

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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18          ROY CAMPOS - HOT SEATER  
19  
20  
21  
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23  
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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 excess 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 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 pharmaceuticals,  
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 pharmaceuticals, 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 )

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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

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23

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25

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