right-hand side. Those are labeled white because
12 there's an example of two different examples that
13 have that claim element only. That's why that's
14 white in that right-hand side. Thank you for
15 correcting me.
16 Q. Okay. And, Dr. Little, I just want to
17 make sure the record is clear here.
18 When it comes to the emulsifier, what's
19 the lowest level of egg yolk lecithin included in
20 an example in CN '845?
21 A. It's 10 percent, in Example 5.
22 Q. Sorry, I said the lowest level.
23 A. Oh, the lowest is .5 percent, in
24 Example 6.
25 Q. Now, I see you have an asterisk by

1 Example 7 and 8. Why is that?
2 A. Yeah, so what I did here is I just am
3 trying to point out to the Court that if the Court
4 goes in and looks, there is a dilution step in
5 Example 7 and 8 to produce the final product.
6 So sometimes what happens is we prepare
7 a stock solution, and then from that stock
8 solution, you're able to take aliquots and you're
9 able to make a number of different sort of final
10 formulations using those aliquots. That's what
11 happens here in Example 7 and 8.
12 So what I've done is I've shown what the
13 final form would be in terms of concentrations
14 after that dilution step.
15 Q. Where, if any, did a --
16 JUDGE BRYSON: Examples 7 and 8 are --
17 as indicated, I take it, the post-dilution
18 calculation?
19 THE WITNESS: Yes, Your Honor.
20 JUDGE BRYSON: All right.
21 BY MR. ASHKENAZI:
22 Q. And does CN '845 explicitly discuss that
23 there is a dilution, for example, 7 and 8?
24 A. It does.
25 Q. Okay. Where, if anywhere, does CN '845

1 disclose the concentration of emulsifier above
2 10 percent?
3 A. It does not.
4 Q. And which, if any, examples use only
5 preferred ingredients and preferred concentrations
6 that we saw in paragraph 9?
7 A. Yeah, none of the examples seem to focus
8 on just the preferred concentrations of the
9 excipients.
10 If the Court remembers, there was a
11 preferred concentration range for each of these in
12 the genus. Although there are instances of one or
13 two of these things in some examples being
14 preferred, the other excipients aren't included in
15 those preferred amounts. So there's no one
16 example that includes only preferred amounts.
17 Q. And the same applies for preferred
18 excipients as well?
19 A. Yes, that's correct.
20 Q. In other words -- and I'll just make
21 sure -- I'll ask my question again.
22 Which, if any, examples use only
23 preferred ingredients and preferred
24 concentrations?
25 A. None.

1 Q. What stability data did CN '845 provide
2 for the formulations that are disclosed therein?
3 A. CN '845 does not provide any stability
4 data, and this doesn't appear to be the focus in
5 the article.
6 Q. So in your opinion, does CN '845
7 disclose physically stable examples?
8 A. No.
9 Q. Did you hear Dr. Rabinow say CN '845
10 refers to human use?
11 A. I did. So my understanding of this is
12 that because the formulations in CN '845 are
13 referred to as formulations that ultimately would
14 be used for human use or they're preclinical
15 formulations, that a person of ordinary skill in
16 the art would assume that they would have all the
17 properties necessary in order for them to be, I
18 guess, administered to humans. I just don't think
19 that's the case.
20 In my experience, I see patents all the
21 time where people are focusing on a particular
22 technology, let's say one aspect of that
23 technology that would be advantageous. They do
24 not go through all the work to make sure that that
25 technology could be used in humans and in fact

1 many times when we make these things -- many,
2 many, many times we make these things and they
3 never get approved for human use.
4 So just because you're working on a
5 technology where you would hope that one of the
6 aspects of that technology would be useful for
7 human use, that does not imply all of the things
8 you would need, including stability.
9 Q. So how, if at all, does that impact your
10 opinion in this case?
11 A. Well, it's just my opinion that the
12 CN '845 is not talking about stability of its
13 formulations. That's not the focus of the
14 reference.
15 Q. If we could please bring back up
16 JTX-71.17. And that's CN '845. I want to focus
17 on paragraph 33.
18 With this paragraph in mind, Dr. Little,
19 do you understand Dr. Rabinow testified that a
20 POSA would think that the use of terminal
21 sterilization by heat in CN '845 suggests that
22 examples in CN '845 were stable?
23 A. Yeah, I think -- I will explain my
24 understanding of this. First, I'll point you down
25 to the bottom, this is where this is coming from.

1 It looks like a sample was filled into a vial and
2 then autoclaved.
3 This is terminal sterilization. So
4 you're making sure the product in its final form
5 that it would be given, you know, would be
6 sterilized. And I do agree with him that
7 sterilization applies a pressure.
8 The assumption, then, after that point
9 is the part that I don't agree with, which is that
10 if the pressure was applied, I guess the
11 assumption is, is that the authors would have
12 observed it and it would have been physically
13 stable and we would know that.
14 There's no discussion of testing being
15 done to meet the court's construction on what
16 physically stable would mean. In fact, there's no
17 implication that there's any testing done at all
18 in terms of physical stability.
19 So I don't think a person of ordinary
20 skill in the art reads that into this reference.
21 Q. Which examples in CN '845 would a POSA
22 view as the best examples?
23 A. Yeah, there's no indication that any one
24 of them would be the best. I mean, I understand
25 that Dr. Rabinow believes that all of them, I

1 guess, we would assume, are physically stable,
2 even the ones that have .5 percent emulsifier in
3 them.
4 I don't take it that far because I don't
5 think anything is talking about stability, and
6 it's not even like there's an example that uses
7 all the preferred concentrations and the preferred
8 excipients.
9 Q. Now, we heard about complexation during
10 Dr. Rabinow's testimony.
11 What, if anything, does CN '845 say
12 about complexation?
13 A. It doesn't say anything about
14 complexation.
15 Q. In your opinion, would a POSA understand
16 that the formulations of CN '845 were made by
17 forming complexes with aprepitant despite that
18 lack of disclosure?
19 A. No, absolutely not.
20 Q. And why not?
21 A. Okay. So I guess my understanding is,
22 is that when reading this reference, a few
23 assumptions have to be here in order to read in
24 what Dr. Rabinow reads in, from my understanding.
25 So first is that I think he understands

1 and tries to incorporate the properties of
2 aprepitant. And he says the only place that it
3 could be is at the interface. And that's
4 assumption one. We haven't seen any reference
5 that says that has to be what happens but that's
6 assumption one.
7 And then what happens is, say -- if you
8 look at it in the context of this reference, you
9 would also see that there is going to be lecithin,
10 okay, at that interface as well. Okay. And
11 that's going to help it to be at the interface.
12 That's assumption two. We also, you know, don't
13 know that from what we see in this reference.
14 But then what a person of ordinary skill
15 in the art is doing standing there and looking at
16 this and thinking about, you know, I guess the
17 implication that Dr. Rabinow has is that you would
18 optimize the concentration up and then you would
19 have this high amount, more than you've seen in
20 the prior art, be there with the aprepitant at the
21 interface.
22 All those assumptions are there whenever
23 you read this, but a person of ordinary skill in
24 the art looking at this reference at the time of
25 the invention would stop for a second and think

1 about it. And I'll use the example he used, which
2 was a person floating in the ocean.
3 So let's say you're the drug molecule or
4 we're both drug molecules and all of us here,
5 we're floating in the ocean. Okay. And I think
6 he used a life vest as the example of the
7 lecithin. So that would be keeping us floating.
8 Now, just for reference, I want to make
9 sure the Court understands the points of reference
10 here, the oil underneath of you and the droplet is
11 the ocean, okay, that's the oil. Above you is the
12 water. Okay.
13 So technically, you know, in his example
14 the water is the ocean and the air above you, but
15 you're on the surface of the water droplet, or we
16 are. And we have these life vests on, that's the
17 lecithin. Okay.
18 But if you take the assumption he makes,
19 which is that you would use concentrations in the
20 claims, if you just look at that, it's 14 percent
21 life vests and 10 percent ocean. So we would all
22 be floating and we'd be heavier than the ocean.
23 So if you start to read all these things
24 in, it doesn't hold together. And I just don't
25 think a person of ordinary skill in the art looks

1 at that when they see this reference.
2 Q. Okay. I just want to go back to that
3 analogy for a moment.
4 What you're saying is the size of the
5 life vest would be 14 times -- would be larger
6 than the size of the ocean you're trying to stay
7 above?
8 A. If you read the assumptions in and say
9 you can go up that high, the mass of the life
10 vests would be more than the mass of the ocean
11 underneath of you. So if you just think about
12 that geometrically, it's impossible.
13 Q. If we could please pull back up PDX-4-4.
14 So -- and you discussed a little bit
15 about this in your last answer or your two
16 previous answers, but I want to go into this a
17 little bit more.
18 How do the examples in CN '845 fit into
19 Dr. Rabinow's theory that CN '845 is discussing
20 complexes of aprepitant to lecithin?
21 A. Okay. So this is another thing I'll
22 point out. If Dr. Rabinow -- Dr. Rabinow sees
23 complexes here, they would be there for all these
24 different emulsifiers. So you wouldn't be forming
25 a chemically specific complex with egg yolk

1 lecithin. And I'll talk about this a little bit
2 later on. I'm not sure that's a great assumption,
3 but if you assume that you form a chemically
4 specific complex at the surface of the droplet
5 with this, you'd be forming it with polysorbate,
6 you'd be forming it with poloxamer.
7 I don't understand how a POSA could get
8 to the point where they would understand that
9 there would be a complex with all these various
10 different possible chemical entities at the
11 surface.
12 In addition to that, I guess this
13 reference would also disclose that you would have
14 a complex at .5 percent, at 10 percent,
15 5.6 percent.
16 So again, this is another instance of
17 where I just don't think that a person of ordinary
18 skill in the art standing at the time of the
19 invention looking at this would see what
20 Dr. Rabinow sees on the reference.
21 Q. Okay. I want to focus on one of the
22 examples you just referenced.
23 Example 6 of CN '845, that has
24 0.5 percent aprepitant?
25 A. It does.

1 Q. And how much emulsifier is in there?
2 A. It's .5 percent.
3 Q. So what's the ratio of aprepitant to
4 emulsifier in Example 6?
5 A. In that instance, it would be one to
6 one.
7 Q. So we'll circle back to complexation a
8 little bit later.
9 Based on your review of CN '845, how
10 would a POSA view its reliability?
11 A. My opinion is that when you review the
12 whole of CN '845, there are some serious questions
13 that you would have about the reliability of the
14 reference.
15 Q. And why is that?
16 A. Well, so there's a number of mistakes
17 throughout it that would cause concern and, you
18 know, some of them you could potentially chalk up
19 to typos, but others you can't.
20 Q. Okay.
21 JUDGE BRYSON: When you say
22 "reliability," what exactly do you mean by that?
23 THE WITNESS: Okay.
24 JUDGE BRYSON: Inaccurate reporting or
25 is that the science is flawed or what?

1 THE WITNESS: As I will show you a few
2 examples of, there are some instance of things
3 that are stated in it that are impossible. Like
4 you wouldn't -- a person of ordinary skill in the
5 art would believe it's even possible to achieve.
6 There's instances of -- there's
7 instances also of -- so there's concentrations and
8 pressures. And if I could just show you, there
9 are some examples of it, but ultimately I think
10 your fundamental question that you have is what do
11 you mean by "reliability." I -- sorry, are you
12 asking --
13 JUDGE BRYSON: I don't want to get ahead
14 of you if the questioning was heading in that
15 direction. I just want to get a sense of when you
16 use the word "reliability," are you covering any
17 form of inaccuracy or problematic science broadly?
18 THE WITNESS: Well, I think a person of
19 ordinary skill in the art would begin to question
20 the science in it. I'm not so sure if I'd go so
21 far to say that a POSA would disregard it.
22 JUDGE BRYSON: Okay.
23 THE WITNESS: I think a POSA would be
24 aware of it, but I would think that they would
25 start to wonder what was going on and whether some

1 of the sciences is as accurate as they say.
2 JUDGE BRYSON: Okay.
3 BY MR. ASHKENAZI:
4 Q. Well, maybe let's walk through some of
5 the examples if we can.
6 Can we --
7 JUDGE BRYSON: At this point, before you
8 begin to go through the examples, we might want to
9 take a break.
10 MR. ASHKENAZI: Sure.
11 JUDGE BRYSON: Let's come back at 10:15.
12 (Recess from the record.)
13 JUDGE BRYSON: Resume.
14 BY MR. ASHKENAZI:
15 Q. Dr. Little, I just want to clarify one
16 thing for the record; if someone was going to
17 adjust the pH down per the range that's in CN '845
18 for pH, what might be used?
19 A. If you're going to adjust the range down
20 in CN '845 --
21 Q. Sorry, let me restate my question.
22 If you're going to adjust the pH range
23 down, what would be used?
24 A. If you're going to go down, it would be
25 hydrochloric acid as Your Honor said.

1 Q. Thank you.
2 MR. ASHKENAZI: I just want to make sure
3 that was clear for the record, Your Honor.
4 JUDGE BRYSON: Yeah, that was my
5 understanding.
6 MR. ASHKENAZI: I just wasn't sure if it
7 was caught on the transcript. That was your
8 question, though, so --
9 JUDGE BRYSON: Okay.
10 BY MR. ASHKENAZI:
11 Q. So let's go to the -- we were talking
12 about some of the potential issues you were going
13 to raise for CN '845.
14 So if we could bring up for CN '845
15 JTX-71. Examples 4, 6, and 10 on the screen. And
16 that's going to be from pages 15, 16, and 9 to 10.
17 And could we also bring up Claim 10, that you have
18 on the right-hand side, which is from page
19 JTX-71.9 to 10.
20 Okay. Dr. Little, you had mentioned
21 there were some technical errors you were
22 referring to in CN '845. Can you explain to us
23 what those are?
24 A. Sure. Okay. So -- okay. So I'm seeing
25 in the second one down here, Example 6, so I'll

1 just start with that one.
2 Here you've got an instance where you've
3 got all these components in there and I'll just
4 mention that one of those components here is water
5 for injection. Okay, that's 69 grams.
6 So 69 grams of water is in -- it takes
7 up 69 milliliters, that's the density of water.
8 So you'd have 69 milliliters.
9 And then if you go down to paragraph 30,
10 when you have example -- when you have the -- the
11 preparation method was the same as Example 5
12 wherein the pH was 7.2, and then you take
13 150 milligrams of aprepitant, you see that. And
14 I'll just note above the amount of aprepitant that
15 was in 69 grams of water was .5.
16 So you're going to take some of this
17 solution that is up here at the top and you're
18 going to transfer it down. And you can see it's
19 about a third. So 150 milligrams is approximately
20 a third, a little over of maybe a third. And
21 you're going to transfer it in.
22 But remember you had 69 milliliters of
23 water. So if you took a third of 69 milliliters
24 of water, that doesn't fit in a 5-milliliter glass
25 vial, for instance.

1 Q. What would a third of 69 milliliters of
2 water be roughly?
3 A. It's like 33 or something like that --
4 or no, a third of 70 is, let's see, it's like,
5 what, 23, something like that, 22, 23. So that
6 would be 22, 23 milliliters in a 5-milliliter
7 glass vial. So that's just one instance.
8 I'll end with the one on the top. If
9 you go to the right here, you see another instance
10 of something that wouldn't be possible. This is
11 the method of preparing the microemulsion it says.
12 Q. And, Dr. Little, if I can interrupt you
13 just because when we say right-hand side, it's not
14 clear for the record. The right-hand side is
15 Claim 10?
16 A. Claim 10.
17 Q. Which is JTX-71.9 to 10?
18 A. Right. Down here you're saying that is
19 using homogenization methods at the bottom, and
20 it's at a pressure, it says, of 1,000 megapascals.
21 So a person of ordinary skill in the art
22 would understand we're not using homogenization
23 methods with a thousand mega -- that's a
24 gigapascal. So that's well beyond the machinery's
25 capability of doing whenever you're doing

1 microfluidization and high pressure
2 homogenization. So that's another instance of
3 this.
4 So I guess you could say that maybe
5 these things are like typos or something like
6 that; right? There's a number of them, but you
7 could potentially say they're typos.
8 JUDGE BRYSON: Would there be a more
9 conventional number that would be -- you're
10 expecting to see where it says a thousand, is
11 there a number if you leave out the M or --
12 THE WITNESS: Yeah, that's what I'm
13 saying. I guess you could possibly imagine that.
14 So in the art --
15 JUDGE BRYSON: I guess what I -- rather
16 than just possibly imagine, is there a natural
17 number that would be associated with that process?
18 THE WITNESS: Yeah, 150 -- 150 is what I
19 think we would typically use. Some of the
20 equipment that you could imagine, like the
21 specialized equipment would go up to 400
22 megapascals, something like that. So you could
23 imagine maybe there was a unit error, which is
24 possible --
25 JUDGE BRYSON: So if just read 100 --

1 THE WITNESS: Maybe it was a hundred.
2 JUDGE BRYSON: -- would it surprise you?
3 THE WITNESS: Maybe it was a hundred.
4 So you could imagine that maybe that's a typo,
5 yeah.
6 JUDGE BRYSON: And how about the
7 5-milliliter glass vial, is there a number that
8 would look more natural than 5 milliliters or is
9 there just one we'd be guessing?
10 THE WITNESS: You'd be sort of guessing
11 on that one, yeah.
12 JUDGE BRYSON: All right.
13 THE WITNESS: But you could chalk these
14 up to potentially typos, right, it's possible.
15 There's several.
16 JUDGE BRYSON: They show up all the time
17 in U.S. patents. I assume the Chinese have the
18 same problem.
19 THE WITNESS: Sure. But I want to
20 finish with Example 4.
21 So what is being discussed in this and
22 the others, you saw this as well, is the word
23 "microemulsion." So it says, "the aprepitant
24 microemulsion." Okay.
25 This isn't a typo. And the reason why

1 is if you look in the specification of the patent,
2 you can see a definition that was copied in for
3 "microemulsion" that is actually a fairly accurate
4 definition of the word "microemulsion."
5 These are formulations in the art that
6 are completely different than the kind of
7 emulsions we're talking about in this patent.
8 And the description of them includes all
9 of those things, the differences, like that
10 they're thermodynamically stable, that they're
11 clear. They would form on their own, okay.
12 So they describe that and teach the
13 regular definition of "microemulsion" and then
14 throughout the rest of the patent, there are no
15 microemulsions, even though they're referred to as
16 "microemulsions."
17 JUDGE BRYSON: All right.
18 BY MR. ASHKENAZI:
19 Q. Now, I also note that in Claim 10 of the
20 patent, it refers to a "coarse emulsion" which is
21 about four lines down -- yes, three lines down,
22 thank you.
23 What would a POSA understand that coarse
24 emulsion, the context of that to be?
25 A. Sure. So what a "coarse emulsion" is,

1 so the Court understands, so before you're going
2 to run this into a homogenization or
3 microfluidization, down at the bottom of this
4 example, you're going to try to mix this stuff up.
5 And you're not going to mix it up as much as the
6 homogenizer is going to. That's going to
7 pulverize it down. But you want what's being fed
8 through there to be generally mixed up. So you
9 make what's called a coarse emulsion. Okay.
10 The issue here is that when you read
11 this, it says that you -- and I'll just read the
12 steps, it says it mixes aprepitant, which is the
13 drug, and the emulsifier, solvents and ethanol,
14 heats to 60 degrees and stirs until the ethanol is
15 evaporated to give a sticky residue.
16 Now, we're keeping the temperature at
17 60 degrees and heating to dissolve the residue to
18 give a coarse emulsion. You don't have a coarse
19 emulsion because you don't have any oil.
20 So maybe they're referring to the
21 residue as a coarse emulsion. But if you then go
22 on, it says, okay, maybe that's a typo or
23 something. That's what they meant.
24 But then if you keep going, it says
25 adding a co-emulsifier to the coarse emulsion,

1 adding an appropriate amount of ethanol to
2 dissolve it, keeping the temperature to get
3 60 degrees and stirring to obtain a clear oil
4 phase. So you're not adding oil until later and
5 they say they're adding oil to the coarse
6 emulsion.
7 So there's some characterizations of
8 things that wouldn't comport to a person of
9 ordinary skill in the art's understanding of
10 what's going on.
11 Q. So in general, if I could take a step
12 back, I know it would help me, an emulsion is --
13 what components are in an emulsion?
14 A. It's oil in water or water in oil.
15 Q. So in order for you to have an emulsion,
16 you have to have both oil and water?
17 A. Yes.
18 Q. And as of -- per the steps you were
19 reading to us, what -- was there any water in
20 oil --
21 A. No.
22 Q. -- before the term coarse emulsion?
23 A. No.
24 Q. Now, Dr. Little -- we could take that
25 down.

1 Dr. Little, CN '845 was described by
2 Dr. Rabinow as a game changer in the field.
3 Do you have an opinion on that?
4 A. Okay. I wouldn't call it a game
5 changer. I think I understand what he's talking
6 about such that if you read, you make a bunch of
7 assumptions and you put those things in, I can see
8 what he's trying to say.
9 But here's the way I look at this, it's
10 a reference that has broad disclosures, in my
11 opinion. It's not even focusing on any particular
12 preferred example. It doesn't display the results
13 of that. There's not some kind of stability data
14 that would show why something was preferred.
15 And then if it's a game changer, then I
16 think there would be something in there that
17 describes like what changed the game, right, some
18 mechanism, some discovery, something if it's a
19 game changer to sort of point the people who are
20 going to look at it to say, I'm going to say I'm
21 going to change the way I play the game now as a
22 result. There's no disclosure of that at all
23 without a lot of importation of assumptions into
24 the reference.
25 You would also expect that if there is a

1 game-changing reference, we would see in this case
2 like the references that we're talking about that
3 follow it would cite it. I haven't seen any
4 references where somebody is citing that whenever
5 they're trying to change the game.
6 So I guess, you know, to put it mildly,
7 I don't -- this is not a reference that I think my
8 students would be running to my office with to say
9 we've got to read this and do what we're talking
10 about in this reference as sort of a game changer.
11 I don't see that.
12 Q. Were you in the field in 2012?
13 A. I was.
14 Q. Was this reference -- how did you view
15 this reference?
16 A. I didn't. I didn't even know about this
17 reference.
18 Q. Was it a game changer to you?
19 A. No.
20 Q. You mentioned earlier that there's no
21 data in CN '845 regarding the stability of the
22 formulations in that application; correct?
23 A. There's not, no.
24 Q. Stepping out of CN '845, is there any
25 data from any other source regarding the stability

1 of any of the emulsions that are covered by
2 CN '845?
3 A. Well, so you do have the Example 4 in
4 the patents-in-suit.
5 Q. If we could please pull up JTX-7.15?
6 This is the '794 patent, and we're going to focus
7 on Example 4.
8 MR. ASHKENAZI: And I also want to
9 apologize to the Court, I think both myself and my
10 colleagues on the other side have been going back
11 and forth between the patents.
12 JUDGE BRYSON: It's fine. I understand.
13 MR. ASHKENAZI: Okay.
14 BY MR. ASHKENAZI:
15 Q. Dr. Little, what are we seeing in
16 Example 4 of the '794 patent?
17 A. So what you're seeing is what the patent
18 refers to as an alternative aprepitant emulsion.
19 Included here in the blowup, you can see, is the
20 components, the amounts, and the weight per weight
21 concentration. And if the Court were to compare
22 that to the claims, you would see that it would
23 not meet the claim elements. So it's not an
24 embodiment.
25 And then if you go just down to the bottom

1 of this, it was prepared, you see, within four days
2 post-preparation at room temperature, crystals were
3 observed in the product by microscopy. So this
4 product was unstable.
5 Q. And the microscopy that's being
6 discussed here, is that -- did you previously
7 refer to that in your testimony?
8 A. Yes, I did. It was according to the
9 court's construction.
10 Q. The testimony you're referring to was
11 from the infringement portion of the case?
12 A. Yes, Monday.
13 Q. Okay. We can take that down. Thank
14 you, very much.
15 We also heard a lot from -- about the
16 Zhou reference from Dr. Rabinow. I'd like to
17 discuss that a little further. It's JTX-115 in
18 your binder.
19 And, Dr. Little, is this the Zhou
20 reference as you understand it?
21 A. Yes.
22 Q. Okay. And the first named author is
23 Zhou Wei?
24 A. Yes.
25 Q. And that's the same Zhou Wei that was

1 identified as one of the authors of the CN '845?
2 A. Yes; correct.
3 Q. Okay. And I'd like to take a little bit
4 closer look at and discussion about your opinions
5 on how these emulsions compared to the emulsion --
6 the emulsion from Zhou compares to the claims.
7 Can we please pull up PDX-4-5?
8 And can you please explain to us what
9 you're showing us on this slide?
10 A. Sure. So first I'll just orient the
11 Court to the right-hand side, which is the claims.
12 I tried to make this the same as what I showed the
13 Court before when I put in the claims.
14 As you see, the percent required by the
15 compositions in the claims and the amount of each
16 ingredient, what the ingredient specified, the pH
17 range, et cetera.
18 On the left-hand side, what I did is I
19 put in what the Zhou formulation -- or the Zhou
20 reference refers to its optimal formulation.
21 And what you can see as you go down is
22 that the pH has a range that's plus or minus that
23 would fall within the pH of the claim. So I
24 included that in yellow.
25 But beyond that, there is no claim

1 element that meets the asserted claims
2 compositional amounts.
3 Q. And, again, just for the record, I
4 understood what you were saying, but the pH is
5 included in white; correct?
6 A. The pH is included in -- the pH is
7 included in Zhou.
8 Q. Sorry, it's -- the cells are white?
9 A. The cells are white whenever it would
10 meet the claim element.
11 Q. Great. I noticed you have oleic acid at
12 the bottom of the separate cell, what are you
13 illustrating there?
14 A. Well, oleic acid is in the optimal Zhou
15 formulation, it's just not going to be being added
16 as a pH modifier. And if it were added to the
17 formulation, it would go in the opposite direction
18 as sodium oleate would because it's the acid of
19 that.
20 JUDGE BRYSON: Am I correct that if you
21 have oleic acid in a solution, that the -- you
22 will naturally have an amount of oleate depending
23 on the pH of the solution? So the oleate will be
24 there no matter even if you just throw a lot of
25 oleic acid, it will convert, depending on the pH,

1 into oleate; isn't that right?
2 THE WITNESS: Okay. So you're correct
3 that and you said it -- you even said it
4 precisely. You would have the oleate. So you
5 would have the conjugate base. Okay. So, yes
6 when you put it in solution, you -- depending on
7 the pH, that's going to disassociate into some
8 oleate and potentially there's going to still be
9 some acid.
10 JUDGE BRYSON: Right.
11 THE WITNESS: But if you're in that
12 range, when you add it -- let's say you're adding
13 it as a pH modifier.
14 JUDGE BRYSON: So the pH would go down.
15 THE WITNESS: The pH will go down;
16 right.
17 JUDGE BRYSON: If you maintain the pH at
18 the level you started with before you at the oleic
19 acid, you end up with oleate; right?
20 THE WITNESS: So -- sorry, let me
21 understand your question. You're saying that when
22 you add oleic acid, if you were to -- how are you
23 maintaining the pH when you add oleic acid?
24 JUDGE BRYSON: You add a certain amount
25 of oleic acid and you toss some NAOH in along with

1 it to make sure that the pH doesn't change from
2 the original pH. And that would, I assume, result
3 in an amount of oleate that would be converted
4 from the oleic acid; isn't that generally right?
5 THE WITNESS: Under the circumstance
6 that Your Honor has just put forth, what would
7 happen is that if you had a solution of oleic acid
8 and you kept adding sodium hydroxide and you just
9 kept adding it, at that point it would -- you can
10 get to the point where it's all oleate.
11 JUDGE BRYSON: Right. But what I'm
12 wondering is you say, well, there's no sodium
13 oleate in the Zhou formulation, and that really --
14 there would be, wouldn't there, if there's oleic
15 acid, a certain amount of oleate, and that amount
16 would depend on the pH?
17 THE WITNESS: I think if you had sodium
18 in the formulation present, like if you added --
19 JUDGE BRYSON: Even if the sodium
20 weren't there, it's some form of oleate; right?
21 THE WITNESS: If you added it in the
22 formulation, if you were to check it, there would
23 be some oleate in there if you're at the right pH.
24 JUDGE BRYSON: All right.
25 THE WITNESS: Yes, there would be some

1 oleate in there. I would just make the
2 distinction that, in my opinion, you're not in
3 this formulation adding sodium oleate as a pH
4 modifier. If anything -- which I don't think
5 that's what you're doing, but if anything, you
6 would be adding oleic acid to change the pH in the
7 other direction, the opposite of what the claims
8 say.
9 JUDGE BRYSON: Okay.
10 BY MR. ASHKENAZI:
11 Q. Just so we're clear, does the Zhou
12 reference -- what, if anything, does the Zhou
13 reference say about adjusting the pH?
14 A. That Zhou -- the Zhou reference, from my
15 recollection, doesn't say anything about adjusting
16 the pH.
17 Q. Is there any discussion of a pH
18 adjustment step in the Zhou patent?
19 A. There is not.
20 Q. I'm sorry, in the Zhou reference?
21 A. There's not, no.
22 Q. Is there any discussion of adding sodium
23 hydroxide to the optimal formulation in the Zhou
24 reference?
25 A. No, there's no discussion of that in any

1 pH modifier.
2 Q. Just so we're clear, which one -- which
3 of the documents is older in terms of the filing
4 dates, the CN '845 or Zhou?
5 A. It's the CN '845.
6 Q. Okay. And how would a POSA view the
7 relationship between CN '845 and Zhou?
8 A. They would see the Zhou article as a
9 follow-on to the CN '845.
10 Q. I'd like to step through a couple of
11 parts of the Zhou article, if we can.
12 MR. ASHKENAZI: Roy, can we please pull
13 up JTX-115.7? That's Section 2.3.
14 And for the record, that's a section
15 titled, "Optimization of Emulsion Recipe." And
16 2.3.1 is "Orthogonal Design."
17 JUDGE BRYSON: We've seen this numerous
18 times, what is the exhibit number again?
19 MR. ASHKENAZI: JTX-115.
20 JUDGE BRYSON: Right.
21 MR. ASHKENAZI: And page 7.
22 JUDGE BRYSON: Oh, this is Zhou?
23 MR. ASHKENAZI: Yes.
24 JUDGE BRYSON: Okay.
25 MR. ASHKENAZI: And I'm just going to go

1 through the Optimization of Emulsion Recipe,
2 Orthogonal Design section.
3 BY MR. ASHKENAZI:
4 Q. Dr. Little, can you walk us through what
5 this section of Zhou is referring to?
6 A. Sure. So what you see here, leading up
7 to this table that we'll get to in a second, is
8 there's a statement leading up to the Orthogonal
9 Design that says: Through pre-experimental and
10 single-factor analysis, it was determined that the
11 emulsion recipe would be.
12 And when you look at the following,
13 you're going to see that that is going to end up
14 being the ranges that they're going to test
15 underneath the table.
16 So it does not say what the
17 pre-experimental -- all the pre-experimental and
18 single-factor analyses are here in the sentence.
19 All you see is what is the ranges that
20 they ultimately ended up trying to finally
21 optimize through. But there was some
22 pre-experimental and single-factor analysis that
23 went into coming up with this for the optimal
24 design.
25 Q. And then afterwards it says, "Orthogonal

1 Design Method."
2 Can you explain to us what that sentence
3 is referring to?
4 A. Sure. So the orthogonal design --
5 actually the Court heard about this already, but
6 what we're going to do now is we're going to take
7 each of these ingredients, A, B, C, and D that are
8 spelled out above, and you're going to choose
9 various levels, which is a discretization of the
10 space of the range that is listed.
11 So for instance, for egg yolk
12 phospholipid, the range that was chosen was 2 to
13 4 percent. So the discretization of that is going
14 to be through the levels that you see presented
15 below in A. So 2, 2.5, 3, and 4. So that means
16 there were four levels.
17 What's going to happen now is that
18 you're going to use a parameter. In this case
19 what they used is the centrifugal stability
20 constant or KE. And they go through a
21 manufacturing of these in a testing, and through
22 statistical methods, you're able to determine what
23 the optimum formulation concentrations would be in
24 the space based on the centrifugal dissociation
25 constant, kinetic constant.

1 Q. So if we could turn our attention to
2 JTX-115.7, the table here.
3 Dr. Little, this is the same thing you
4 were just discussing, correct, the table that
5 we're seeing right in Section 2.3.1?
6 A. Yes.
7 Q. Okay. And to be clear, this is giving
8 the components A, B, C, and D, those are the ones
9 that are referred to in the previous paragraph;
10 right?
11 A. Correct.
12 Q. And A is egg yolk phospholipid, B is
13 oleic acid, C is poloxamer, and D is glycerol;
14 correct?
15 A. Yes.
16 Q. And I want to focus on the abstract for
17 a minute and the results that Zhou is reporting
18 on.
19 If we could go to JTX-115.1. And focus
20 on the abstract there. And in the fourth line,
21 there's a sentence that begins, The optimal
22 formulation of aprepitant emulsion was as follows:
23 Aprepitant was 0.25 percent, soybean was 15 -- oil
24 was 15 percent, egg yolk, lecithin E80 was
25 2.5 percent, and oleic acid was 0.125 percent.

1 Dr. Little, what was the conclusion of
2 the Zhou authors here?
3 A. Yeah, when optimizing in the way I just
4 described to the Court, the final concentrations
5 of the components in this formulation that were
6 optimal are shown right here in the slide.
7 Q. And what was the amount of aprepitant
8 that was in the optimal formulation?
9 A. It's .25 percent.
10 Q. Just so we're clear, apologies for
11 restating the obvious, but what was the amount of
12 egg yolk lecithin included in the optimal
13 formulation for Zhou?
14 A. It was 2.5 percent.
15 Q. And I want to go back to the -- what, if
16 anything, does Zhou say about complexation?
17 A. It doesn't say anything about
18 complexation.
19 Q. In your opinion, would a POSA think Zhou
20 discloses complexation?
21 A. No, for the same reasons that I said
22 before in CN '845, you would have to read in a
23 handful of assumptions that I don't think a person
24 of ordinary skill in the art would make reading
25 the reference.

1 Q. For the sake of argument, though, if
2 complexation did happen in the optimized Zhou
3 formulation, what would that teach a POSA about
4 the amount of egg yolk lecithin to use in an
5 emulsifier?
6 A. Yeah, so I guess if I were to have to
7 assume that a person of ordinary skill in the art
8 is reading complexation into the reference, he
9 would see that the ratio here of egg yolk
10 lecithin, you're using 2.5 percent in order get
11 it, I guess, to have the stable formulation
12 optimized using at least the method they used to
13 .25 percent aprepitant.
14 Q. Okay. And what about the amount of egg
15 yolk lecithin used in the formulation, what, if
16 anything -- assume Dr. Rabinow's assumption of
17 complexation -- would be able to presume from the
18 optimized formulation of Zhou?
19 A. That you would be wanting to add
20 2.5 percent to the optimized formulation in the
21 context of complexes.
22 Q. And, again, do you agree with
23 Dr. Rabinow that Zhou is discussing complexation?
24 A. I don't, no.
25 Q. If there was complexation from -- in the

1 Zhou reference, how, if at all, would that impact
2 your opinions?
3 A. Okay. So if there was complexation,
4 we're assuming that it's at the interface and it's
5 complexing a phospholipid, ultimately what you
6 would do is you would use -- you would be using
7 this optimized formulation, 2.5 percent egg yolk
8 lecithin.
9 Q. Okay. And, again, the ratio of egg yolk
10 lecithin to aprepitant in Zhou was 10 to 1?
11 A. It would be 10 to 1, yeah.
12 Q. Okay. Can we please move to JTX-115.10,
13 Section 2.5 of Zhou?
14 What is described in this Section 2.5 of
15 Zhou?
16 A. Okay. So this is the section of Zhou
17 that talks about their stability analysis. And
18 what you see is, first, it just states that they
19 were observed over a three-month storage after
20 sterilization.
21 And it says that over that three months
22 now, the product appearance had no significant
23 change and was still milky white and no
24 stratification or deemulsification was detected.
25 And then in addition in Table 4, there's

1 some other parameters that one could use for
2 stability. I'll focus the Court's attention in on
3 the KE value which is what was ultimately used for
4 the optimization. And maybe I'll just describe
5 what that is so you can understand that.
6 The centrifugal stability constant is
7 you're going to take this milky white solution
8 that you were talking about, you're going to apply
9 a centrifugal stress to it. So if there is
10 flocculation or coalescence or something like
11 that, what would happen when you apply that
12 pressure is that perhaps there will be more now
13 globules at the top and less globules at the
14 bottom.
15 So if you were to measure using a
16 particular wavelength, you typically use a high
17 wavelength for this so you're not getting
18 interference with any of the molecules. You're
19 just looking to see does it goes through or does
20 it not.
21 If you apply that to the milky white
22 solution before centrifugation, you're not going
23 to get anything that goes through. But when you
24 apply the stress if there is deemulsification
25 that's occurring, you're going to get transference

1 of that light at the bottom whenever you measure
2 it.
3 So the way you calculate this ultimately
4 has to do in the numerator with a subtraction of
5 those two amounts. And the larger that number,
6 the larger the KE in this case.
7 Q. Now, you mentioned KE in this case is a
8 way of analyzing flocculation or coalescence.
9 Did I understand that correctly?
10 A. Yes, it's a way to measure the clarity
11 of the phase at the bottom as a result of the
12 stress, as a result of some kind of
13 destabilization.
14 JUDGE BRYSON: And the clarity at the
15 bottom correlates with the flocculation at the
16 top.
17 THE WITNESS: If you had -- let's say
18 you had something that had completely broken, that
19 would be clear.
20 JUDGE BRYSON: There would be nothing
21 remaining at the bottom?
22 THE WITNESS: Correct.
23 JUDGE BRYSON: Okay.
24 THE WITNESS: Well, there would be
25 water.

1 JUDGE BRYSON: Right.
2 THE WITNESS: There would be one of the
3 phases but you wouldn't have globules.
4 JUDGE BRYSON: Right. And what do you
5 use, ultraviolet?
6 THE WITNESS: No, you use light in a
7 range. So in this case they use 600 nanometers,
8 in other cases you see maybe 500 nanometers.
9 JUDGE BRYSON: But that's just basically
10 yellow light.
11 THE WITNESS: Yeah, it's not --
12 JUDGE BRYSON: So it's not -- I thought
13 you said that you use a very high --
14 THE WITNESS: Compared to like in the
15 200s from the ultraviolet light which would detect
16 molecular signatures.
17 JUDGE BRYSON: I see. Okay. Okay. I
18 understand.
19 BY MR. ASHKENAZI:
20 Q. Dr. Little, just -- you testified about
21 this during your direct examination on
22 infringement, but I want to make sure we're clear.
23 Flocculation and coalescence, those are
24 different properties -- different instabilities as
25 compared to crystallization; correct?

1 A. Yes, that's right. You can have --
2 that's why we use multiple measures. You can have
3 one without the other.
4 Q. Now, if you could explain to us,
5 please -- I'm not sure if the record got it.
6 Apologies if it did -- what's being discussed in
7 the paragraph itself under "stability analysis"?
8 A. It's the visual observation and the
9 visual observation is that no stratification or
10 deemulsification was observed visually over the
11 period of time which is three months here.
12 Q. Okay. And Zhou does report KE values;
13 correct?
14 A. Yes.
15 Q. Now, did you hear Dr. Rabinow's
16 testimony that Zhou does not directly disclose
17 data on aprepitant crystals?
18 A. I did.
19 Q. And do you agree with that?
20 A. I do.
21 Q. Did you hear Dr. Rabinow say that the
22 authors would have discussed crystals if there
23 were any present in the Zhou formulation?
24 A. Yeah, so this is, I guess, another
25 instance of how he looks at the reference and says

1 I guess that if they did observe crystals they
2 would have said so.
3 It's just not -- it's just my opinion
4 that when a person of ordinary skill in the art
5 looks at a reference like this for something, the
6 absence of a discussion of it to me doesn't mean
7 that it meets like the construction for crystals.
8 If it didn't say that it's there, that doesn't
9 mean they did that analysis, it just doesn't mean
10 they did it.
11 Q. In other -- maybe I'll ask a follow-on
12 question.
13 Does the absence of information have any
14 impact on whether or not you believe there's a
15 presence of a property?
16 A. Well, I mean, I think generally the
17 absence of information could mean something. It's
18 just in these circumstances I don't think it does,
19 no.
20 MR. ASHKENAZI: Can we please pull up
21 JTX-115.12? And this is Section 3.3 of Zhou.
22 BY MR. ASHKENAZI:
23 Q. What would a POSA understand about
24 aprepitant crystallization from this section of
25 Zhou?

1 A. Yeah, so this is one of the, I guess,
2 reasons Dr. Rabinow believes this. Basically,
3 what is said here is that aprepitant isn't water
4 soluble. So once deemulsification of the emulsion
5 occurs, the drug would leak from the oil phase
6 into the aqueous phase and cause crystallization.
7 Therefore, the presence or absence of crystals can
8 be used to determine whether deemulsification
9 takes place.
10 So in this case, you know, I'll just --
11 it just says that if you were to think about it
12 this way, that if that first sentence is correct,
13 that if the drug leaks from the oil phase when
14 deemulsification occurs, then you would see
15 crystals. So that's true, if the drug were to
16 leak from the place where it's stable to a place
17 that isn't stable, it would be subject to
18 crystallization, right.
19 It's just that that doesn't always
20 occur. So, for instance, if you were to have some
21 deemulsification, so some flocculation or some
22 coalescence, that doesn't mean you're going to
23 have crystals, right. If you had demulsification
24 completely if it broke, then you have a higher
25 probability of seeing the crystals.

1 But I still think that it's necessary to
2 look at it from different perspectives and use the
3 criterion that we're using, for instance, in the
4 specification, because it's possible that you
5 would have one without the other, depending upon
6 the circumstance.
7 Q. When you say it's possible you could
8 have one without the other, can you elaborate on
9 whether or not the presence of a crystal means
10 that you have flocculation or coalescence?
11 A. Yeah, I mean, it's possible that you
12 would have crystals and have no deemulsification
13 at all, right. It's also possible that you could
14 have some deemulsification but you don't have
15 crystals, the aprepitant is still in there.
16 If you use this, what that means is
17 that, you know, all of the measures that we would
18 use just consolidate. You know, if you just
19 measure one thing, then you know you have all of
20 the rest of them, and that's not how we do it.
21 Q. When you say "all of the measures," you
22 mean all the different measures of stability?
23 A. Yes.
24 Q. Does Zhou say anything about PFAT5?
25 A. It does not.

1 Q. Do you think a POSA would be motivated
2 to modify the formulation of Zhou based on the USP
3 stability criteria?
4 A. I don't, no.
5 Q. And why not?
6 A. Okay. So the USP stability criterion is
7 a standard that's put forth that you would have to
8 meet for stability if you were making a commercial
9 product. So it's there, and a person of ordinary
10 skill in the art is aware of it. But, again, it's
11 sort of like one of the things that you would have
12 to do.
13 And remember, the USP does not give you
14 how to do it. There's, like, no guidance
15 whatsoever as to how to do this, right. It just
16 says, you need to meet this, okay, in order to
17 meet the USP standards, which I agree the FDA is
18 wanting to see, like, do you either meet that
19 standard or can you justify another one that you
20 believe is appropriate, right.
21 So I agree it's there, but it just
22 doesn't give you any motivation other than the
23 fact that it's just a barrier that you have to go
24 through. And, by the way, there's a lot of other
25 ones, as well, right. This isn't the only one.

1 So I think it's difficult for me to
2 understand how you would say that the presence of
3 all these USP standards makes somebody optimize,
4 especially in a given direction for any drug
5 product. I mean, we want to make drug products, I
6 agree that's a motivation, but that's all that it
7 is, is a standard on the way.
8 Q. When you say the USP doesn't provide any
9 guidance on how to do it, you're referring to the
10 optimization, or are you referring to how to
11 conduct the experiments for USP 729?
12 A. Yeah, so it tells you how to conduct the
13 experiments to test if you have stability, to
14 follow that particular monograph, but it doesn't
15 tell you how to get there.
16 Q. Based on your review of the Zhou
17 reference, have you formed an opinion on whether
18 the Zhou reference discloses a physically stable
19 emulsion?
20 A. It does not give you enough information
21 to say that you have a physically stable emulsion,
22 according to the court. It gives you some
23 stability criterion. So to the extent that you're
24 looking at that, it gives you an optimized
25 formulation under that stability criterion. It's

1 just different from the physically stable emulsion
2 that we're talking about in the specification of
3 the patents-in-suit.
4 Q. Stepping outside of Zhou, is there any
5 data from any other sources regarding the
6 stability of emulsions from Zhou?
7 A. You have Example 5 in the
8 patent-in-suit.
9 MR. ASHKENAZI: So if we could turn to
10 JTX-7.15, which continues onto page 16.
11 BY MR. ASHKENAZI:
12 Q. This is the '794 patent, Example 5.
13 Dr. Little, is this the example you were
14 just referring to?
15 A. Yes.
16 Q. And if you can please walk us through
17 this exam- -- what you were referring to about
18 this example.
19 A. So this is another formulation in the
20 specification of the patent that doesn't meet the
21 elements of the claim. If you look down at the
22 bottom here, so this is another alternate
23 formulation that's used. And at the very bottom,
24 you see, within four days post preparation at room
25 temperature, crystals were observed in the product

1 by microscopy.
2 Q. I'd like to focus now on what you
3 believe a POSA in 2014 -- the path they would have
4 considered at that time. We've been talking a lot
5 about aprepitant. So to frame ourselves, I want
6 to take a step back and discuss that.
7 How would a POSA have viewed the
8 properties of aprepitant from a formulation point
9 of view in 2014?
10 A. Yeah, I mean, we would have viewed it as
11 a tough compound. You know, it's insoluble in
12 water. It has very limited solubility in oil.
13 It's referred to as a brickdust compound. So, you
14 know, if one of my colleagues in the medical
15 school or medicinal chemists brings me something
16 like this, which has even happened in the last
17 year, and they give it to me and they either say
18 that it doesn't dissolve in those things or they
19 give it to my students and my students try it and
20 they come to me and say it doesn't dissolve in
21 anything. So that's tough. I mean, this case at
22 least dissolves in ethanol, but this is one of
23 those tough compounds.
24 Q. Did you review Dr. Hale's testimony?
25 A. I did.

1 Q. Dr. Hale testified about the physical
2 properties of aprepitant. How would a POSA have
3 taken those -- those properties into account?
4 A. Yeah, so if I recall correctly, he's
5 talking about the molecular structure of it and
6 how it stacks. And although that's great from the
7 standpoint of it binding to the receptor, and I
8 could see how you would get really excited about
9 that from the standpoint of formulation, it forms
10 those crystals, and it's likely to form those
11 crystals even whenever you take it and put it into
12 something, so if you dissociate it, if it's
13 possible, that it will go right back into that
14 configuration again. That's tough. That's tough
15 from a formulation standpoint.
16 Q. And did you hear Dr. Rabinow's testimony
17 that a POSA would focus on NK-1 antagonists that
18 were in development and mostly those either in
19 Phase 1 or Phase 2?
20 A. I did hear that.
21 Q. What was your reaction to that?
22 A. So what I would say about this is that I
23 don't disagree that a person of ordinary skill in
24 the art would consider that. I think it's
25 something a person of ordinary skill in the art

1 would know about, and they'd factor it into the
2 analysis.
3 The issue here is that from my
4 understanding, that didn't include a handful of
5 other drugs that met that criterion, including
6 fosaprepitant, rolapitant, and netupitant, I think
7 is how you say it. So there were other compounds
8 that had passed Phase 3 clinical testing that
9 weren't considered in his analysis.
10 Q. And just so we're clear, as of
11 September 2014, you're referencing fosaprepitant,
12 netupitant, and rolapitant?
13 A. Yes.
14 Q. Okay. With this in mind, what was the
15 gap in the market that a POSA would have
16 considered a problem in September 2014?
17 A. Yeah, I think a person of ordinary skill
18 in the art in September of 2013 [sic], looking at
19 the state, would be looking to make an intravenous
20 NK-1 receptor antagonist intravenous formulation.
21 They would have -- you know, you're looking for
22 something that would have minimal side effects.
23 Q. And have you reviewed Dr. Roeland's
24 testimony?
25 A. I have.

1 Q. And how does that impact your view of
2 the issue you just raised?
3 A. Yeah, so I agree with his analysis. I
4 considered it whenever I wrote my reports. And
5 it's my understanding that fosaprepitant at the
6 time had some issues with tolerability because the
7 addition of an ingredient, polysorbate 80.
8 Q. How would a POSA view fosaprepitant
9 versus aprepitant in this September 2014 time
10 period for formulation purposes?
11 A. It's in a complete different category.
12 Fosaprepitant is soluble. So my understanding is
13 that the Merck formulators designed it as a
14 prodrug. So these prodrugs, you know, you have
15 the ability now to transform the physical
16 properties of something to make it much more easy
17 to formulate.
18 For instance, it dissolves straight in
19 water. I think the testimony is 6,000 times more
20 soluble in water. So from a formulation
21 standpoint, it's in a completely different
22 category, it's much easier.
23 Q. And the Emend IV that was on the market
24 did have polysorbate 80 in it; correct?
25 A. It did, yes.

1 Q. But how would a POSA consider
2 fosaprepitant with that in mind, if they were
3 sitting in 2014?
4 A. Oh, I think it would be a very
5 attractive compound to try to reformulate and try
6 to do something with under those circumstances. I
7 think definitely a more attractive candidate than
8 aprepitant.
9 Q. And, Dr. Little, I'd like you to assume
10 for the sake of argument that Dr. Rabinow is
11 correct that a POSA would consider working on an
12 intravenous aprepitant formulation.
13 A. Okay.
14 Q. How would such a POSA approach
15 formulating in this intravenous aprepitant
16 formulation?
17 A. Okay. So now we are in the world where
18 we're focused in on aprepitant and the claims. So
19 if we were focusing on that, a person of ordinary
20 skill in the art would begin to try to see if
21 there are other formulation approaches that are
22 simpler. So you'd work from simpler to more
23 complex.
24 Q. Okay.
25 MR. ASHKENAZI: Can we turn to

1 JTX-105.26?
2 BY MR. ASHKENAZI:
3 Q. And this is the Strickley reference in
4 Table 8 that Dr. Rabinow discussed.
5 Can you please explain to us what we're
6 seeing here? And I'd ask you to focus under the
7 "intravenous" heading, if you can.
8 A. Sure. So this has already been
9 discussed. As you can see, there's categories by
10 which you would begin to go down a path if this
11 were an intravenous.
12 So for aprepitant, what you would do is
13 you'd start at the top and you'd say, do you think
14 these things are viable. You know, for instance,
15 there are some things in here that you can
16 potentially look at the molecule itself and say,
17 okay, you know, maybe this isn't going to work.
18 So, for example, like the PKAs in
19 aprepitant, you're not going to get charge
20 induction.
21 JUDGE BRYSON: The PKAs?
22 THE WITNESS: The PKAs. So it's -- the
23 molecule has groups, and those groups are known to
24 be charge inducible. So, you know, a tertiary
25 amine is a great example of this. If you've got

1 an amine, you've got an N with three bonds, that
2 guy has the ability to take on a proton. And when
3 it does that, it charges.
4 So, for instance, you know, in my
5 thesis, I made molecules, I synthesized molecules
6 that had these in particular places, and that
7 molecule was insoluble. But once you get to a
8 certain point with the pH, you're able to make
9 it -- depending on how you design it, you can make
10 it so that when it hits that pH, it charges, and
11 the whole thing dissolves.
12 Aprepitant, actually, if I remember
13 correctly, has two of these. And they're
14 different, right. You can do this other ways too.
15 So, for instance, the amine I just told you about
16 has a positive charge, but you can also have
17 groups that are, like, carbocyclic acids that the
18 proton comes off, depending on the circumstance,
19 and now you have a negative charge.
20 So aprepitant has two of these groups,
21 and the PKAs, which means the pH at which you'd
22 see all that happen, are sort of spread out and
23 they're not within the range that you would use an
24 intravenous emulsion for.
25 So if you knew that, you could say --

1 JUDGE BRYSON: Because you want to keep
2 the tonicity at the same level?
3 THE WITNESS: Well, no, it's not about
4 tonicity. It's about --
5 JUDGE BRYSON: You want to keep the pH
6 at the --
7 THE WITNESS: Yes, you want to keep the
8 pH in that range. So you would have to -- you
9 know, what you don't want to do is go down a pH
10 too to get it to charge and now it dissolves.
11 JUDGE BRYSON: Because it goes into the
12 blood, and you got real problems in the blood.
13 THE WITNESS: Yeah, yeah, yeah.
14 JUDGE BRYSON: Okay.
15 THE WITNESS: So perhaps -- what I'm
16 trying to explain is that you could look at this
17 and you could say, Maybe I could rule that one out
18 because I -- you could try it if you wanted to,
19 but I think given the solubility properties,
20 that's unlikely. Okay?
21 But there are other ones here that you
22 certainly would explore. But you certainly
23 wouldn't just go down to the bottom. You'd do an
24 earnest evaluation of viability of these,
25 preferably doing the simpler ones, working your

1 way down to the more complex.
2 MR. ASHKENAZI: If we could go to
3 JTX-105, that's the same Strickley reference, at
4 page 25.
5 BY MR. ASHKENAZI:
6 Q. I want to focus on the right-hand column
7 for a moment, if we can.
8 How would a POSA view the emulsion
9 approaches for aprepitant in view of Strickley?
10 And we probably got to blow that up a
11 little better for you.
12 Dr. Little, you have -- I'm having a
13 hard time reading this on the screen. So you have
14 the reference in front of you, JTX-105. And turn
15 to page --
16 A. Yes, so this whole column is about the
17 various approaches. And it talks about, you know,
18 each of them. At the bottom, it does talk about
19 emulsions. So it says that they -- that drugs
20 that don't work by all of the methods above could
21 be used in emulsions, but it says that the
22 formulation strategy is rarely used for the
23 commercial product.
24 And I think the idea here is it's just a
25 more complex formulation where things can happen

1 and go wrong, so you would prefer the other ones.
2 Q. And we have the third-to-last sentence
3 of the paragraph highlighted -- I believe it's
4 highlighted.
5 Does Strickley say what -- say anything
6 about the prevalence of emulsion approaches for an
7 intravenous product?
8 A. Yeah, they're rare.
9 Q. When you say "rare," at this point in
10 time -- let's go to 2014. How many FDA-approved
11 emulsions were on the market?
12 A. There were two. There was a Cleviprex
13 product, and there was a Diprivan product that had
14 drugs, yeah.
15 Q. So with this all in mind, if a POSA was
16 working on an intravenous aprepitant product, what
17 approach would they take, generally?
18 A. If they're working on an intravenous
19 drug product, they would highly prefer
20 water-soluble compounds, and then they would
21 attempt to explore some other strategies that
22 would allow you to solvate in that phase or do
23 something. You could work your way down to this,
24 but it would be one of your later options.
25 Q. And if we could go -- the first -- we're

1 still looking at JTX-105 at page 25, the last
2 paragraph.
3 Can you read the first sentence into the
4 record, please?
5 A. "Drugs that are not soluble by
6 cosolvents, pH modification, or complexation but
7 are soluble in oils can be formulated for
8 intravenous administration by employing
9 oil-in-water emulsion."
10 Q. And I think you did discuss this, but
11 can you briefly explain what that sentence means?
12 A. Yeah, it just means you try these other
13 ones first. That's why you have the long
14 beginning of the sentence before the verb.
15 Q. Okay.
16 MR. ASHKENAZI: Can we take that down.
17 Thank you.
18 BY MR. ASHKENAZI:
19 Q. Did you hear Dr. Rabinow's testimony
20 that a POSA would not pursue other formulation
21 approaches in view of Zhou and CN '845?
22 A. Yes, I did hear that.
23 Q. And do you agree with that?
24 A. I don't. I think the presumption there
25 is because Zhou and CN '845 were working on

1 emulsions, that must mean that all of the other
2 ones were expended. And that's not something that
3 I would read in.
4 It's possible that somebody could have
5 played around with an emulsion, but it doesn't
6 mean that they necessarily tried -- I mean, it's
7 an assumption that they tried all of the other
8 ones, and they didn't work.
9 Q. And did you hear Dr. Rabinow's testimony
10 that a POSA would have been motivated to increase
11 the amount of emulsifier to improve stability?
12 A. Yes, I did.
13 Q. And do you agree with that?
14 A. I do not.
15 Q. Why not?
16 A. Well, so we've been talking about this,
17 and I think the Court even recognized that if
18 you're going to change things in a formulation, if
19 you change it such that the emulsifier
20 concentration goes up, there's going to be at one
21 point in time an issue with that, too.
22 Okay. So, first of all, there's an
23 assumption that in a formulation, if you're going
24 to modify it -- so, for instance, Zhou, that Zhou
25 formulation, if you're going to modify it, that

1 you'd be modifying the emulsifier in the first
2 place. That's not necessarily true.
3 You may modify something else from the
4 Zhou formulation. And in fact, you would need to
5 modify the other things from the Zhou formulation
6 in order to be within the claims anyway. So
7 you're not always just working with emulsifier.
8 But if you are working with an
9 emulsifier, you don't just go up, okay, because
10 you could have a stability problem if you go up,
11 as well. And there's lots of scientific reasons
12 as to why that would be the case.
13 And certainly if you're going up beyond
14 the stability -- or beyond the concentrations of
15 emulsifier that you see in the art -- I mean, the
16 standard amounts in the art are like 1.2 percent.
17 So then going up to 14 percent is not what a
18 person of ordinary skill in the art would even be
19 thinking about doing.
20 Q. Did you hear Dr. Rabinow's testimony
21 that a POSA would have tried 14 percent egg
22 lecithin based on routine optimization?
23 A. Yes.
24 Q. And can you please provide us your
25 opinion on that?

1 A. Yeah, so this is based on the idea that
2 you're going to routinely optimize. But as we can
3 see in the Zhou article, if you just start with
4 CN '845, there was an optimization that was done
5 there, and a person of ordinary skill in the art
6 has access to that.
7 And what you see is that you see that
8 ultimately the emulsion concentration was -- went
9 down from what was disclosed in CN '845, which is,
10 again, more consistent in what you see in the
11 standard concentrations in the field, like
12 1.2 percent, low single digit percents.
13 That you would go up like that is not
14 something somebody would be thinking of in terms
15 of routine optimization. It's anything but
16 routine, in my opinion.
17 Q. In any of the references that you've
18 seen in this case from Dr. Rabinow for emulsions,
19 outside of CN '845, what was the highest amount of
20 lecithin?
21 A. The highest amount of lecithin that I've
22 seen in the references was like 3 percent, if I
23 can remember correctly. It went from .5 percent
24 to 3 percent.
25 Q. Now, I'd like to please go back to the

1 Strickley reference, JTX-105.23. And I want to
2 focus on the heading "Emulsion Injectable
3 Formulations."
4 And just so we're clear, it says --
5 MR. ASHKENAZI: It starts "Atypical,"
6 yes, four lines down. Perfect.
7 BY MR. ASHKENAZI:
8 Q. Dr. Little, what are we seeing here when
9 it refers to emulsions?
10 A. Yeah, it talks about the typical
11 emulsion. And you see here it says, in that
12 typical emulsion, you have 1 percent egg lecithin.
13 Q. And here it says a pH of 7.8 to 8.
14 A. PH of 7 to 8.
15 Q. Sorry. Thank you.
16 MR. ASHKENAZI: We can take that down.
17 Roy, let's move to Hingorani for a
18 moment, please. Thank you. That's JTX-21 at
19 pages 7 to 8.
20 And specifically I want to focus on
21 paragraphs 54, 55, and 56, and the tables below.
22 Thank you.
23 BY MR. ASHKENAZI:
24 Q. Dr. Little, can you please explain to us
25 what we're seeing here?

1 A. Yeah, in this reference, there were two
2 emulsions that were formed. In this case, though,
3 we actually are using aprepitant. So this is
4 another instance of an attempt at an aprepitant
5 emulsion.
6 And if you go down to the tables, you
7 can see the amounts of each of the ingredients.
8 Now, what you'll see here is that each of these
9 are listed in milligrams and microliters. So what
10 that requires is some densities to be used.
11 So if you convert the volumes to masses,
12 using the density of each of these, what you end
13 up being able to do at that point in time is
14 convert each of the ingredients to a
15 weight-per-weight percent, which is what you see
16 in the claims.
17 And whenever you do that, you see that
18 the lipoid E80, which is the lecithin in this
19 case, is present in 1.2 percent in both of the
20 formulations.
21 Q. And if we can just go to the front,
22 JTX-21.1, for a moment.
23 What's the date of filing -- the
24 earliest date of any of the provisional
25 applications for the Hingorani reference?

1 A. The earliest date is May 24th, 2012.
2 Q. Okay. And just to put this into
3 context, Hingorani discusses emulsions with
4 1.2 percent egg yolk lecithin and aprepitant; is
5 that right?
6 A. 1.2 percent -- with an aprepitant
7 emulsion, that's 1.2 percent lecithin.
8 Q. Okay. And the optimal formulation in
9 Zhou, how much egg yolk lecithin did that have?
10 A. I think it was 2.5 percent.
11 Q. Okay. Now, you did discuss that there
12 could be problems increasing the amount of
13 emulsifier.
14 Can you just explain to us just a little
15 bit more what types of problems can be caused by
16 adding too much emulsifier?
17 A. Yeah, so when you add too much
18 emulsifier, you get -- you get to the point -- I
19 mean, if you look at these through phase diagrams,
20 and phase diagrams are notoriously nonlinear, you
21 have a space in this diagram where something is
22 stable and then outside of that space on the
23 diagram, it's not anymore.
24 It's not the case you typically see when
25 you just go up. If you just keep adding more,

1 it's always stable. That's not the way you would
2 think about it. So if you keep adding
3 emulsifier -- I mean, I can think of a handful of
4 things, but at one point in time, you'll saturate
5 your surfaces. There's no more real estate on
6 your surfaces for any more of this.
7 And at that point in time, now all of a
8 sudden you've got lecithin in the various phases,
9 right. So now there's nowhere for them to be up
10 there. So they're getting in other places and
11 doing things that you're not intending them to do
12 anymore, because they're no longer there as an
13 emulsion stabilizer because they're not at the
14 interface of the emulsion.
15 So now you've added them to the degree
16 that they're doing other things. And, in fact, it
17 can get in between the particles and actually
18 cause them to come together and stick together.
19 So you can see deemulsification when you add too
20 much.
21 And this really follows a general
22 principle that we have in the formulation
23 sciences, which is that, first of all, you never
24 add something unless you have to. And, second of
25 all, when you add something, you want to add it to

1 the smallest amount that you can.
2 So I heard testimony at one point that
3 might imply -- Dr. Rabinow might have implied that
4 what you do is you'd increase it to the point
5 where you wouldn't increase it anymore where you'd
6 have a problem.
7 I just want to clarify. As a
8 formulation scientist, what you're doing is you're
9 trying to decrease it, to get the lowest amount
10 that you can for it to be stable. Because if you
11 add any more than that, you're going to cause
12 problems with other design parameters that you
13 have and potentially cause instabilities.
14 Q. And you're talking generally as a POSA
15 would view this science in 2014; correct?
16 A. Correct.
17 Q. Now, you've talked about this gap
18 between 2.5 egg yolk lecithin in Zhou and
19 14 percent in the claims.
20 If Zhou had selected 2.5 as the optimal
21 formulation instead of anything else in the
22 broader ranges of CN '845, what is Dr. Rabinow's
23 justification for nonetheless finding 14 percent
24 in the prior art?
25 A. Okay. Yeah, so, first of all, it's the

1 assumption that somebody would be reoptimizing it.
2 So it was optimized in Zhou, but he's saying that
3 we're going to optimize it again, and we're going
4 to come to a different value than what it is in
5 Zhou when we reoptimize again. And I disagree
6 with that.
7 But if you are going to reoptimize, what
8 he does is he looks to literature that talks about
9 different formulations in order to get that high
10 percent of egg yolk lecithin.
11 Q. And that's the Liu reference?
12 A. Correct.
13 Q. Okay. In your opinion, does the Liu
14 reference provide any information to a POSA that
15 would be useful in optimizing Zhou or CN '845, as
16 Dr. Rabinow asserts?
17 A. No, in my opinion, they would not.
18 Q. And why not?
19 A. Well, so when you go to that reference,
20 the first thing that's important to recognize is
21 you're talking about completely different kinds of
22 formulations. They do use higher concentrations
23 of surfactants as a whole in that reference, but
24 that's because of the difference.
25 The difference between them is that

1 these are formulations that just naturally
2 thermodynamically snap together. So as a design
3 constraint, that's what you're trying to do. So
4 it talks about, for instance, and the references
5 we'll see, that you have surfactants that have
6 different kinds. And they have big tails and
7 small heads or small heads and big tails. So if
8 you imagine like a triangle for the one and then
9 an inverted triangle on the other. They're
10 specifically designed to mix and match so that
11 they fit on that interface.
12 So you're adding enough of them and then
13 combinations of them so that as a design
14 constraint, when you put everything together, even
15 without hitting it with a hammer to make it
16 pulverize, even without that, you just put them in
17 and everything snaps together. So that's the kind
18 of formulations that we're talking about in the
19 Liu reference.
20 Q. And those are different than the types
21 of formulations we've been discussing, the
22 emulsions we've been discussing for this case with
23 respect to the patents-in-suit and Zhou?
24 A. And CN '845, yes.
25 Q. Okay. Now, you mentioned that they're

1 different formulation systems.
2 Is there anything else in Liu that would
3 explain why it would not be applicable to
4 Dr. Rabinow's opinions, as you've described?
5 A. Well, whenever you actually go into the
6 Liu reference, what you see is that it's talking
7 about using various surfactant concentrations. It
8 doesn't say just egg yolk lecithin. It says --
9 it's a percent. That percent is combinations of
10 things. If you look in the prior art, they do
11 this, they mix things back and forth.
12 Also, whenever you look in the Liu
13 reference, when it talks about egg yolk lecithin,
14 it says in the context of that formulation,
15 because of the triangle, that thing is actually
16 better suited for a water-in-oil emulsion. So
17 because of its shape, whenever you're using it
18 that way, it's going to orient in the other
19 direction. So it's the opposite of what we see in
20 the Zhou and the CN '845.
21 Q. So, I mean, if we can, just to be clear,
22 does Liu discuss emulsions?
23 A. It does not discuss the emulsions we're
24 talking about in CN '845 and Zhou, you'd be
25 optimizing, according to Dr. Rabinow, no.

1 Q. Okay.
2 MR. ASHKENAZI: Can we please bring up
3 the Liu reference? That's JTX-93. And if we
4 could go to page 10.
5 BY MR. ASHKENAZI:
6 Q. If we could take a moment to focus on
7 that first paragraph.
8 Dr. Little, can you please explain to us
9 what we're seeing here in the first paragraph on
10 page 10 of Liu?
11 A. Sure. So this is the selection of the
12 oil phase. So what you're doing is you're saying
13 first I'm going to select an oil phase that has
14 adequately high solubility for the drug. So what
15 you're doing is -- they're saying here that you
16 want -- you want the drug here to go into the oil
17 phase. That's the first thing that it's teaching.
18 If you go down a little bit further,
19 what you see is that oils with excessively long
20 carbon chains, excessively big volume, or
21 excessively high viscosity can hardly form any
22 microemulsion. And then it goes on to say that
23 what you want is you want medium-chain
24 triglycerides. Those are the things that would
25 work in the kind of formulations that are

1 thermodynamically stable.
2 This is important because, remember, in
3 the Zhou article and CN '845 and in the
4 patents-in-suit, what we're talking about is large
5 oils, like soybean oils. So those have long
6 chains. But here what it's saying is that you
7 want to use these medium chain triglycerides.
8 Q. Now, you had mentioned in the second
9 sentence, it says the oil phase has adequately
10 high solubility for the drug.
11 Is aprepitant -- what is aprepitant's
12 solubility in oil?
13 A. It's very poor solubility in oil.
14 Q. Okay. So could aprepitant be used in
15 the formulation systems described in the Liu
16 reference?
17 A. It's teaching a person of ordinary skill
18 in the art that you don't want to do that. You
19 want to use these for adequately high solubility
20 drugs that don't involve these.
21 Q. Now, you did reference that there's a
22 discussion of phospholipids in Liu; correct?
23 A. There is a discussion of phospholipids,
24 yes, but overall it's a discussion generally of
25 emulsifiers, but phospholipids are mentioned.

1 Q. Does Liu discuss phospholipid
2 complexation with emulsifiers like egg lecithin?
3 A. No, it does not.
4 Q. Okay. Does Liu discuss any specific
5 formulations with egg yolk lecithin?
6 A. It does not discuss specific
7 formulations with egg yolk lecithin, no.
8 Q. Okay. I'd like to turn to something
9 that Dr. Rabinow said about this reference.
10 Did you hear Dr. Rabinow's testimony
11 regarding the sentence in Section 1.2?
12 MR. ASHKENAZI: If we could go to that,
13 please.
14 BY MR. ASHKENAZI:
15 Q. And it's the sentence that says, The
16 amounts of surfactant used in Liu -- I mean,
17 sorry. I'm going to start again.
18 A. Uh-huh.
19 Q. Did you hear Dr. Rabinow's testimony
20 regarding the sentence in Liu that says, the
21 amounts of surfactants used here in these
22 formulations are 5 to 8 -- 5 to 30 percent and are
23 relatively large?
24 Do you see that?
25 A. Yes, I see that.

1 Q. And just to be clear, because I misread
2 it in my fumbling here, the sentence states, Given
3 the amounts of surfactants used in microemulsions,
4 5 to 30 percent are relatively large.
5 Do you see that?
6 A. Yes.
7 Q. And you heard Dr. Rabinow's testimony
8 about that?
9 A. Yes.
10 Q. Okay. Does this suggest the use of
11 30 percent egg yolk lecithin in an emulsion?
12 A. No, it does not.
13 Q. Why not?
14 A. Well, this is talking about surfactants
15 in general. And there's actually a section that
16 wasn't shown yesterday that shows all of them.
17 And, in fact, when you're talking about this, the
18 reference even says you're mixing them together.
19 And by the way, if you were to use large amounts
20 of egg yolk lecithin, you'd actually get an
21 inverse emulsion, this reference also teaches.
22 So this reference is not teaching to use
23 30 percent egg yolk lecithin in a standard
24 emulsion, no.
25 Q. Okay. And to be clear, this sentence is

1 referring to microemulsions?
2 A. Yeah, it's referring to the
3 thermodynamically stable emulsions.
4 MR. ASHKENAZI: And if we could turn to
5 JTX-93.11. And I want to focus in on Table 1.
6 BY MR. ASHKENAZI:
7 Q. I think this is what you were referring
8 to a little earlier, but can you explain that,
9 what we're seeing here in the table that's titled,
10 "Types of Commonly Used Surfactants for Injectable
11 Microemulsions"?
12 A. Yeah, so here are the surfactants that
13 are used. And I'll just orient the Court here,
14 because there's lists of them on the left-hand
15 side, and the Court may have seen some of these
16 names before in the other references.
17 On the right-hand side, you have what's
18 called hydrophilic-lipophilic balance, HLB. So
19 this is sort of like a ration. You know, the
20 hydrophilic portion, if it's big, okay, to the
21 lipophilic portion being small, the number will be
22 big.
23 If the lipophilic portion is big and the
24 hydrophilic portion is small, the number will be
25 small. That's what we use when we talk about it.

1 So it's generally like this idea of, you know,
2 what's the shape of the molecule.
3 And what you see here, when you go down
4 through, is you see big ones at the top for some
5 of these. There's some small ones at the top, for
6 instance, Span 80. And then whenever you go down
7 to the bottom, that's where your phospholipids are
8 mentioned here. So that's like your lecithin.
9 And you see the hydrophilic-lipophilic balance is
10 3-8.
11 Q. And to be clear, this reference in this
12 table doesn't identify egg yolk lecithin; correct?
13 A. It does not.
14 JUDGE BRYSON: Was there -- is there a
15 balance for lecithin?
16 THE WITNESS: Is there a balance?
17 JUDGE BRYSON: Is there a hydrophilic --
18 THE WITNESS: Yes.
19 JUDGE BRYSON: -- lipophilic balance?
20 THE WITNESS: It's 3 to 8. You see at
21 the bottom there?
22 JUDGE BRYSON: Oh, is that --
23 MR. ASHKENAZI: Your Honor, maybe if I
24 can ask a question, I think we'll get to your
25 question.

1 JUDGE BRYSON: All right.
2 BY MR. ASHKENAZI:
3 Q. You'll see on the bottom -- the last row
4 it says, Phospholipid and phospholipid
5 derivatives, Dr. Little?
6 A. Yes.
7 Q. Can you explain to us what those are?
8 A. Yeah, that would be -- I mean, there's
9 examples of them that are listed here, these
10 phosphocholines, but that would include lecithin.
11 JUDGE BRYSON: All right.
12 BY MR. ASHKENAZI:
13 Q. In other words, is lecithin a
14 phospholipid?
15 A. It is a phospholipid, yes.
16 Q. Okay.
17 JUDGE BRYSON: All right.
18 BY MR. ASHKENAZI:
19 Q. So, Dr. Little, I just want to make sure
20 we have something clear. Liu refers to
21 microemulsions; correct?
22 A. It does, yes.
23 Q. Okay. In Zhou or CN '845 or the
24 patents-in-suit -- is Zhou, CN '845, or the
25 patents-in-suit, a microemulsion like that in Liu?

1 A. No, when you look at the methods that
2 are used, these are not the kind of emulsions that
3 they're talking about here, where everything just
4 snaps together, that they're thermodynamically
5 stable.
6 MR. ASHKENAZI: Now, if we could look at
7 the paragraph that's under Table 1. Okay. Thank
8 you.
9 BY MR. ASHKENAZI:
10 Q. Dr. Little, what does this --
11 MR. ASHKENAZI: So let's go to the
12 second paragraph under the table. That would be
13 better. Thank you.
14 BY MR. ASHKENAZI:
15 Q. Can you please explain to us what's
16 being discussed in this paragraph?
17 A. Yeah. So what you see in the second
18 paragraph underneath is it's referring to the
19 hydrophilic-lipophilic balance, and then it talks
20 about when you would use these various
21 surfactants. So if you have a low
22 hydrophilic-lipophilic balance, so it says here 4
23 to 8, but specifically what they're referring to
24 when they say "low" is the phospholipids, you see
25 in the parentheses right afterwards.

1 So when you have those, what it says
2 right afterwards is that they're suitable for
3 oil-in-water emulsions. So if you have a big tail
4 and a small head, think about that triangle and
5 stacking them around, right, if you go like this,
6 what will happen is the tail would be sticking
7 out. So that would be suitable for the opposite
8 type of emulsion that we're talking about in the
9 patent-in-suit and CN '845 and Zhou.
10 Q. Okay. To be clear, it says, are
11 suitable for water-in-oil emulsions?
12 A. Water-in-oil emulsions, correct. So
13 that's like having the oil in the continuous phase
14 and the water here. Whereas, in the
15 patents-in-suit and Zhou and CN '845, it's the
16 opposite.
17 Q. Okay. Can you -- and I think you've
18 mentioned the patents-in-suit, but also CN '845
19 and Zhou are talking about oil-in-water emulsions;
20 right?
21 A. They are, yes, oil-in-water.
22 Q. So, in your opinion, what does this show
23 about the Liu formulations relative to the
24 emulsions of CN '845 and Zhou?
25 A. Yeah, I mean, this is just all evidence

1 of what I'm saying, is that a person of ordinary
2 skill in the art isn't looking at this in order to
3 get surfactant concentrations to apply to an
4 emulsion like CN '845, Zhou, and the
5 patents-in-suit.
6 MR. ASHKENAZI: If we could please turn
7 back to JTX-93.10. That's the Liu reference. And
8 I want to focus on Section 1.1, the second
9 paragraph.
10 Sorry, yes, thank you.
11 BY MR. ASHKENAZI:
12 Q. What does the second paragraph in
13 Section 1.1 of Liu say about the selection of oils
14 for its formulations?
15 You know what, Dr. Little, I realize I
16 think we covered this already. So we can skip
17 this.
18 A. Okay.
19 Q. Thank you.
20 Does the disclosure in Liu affect your
21 opinion on whether a POSA would have been
22 motivated to combine Zhou and CN '845 with Liu's
23 teaching of using up to 30 percent surfactant?
24 A. No, in my opinion, it does not.
25 Q. And can you please explain why?

1 A. Yeah, so the Liu reference is talking
2 about different formulations that have different
3 design constraints and considerations. In the
4 context of meeting those design constraints, you
5 have different things you have to do, specifically
6 including picking the right kind of surfactant,
7 picking the right combinations of them in order to
8 do it, picking concentrations, but that's to
9 achieve something in those formulations that is
10 different than what we're talking about in the
11 formulations of the CN '845, Zhou, and the
12 patents-in-suit.
13 Q. And did you hear Dr. Rabinow's testimony
14 that a POSA would increase the amount of egg
15 lecithin based on the disclosure of phospholipid
16 complexes in EP279, Agarwal, and Yue?
17 A. I did hear that, yes.
18 Q. Do you agree with that?
19 A. I do not.
20 Q. And maybe why don't we -- we'll put
21 those up on the screen.
22 MR. ASHKENAZI: So can we please pull up
23 JTX-74, that's EP279; JTX-67, that's the Agarwal;
24 and JTX-114, and that's Yue.
25

1 BY MR. ASHKENAZI:
2 Q. We could go into -- any of the
3 references, if you want, Dr. Little, but just
4 generally, what do these references talk about
5 with respect to complexation?
6 A. Okay. So they are talking about making
7 complexes in these particular references. Did you
8 want --
9 Q. Dr. Little, once second, I just want to
10 make sure that the record is clear.
11 MR. ASHKENAZI: Your Honor, do you have
12 the JTX numbers?
13 JUDGE BRYSON: Well, I'm having a hard
14 time reading the one on the left on my screen.
15 MR. ASHKENAZI: The one --
16 JUDGE BRYSON: Why don't you give me the
17 three numbers, and I'll be fine?
18 MR. ASHKENAZI: Yes. JTX-74, that's the
19 EP279.
20 JUDGE BRYSON: I got that.
21 MR. ASHKENAZI: JTX-67.
22 JUDGE BRYSON: 67, that's the one I was
23 missing. I'm good.
24 MR. ASHKENAZI: Thank you.
25

1 BY MR. ASHKENAZI:
2 Q. So sorry for interrupting you,
3 Dr. Little, but why don't we start again.
4 A. Sure. Let me just start by saying that
5 I do agree that these three references are talking
6 about complexes. So these three references
7 Dr. Rabinow is pointing at is looking at making a
8 complex. But I do want to point a few things out.
9 First of all, the drugs that are being
10 used here, resveratrol, oxymatrine, and
11 bilobalide, these are different molecules with
12 different chemical drugs. And I don't even see
13 common chemical structures in this than what you
14 would see with aprepitant.
15 So it's not as if a person of ordinary
16 skill in the art looks at these and says, Okay, I
17 can see this common chemical structure in all of
18 these, and that's what you'd use to make a
19 phospholipid complex. And I see that same
20 structure in aprepitant. So I think that it would
21 form a complex.
22 That's not there. So there's no
23 chemical specificity, and to my knowledge, there
24 was never really any group in the aprepitant
25 molecule that was even pointed out as being

1 subject to making a complex. So that's the first
2 thing that I want to just mention for complex.
3 Whenever you look at these references,
4 though, what you see in some of these references,
5 they're talking about making these complexes in
6 order to make a water soluble compound. So you're
7 picking one of these and you're then making a
8 complex and now it dissolves in water, right.
9 But that's not what we're talking about.
10 In these references, you know, what a person of
11 ordinary skill in the art is not doing is saying
12 it's forming a complex, and then that complex is
13 suitable for the interface between oil and water.
14 So that piece is not here either. So I
15 don't see how a person of ordinary skill in the
16 art is looking at these references and then
17 saying, I'm going to assume that there is a
18 phospholipid complex with aprepitant at the
19 interface of an oil-in-water emulsion.
20 Q. Dr. Little, I think you've mentioned --
21 touched on some of this in your previous answer,
22 but I wanted to get a couple of things clear.
23 What do these three documents discuss in
24 terms of the types of formulations that are being
25 contained in these references?

1 A. Yeah, so two of them, if I can remember
2 correctly, are water, water-soluble formulations,
3 and I think one of them is a cream.
4 Q. Okay. Are these for intravenous use?
5 A. No.
6 Q. What, if anything, can you infer from
7 these documents regarding whether a POSA would
8 have believed that aprepitant can form a complex
9 with phospholipids for emulsions?
10 A. I don't think a person of ordinary skill
11 in the art is looking at this and saying that you
12 would have a complex with aprepitant.
13 Q. Now, what's the ratio being discussed
14 between the phospholipid and the compounds in each
15 one of Yue, EP279, and Agarwal?
16 A. My recollection is that it's anywhere
17 from like .5 to 3, or something like that.
18 Q. So .5 to 3 phospholipid per molecule of
19 the drug being discussed in those references?
20 A. Yes.
21 Q. Okay. Was Zhou the first disclosure of
22 an idea of using a poorly insoluble molecule with
23 an emulsion?
24 A. Well, no, there was the general
25 discussion back in the early 1990s, I guess,

1 wherein the Washington reference talked about that
2 it would be possible for you to have a molecule
3 that could orient itself at the surface of an
4 emulsion. So no, CN '845 -- I don't see
5 complexation in CN '845, but if it is, it's not
6 the first communication of it.
7 Q. And for that reference -- looking --
8 considering the Washington reference, which for
9 the record is JTX-113.9, if there is a molecule
10 situating itself at the surface, what was the
11 amount of egg lecithin discussed to be used in
12 that example?
13 A. 14 percent total. So I think it's like
14 a -- if I can remember correctly, I think it's 20
15 to 1, or something like that.
16 Q. I'm sorry, are you referring to the
17 patent or Washington right now?
18 A. I'm referring to the patent in that
19 case, yeah.
20 Q. Okay.
21 A. In Washington, there's no discussion of
22 ratios of the compound.
23 Q. Okay. In Washington, does it reference
24 an amount of lecithin used in any of the examples?
25 JUDGE BRYSON: I didn't understand what

1 the reference to the patent was.
2 MR. ASHKENAZI: Sorry, I think
3 Dr. Little, when he meant 14 to 1, was referencing
4 to the patents-in-suit.
5 JUDGE BRYSON: Oh, the patents-in-suit.
6 MR. ASHKENAZI: Yes. I think there was
7 some confusion in the discussion.
8 JUDGE BRYSON: Very well. I follow.
9 Go ahead.
10 MR. ASHKENAZI: Okay. Let me start
11 again.
12 BY MR. ASHKENAZI:
13 Q. Dr. Little, the patents-in-suit, they
14 had a ratio of lecithin -- if you were to
15 calculate the ratio of lecithin to aprepitant in
16 the asserted claims in the patents-in-suit, the
17 claims we're focused on today, what would that
18 ratio be?
19 A. My recollection is it was like 20 to 1.
20 Q. Okay. Thank you.
21 JUDGE BRYSON: All right.
22 BY MR. ASHKENAZI:
23 Q. With respect to the Washington
24 reference, you mentioned that certain compounds --
25 it discusses compounds being situated at the

1 interface?
2 A. It could, yes.
3 Q. Do you recall if it gave an example of a
4 compound that was situated at the interface?
5 A. It's possible that it did. I can't
6 remember off the top of my head. It's possible.
7 Q. Okay. Well, we can move on, and I'll
8 touch on that later.
9 Did you hear Dr. Rabinow's testimony
10 that a POSA would have been motivated to use
11 sodium oleate in an aprepitant emulsion based on
12 the disclosure of a pH modifier in CN '845?
13 A. Yes, I did hear that.
14 Q. And what's your opinion on that?
15 A. I think in this instance a person of
16 ordinary skill in the art would not be motivated
17 to use sodium oleate as a pH modifier.
18 Q. Okay. Can you please explain why?
19 A. Yeah, there's a couple of reasons why.
20 The first is, is that if you're going to use a pH
21 modifier, it would be extremely simple to use
22 something like sodium hydroxide or hydrochloric
23 acid, depending on the circumstance. But if
24 you're trying to make it more basic, you would use
25 sodium hydroxide.

1 That would go in there, and it would
2 dissociate. So it's doing the job you asked it to
3 do, which is to be a pH modifier, and then it's
4 not doing something else that would cause
5 problems.
6 If you put something like oleic acid
7 into -- or sorry, sodium oleate, we're talking
8 about now. If you put sodium oleate in, it's
9 going to dissociate into oleate, as Your Honor
10 said before, and then also the sodium ion that's
11 going to go in. And it's going to distribute, and
12 it has the potential to do other things, as well.
13 So if you're trying to use a pH modifier, the
14 simplest thing to do would be to use sodium
15 hydroxide.
16 But, second of all, what we're doing, if
17 you remember, is we're trying to come up with an
18 intravenous NK-1 formulation that has minimal side
19 effects. In my opinion, from reviewing the prior
20 art, there would be concerns about using sodium
21 oleate from a side effect standpoint. So I don't
22 think, if you're trying to have high tolerability,
23 you would use sodium oleate.
24 Q. Okay.
25 MR. ASHKENAZI: If we could please open

1 up JTX-112 at page 38.
2 BY MR. ASHKENAZI:
3 Q. This is the Wan reference.
4 And this is a reference that Dr. Rabinow
5 discussed during his testimony?
6 A. Yes.
7 Q. Okay. I want to focus in on
8 paragraph 358 and Table 19. And if we could focus
9 on the second sentence in paragraph 358.
10 A. It says, "Sodium oleate was added as an
11 additional ingredient but did not produce
12 favorable hemolytic results in all delivery
13 routes."
14 Q. And what is notable about the emulsions
15 that are disclosed in Table 19?
16 A. Yeah, as you see in Table 19, there's
17 sodium oleate that was present in the formulation.
18 And as they show in each of them, there was
19 instances of hemoglobinuria.
20 Q. Okay. And what is hemoglobinuria?
21 A. It's when you have blood in the urine.
22 So it's a result of the lysis of red blood cells.
23 Q. So -- and does Wan -- what does Wan say
24 about what is causing that hemoglobinuria in the
25 formulations contained in Table 19?

1 A. It's sodium oleate.
2 Q. Now, if we can please take us back one
3 page, so JTX-112 at page 37. I want to focus on
4 paragraph 357 and Table 18, which is on the next
5 page.
6 Now, what emulsion was Wan disclosing in
7 this section?
8 A. So this is the example right before it.
9 So in that instance, you don't have sodium oleate.
10 And if you see from the paragraph that's
11 associated with it, it says that there was clean
12 hemolysis results in both of the routes of
13 administration.
14 Q. How do Wan's results for emulsions
15 with -- and just to be clear, do both the -- do
16 all of the emulsions contained in Tables 18 and 19
17 include Myglyol?
18 A. They do.
19 Q. Okay. So how do Wan's results for
20 emulsions with Myglyol and sodium oleate compare
21 to similar emulsions without sodium oleate?
22 A. Yeah, the ones that had sodium oleate in
23 it caused an issue, and the inventors of this
24 patent specifically pointed that out as being a
25 problem.

1 JUDGE BRYSON: The claimed hemolysis
2 results means no hemoglobin in the urine; is that
3 right?
4 THE WITNESS: Correct. And if you look
5 at the -- Your Honor, on the right-hand side, see
6 the helium hemoglobinuria scores, there's zero.
7 JUDGE BRYSON: I see.
8 BY MR. ASHKENAZI:
9 Q. In your opinion, does Wan suggest adding
10 sodium oleate to an emulsion?
11 A. No, it doesn't. It tells you that when
12 you add it to the formulation, that you would have
13 potential problems by all delivery routes.
14 Q. Do you recall Dr. Rabinow's testimony
15 that the combination of oleic acid and
16 median-chain fatty acids is responsible for
17 hemolysis such that a POSA would use -- would not
18 use medium-chain fatty acids with oleic acid?
19 A. I did.
20 Q. And do you have an opinion on that?
21 A. Yeah, I disagree with that. My
22 understanding of what Dr. Rabinow is doing is he's
23 looking at this reference. And he says the people
24 who wrote this are wrong, is basically what he's
25 saying. That's a high standard for a person of

1 ordinary skill in the art to be looking at this,
2 and there's a teaching in it, right.
3 There would have to be a clear
4 indication that these people don't know what
5 they're talking about or something, completely
6 missing it. I don't see that here.
7 My understanding of the justification is
8 that when a person of ordinary skill in the art
9 looks at it, they see Myglyol, which are the
10 medium-chain fatty acids in the formulation. And
11 they would see there's an interaction between the
12 two.
13 Well, first of all, that's an
14 assumption, it's speculation that there would be
15 an interaction between the two. We don't know
16 that. But if you start thinking about it, Myglyol
17 is in the oil phase.
18 If Your Honor can remember earlier in
19 the Liu reference, we were talking about the
20 preference of those formulations. Instead of
21 using the long-chain oils, you're using the
22 medium-chain oils, like Myglyol. So that's in the
23 oil phase.
24 I think what Dr. Rabinow is saying is he
25 thinks that some of those would be at the surface

1 and, you know, marching together with the oleate
2 and that would cause a stacking problem or
3 something and the oleate would then leave and
4 cause a problem. I don't see that. I think it's
5 just speculation. We don't know. We don't know
6 that.
7 I'll also mention that in the prior art
8 references that I've reviewed so far from
9 Dr. Rabinow in his analysis, they don't even say
10 that you should use Myglyol and that, like, sodium
11 oleate is preferable. So we've got all these
12 other references that use sodium oleate and
13 Myglyol together.
14 So, if anything, the evidence that I've
15 seen is that there's a preference to using those
16 two, if anything, but there's no teaching that
17 there's some kind of interaction.
18 But what do you see when a person of
19 ordinary skill in the art just reads this
20 reference? When you just read the reference, it
21 says that in the formulation that had sodium
22 oleate, you had problems with hemolysis. That's
23 what I think a person of ordinary skill in the art
24 would see when they read this reference.
25 JUDGE BRYSON: Go ahead.

1 MR. ASHKENAZI: Your Honor, we're at
2 11:43. I'm going to continue moving on. I just
3 want to know, is there a time that you would like
4 us to break?
5 JUDGE BRYSON: I think around noon for a
6 break.
7 MR. ASHKENAZI: Sounds good.
8 JUDGE BRYSON: How much more direct do
9 you have?
10 MR. ASHKENAZI: I'd say roughly
11 30 minutes, maybe 45.
12 JUDGE BRYSON: Okay. We'll break at
13 noon, and then you can continue after that.
14 MR. ASHKENAZI: Okay. I'll try to go a
15 little bit faster, though.
16 BY MR. ASHKENAZI:
17 Q. Dr. Rabinow went through individual
18 components of the claims and discussed his
19 assertions on where they could be found in the
20 prior art.
21 What do you think about that,
22 Dr. Little?
23 A. Yeah, I don't think that that's how a
24 person of ordinary skill in the art would look at
25 this. I don't think a person of ordinary skill in

1 the art forming an obvious analysis would take a
2 component of the claim and then search backwards
3 to see if they could find that component someplace
4 else in a formulation, and regardless of what that
5 other formulation is or the teaching of the
6 reference, say that that could be used in the
7 context of the formulation of the claims, and then
8 do it again for the next claim element and the
9 next claim element.
10 I think there's got to be some form of
11 looking at the references in context so a person
12 of ordinary skill in the art is aware of all the
13 art, but they're also aware of all the context in
14 the art.
15 So I think what they need to do is look
16 at those formulations in context and you have to
17 be a little careful about going back and finding
18 it one place and pulling it in and finding another
19 piece and pulling it in and then finding another
20 piece and pulling it in. I think that you need to
21 be careful about it. I don't think that's what a
22 person of ordinary skill in the art would do.
23 Q. And why do you need to be careful? Can
24 you explain a little bit more about that?
25 A. Yeah, because formulation is done in

1 context. When you're looking at a formulation in
2 the prior art, if it had other things in it,
3 especially if it said that some of those other
4 things would cause a problem, you wouldn't take
5 one thing from that formulation and then not
6 something else.
7 Q. And how do the different components of a
8 formulation interact with respect to stability?
9 A. Yeah, so the stability in the
10 formulation is a result of several things
11 together. It's not like -- you know, if you have
12 no information at all and you're looking at it and
13 you go back into the prior art, you can't just
14 say, for instance, that stability is driven by
15 emulsion concentration. So what you're going to
16 do is you're just going to increase the emulsion
17 concentration to get that stability.
18 First of all, that's not an accurate
19 view of how emulsion stability works and
20 emulsifiers work. But you would be looking at
21 that whole thing and what all the components are
22 in terms of how that contributes to stability.
23 Q. You said -- I think you misspoke. So I
24 want to make sure the record is clear.
25 You meant emulsifier concentration?

1 A. Yes, you would not just be looking at
2 the emulsifier concentration and trying to
3 increase it. Did I misspeak?
4 Q. Or I misheard. Either way the record is
5 clear.
6 JUDGE BRYSON: Let me go back to the Wan
7 reference very briefly. Would you think that a
8 person of ordinary skill would understand the Wan
9 reference to be distinguishing between oleate and
10 oleic acid in the presence of the two?
11 THE WITNESS: I think in the Wan
12 reference -- if I can remember correctly, first of
13 all, I don't think that that is being added first
14 as a pH modifier. I'd have to look and see, but
15 it's just in the formulation. Okay?
16 JUDGE BRYSON: All right.
17 THE WITNESS: So what I'm doing is I'm
18 looking at that reference and I'm saying, What
19 does a person of ordinary skill in the art see
20 when they see the reference? They see that when
21 it's in there, that it could cause lysis of red
22 blood cells in the urine, right.
23 But it's listed for what it's there for.
24 So I guess when you think of what would cause the
25 lysis, you're thinking of that being more oriented

1 in an interface between the droplets and those
2 droplets potentially interacting with red blood
3 cells.
4 JUDGE BRYSON: But would the person of
5 ordinary skill say, Okay, that applies to sodium
6 oleate, but I can use oleic acid without a
7 problem?
8 THE WITNESS: No, I think if you're in a
9 situation where you added it, like they did, and
10 it is at the interface, it's going to be, as
11 Your Honor noted, in this sort of various
12 dissociation state.
13 JUDGE BRYSON: So whether it's in the
14 acid form or the oleate form, it's going to be
15 equally problematic, potentially?
16 THE WITNESS: Potentially, as long as
17 you did what Your Honor said before, and you're
18 adjusting the pH appropriately to the amount of
19 pHs you'd expect in that prior art reference, yes.
20 BY MR. ASHKENAZI:
21 Q. Dr. Little, you've been discussing your
22 opinion on how a POSA would view the art in 2014;
23 correct?
24 A. Yes.
25 Q. Okay. I'd like to talk about reasonable

1 expectation of success now. And I want to focus
2 regarding your opinions on whether a POSA would
3 have had a reasonable expectation of success in
4 arriving at the claimed formulation based on the
5 prior art.
6 Can you remind us how would a POSA have
7 viewed the properties of the aprepitant molecule
8 from a formulation point of view in 2014?
9 A. Sure. I mean, just to say again, it's
10 very difficult. They would recognize that it's
11 insoluble in water, had poor solubility in oil,
12 and was characterized as brickdust. So it's
13 problematic from a formulation standpoint.
14 Q. And how would a POSA have viewed the
15 formulations of aprepitant as in particular an
16 emulsion for intravenous use at that time?
17 A. Yeah, so now you're adding emulsions on
18 top of it, which is one of the more complex
19 formulation strategies. Those weren't typically
20 used. So you're adding complexity now.
21 Q. And in your opinion, assuming a POSA did
22 consider using 14 percent egg lecithin, as
23 Dr. Rabinow suggests, would that POSA reasonably
24 expect that such a formulation would be physically
25 stable?

1 A. Now you're going way up higher than what
2 you would consider as the industry standard values
3 and what people have shown in the art as being
4 workable for emulsion formulations and even
5 optimal for aprepitant formulations, according to
6 the Zhou reference.
7 Q. And in your opinion, assuming a POSA did
8 consider using sodium oleate as a pH modifier, as
9 Dr. Rabinow suggests, how would a POSA have viewed
10 the question of whether there would be a
11 reasonable expectation of success that such a
12 formulation would be physically stable?
13 A. Yeah, I mean, you know, there's not a
14 disclosure in the references of using sodium
15 oleate as a pH modifier for aprepitant
16 formulations. And I think given what we saw, now
17 you're -- to solve a problem in the art, now
18 you're adding in the possibility that somebody
19 might see a tolerability problem with that
20 molecule. So I think that also compounds it.
21 Q. And how would a POSA view the efforts of
22 other researchers in the field in making an
23 intravenous aprepitant formulation in the context
24 of a reasonable expectation of success?
25 A. Yeah, so my understanding of this is

1 that the molecule is about 20 years old at this
2 point. So up to that point, you have a
3 fosaprepitant intravenous product, but you don't
4 have an aprepitant product. It's the only IV
5 product there. And you see, from what I've
6 understood, Merck tried all of these different
7 techniques and couldn't make it work.
8 When you look in the art here, you see
9 like the CN '845, my understanding of that is that
10 there's that patent application, it didn't have
11 all the components, it's under that, but that
12 patent application was trying to make water --
13 oil-in-water emulsions. I don't think that patent
14 even ever issued.
15 My understanding is the public records
16 say that that patent was rejected. So you don't
17 see a formulation coming from that. And you don't
18 even see a formulation coming from the optimized
19 formulation of Zhou. So from my review, I've seen
20 a lot of reasons why I don't think it would be
21 expected to succeed.
22 Q. So you touched on it on the back of your
23 last question, but I want to make sure we have
24 this clear.
25 How would a POSA view the efforts of the

1 Zhou group in making an intravenous aprepitant
2 emulsion in the context of reasonable expectation
3 of success?
4 A. Yeah, I mean, I think that you don't
5 have stability data, according to the court's
6 construction in the Zhou reference. You have, if
7 anything, an optimized formulation that would go
8 in the other direction. So it would sort of teach
9 you away from doing the higher concentration
10 amounts to make a stated formulation.
11 MR. ALY: I object, Your Honor. The
12 witness is offering a new opinion about teaching
13 away that is not a position or opinion that
14 plaintiff has ever offered.
15 MR. ASHKENAZI: Your Honor, we're not
16 talking about teaching away right now. We're
17 talking --
18 JUDGE BRYSON: I'll tell you what, I'll
19 sustain the objection. Why don't you reask the
20 question, and let's stay away from teaching away.
21 Teaching away is a term of art in patent law, and
22 I think we best stay away from the use of that
23 term, if that satisfies your objection.
24 MR. ALY: May I move to strike?
25 JUDGE BRYSON: Yes, move to strike.

1 If you could reask the question.
2 MR. ASHKENAZI: Sure.
3 BY MR. ASHKENAZI:
4 Q. How would a POSA have viewed the efforts
5 of the Zhou group in making an aprepitant
6 formulation in the context of reasonable
7 expectation of success?
8 A. I think that a person of ordinary skill
9 in the art, if anything, viewing the Zhou
10 reference, would be working towards an emulsion
11 that does not have the compositional properties of
12 the claim. There's not stability there.
13 And, you know, even as we've seen in the
14 specification of the patent-in-suit, those
15 emulsions ultimately had crystals that were
16 formed. So they didn't meet the claim
17 construction of the court. So I think that from
18 all that information, you wouldn't expect it to
19 succeed.
20 Q. Based on all the information you
21 reviewed in this case, have you formed an opinion
22 on whether a POSA would have had a reasonable
23 expectation of success for the claimed emulsions?
24 A. It's my opinion they would not have a
25 reasonable expectation of success for the claimed

1 emulsions.
2 Q. I'd like to focus on Example 4, which
3 you just referenced, of the asserted patents.
4 And, specifically, Dr. Rabinow -- did
5 you hear Dr. Rabinow testify that Example 4 of the
6 asserted patents did not accurately represent
7 CN '845 because the pH was too low?
8 A. Yes, I did hear that.
9 Q. Okay.
10 MR. ASHKENAZI: Can we please pull up
11 JTX-71.13? That's the CN '845 patent. And I'm
12 going to paragraph 11.
13 BY MR. ASHKENAZI:
14 Q. Dr. Little, what is the pH identified in
15 CN '845 for the formulations, generally, there?
16 A. It says 6 to 8.
17 MR. ASHKENAZI: And if we could please
18 pull up PDX-4-4.
19 BY MR. ASHKENAZI:
20 Q. What is the range of pHs in the actual
21 examples of CN '845?
22 A. You see 7.2, 6.8, 8.0, 6.8, 7.2, 8.0,
23 and 7.2.
24 MR. ASHKENAZI: And now can we please
25 pull up JTX-7.15? That's the '794 patent, at

1 Column 18, line 36. And this is Example 4.
2 Can we highlight -- sorry, on line 36,
3 can we highlight the sentence that starts "The pH
4 of this crude emulsion was adjusted to 7.0."
5 BY MR. ASHKENAZI:
6 Q. Dr. Little, can you please explain to us
7 what the pH of Example 4 was?
8 A. Yeah, the pH that it was adjusted to was
9 right in the middle of the range that was used in
10 CN '845.
11 MR. ASHKENAZI: We can take that down.
12 Thank you.
13 BY MR. ASHKENAZI:
14 Q. Considering what you just walked
15 through, do you agree with Dr. Rabinow that
16 Example 4 of the asserted patents did not
17 accurately represent CN '845 because the pH was
18 too low?
19 A. No, I don't agree with that.
20 Q. And why not?
21 A. Because, as we see, you know, even he
22 said that he believes all those examples to be
23 stable. I mean, all those values go right around
24 7, and it's right in the middle of the range
25 that's taught by that reference.

1 MR. ASHKENAZI: Your Honor, it is 11:55,
2 and I'm moving to objective indicia. Would this
3 be a good time to take a break?
4 JUDGE BRYSON: This is a good time to
5 break. Why don't we come back at, let's say,
6 12:35.
7 Now, one thing that the parties should
8 be -- you may be aware of this, but you're getting
9 on towards running low on time and so you should
10 be aware of the time you have. I don't want to
11 put you in a position that you have extra
12 witnesses or other material that you want to
13 explore, and you suddenly realize you have no time
14 left.
15 So I want to counsel you to check on the
16 time and budget your time from here on out
17 carefully.
18 MR. ALY: We will.
19 MR. ASHKENAZI: Thank you, Your Honor.
20 JUDGE BRYSON: You may already be quite
21 aware of how much time you have, but if you're
22 not, then counsel need to check.
23 MR. ASHKENAZI: We've been checking
24 every day, Your Honor. And Mr. Albano has done a
25 great job of keeping us informed of that time.

1 JUDGE BRYSON: Excellent. Good. Thank
2 you.
3 (Recess from the record.)
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1 DISTRICT OF COLUMBIA)
2
3 I, Matthew Goldstein, RMR, CRR, Notary
4 Public within and for the District of Columbia, do
5 hereby certify:
6
7 That I reported the proceedings in the
8 within entitled matter, and that the within transcript
9 is a true record of said proceedings.
10
11 I further certify that I am not related to
12 any of the parties to the action by blood or marriage,
13 and that I am in no way interested in the outcome of
14 this matter.
15
16 IN WITNESS WHEREOF, I have hereunto set my
17 hand this 27th day of June, 2024.
18
19
20 Matthew Goldstein, RMR, CRR
21
22
23
24
25

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