

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

DR. FALK PHARMA GMBH )  
Petitioner, ) Case No. IPR2024-01197  
vs. ) U.S. Patent No.  
ELLODI PHARMACEUTICALS, L.P., ) 8,771,729 B2  
Patent Owner )  
\_\_\_\_\_)

DEPOSITION OF ALAN PARR, PHARM.D  
AUGUST 25, 2025

Reported by: Rosalie A. Kramm, CSR No. 5469, RPR, CRR

1 APPEARANCES

2  
3 FOR DR. FALK PHARMA GMB

4 KNOBBE MARTENS

5 BY: NATHANAEL R. LUMAN, PH.D., ESQ.

6 BY: PHILLIP J. MINNICK, PH.D., ESQ.

7 3579 Valley Centre Drive, Suite 300

8 San Diego, California 92130

9 858.707.4000

10 nate.luman@knobbe.com

11 phillip.minnick@knobbe.com

12  
13 FOR PATENT OWNER ELLODI PHARMACEUTICALS, L.P.:

14 COOLEY

15 BY: ISHA AGARWAL, ESQ.

16 BY: JONATHAN COUSIN, PH.D.

17 1299 Pennsylvania Avenue, NW, Suite 700

18 Washington DC 20004-2400

19 202.776.2102

20 iagarwal@cooley.com

21 jonathan.cousin@cooley.com

I N D E X

EXAMINATION

PAGE

By Ms. Agarwal

4

EXHIBITS PREVIOUSLY MARKED THAT WERE REFERRED TO:

Exhibit 1005

Exhibit 1073 - 1083

Exhibit 1085

Exhibit 1091

Exhibit 1092

Exhibit 1093

Exhibit 2007

(No exhibits were marked and attached.)

1 AUGUST 25, 2025 MONDAY 9:02 A.M. SAN DIEGO, CALIFORNIA

2 \* \* \*

3 THE REPORTER: My name is Rosalie Kramm,  
4 California CSR No. 5469.

5 \* \* \*

6 ALAN PARR, PHARM.D,  
7 having been first duly sworn, testified as follows:

8  
9 EXAMINATION

10 BY MS. AGARWAL:

11 Q. Hi, Dr. Parr.

12 A. Good morning.

13 Q. Nice to see you again.

14 Just for the record, could you please state  
15 your name and address.

16 A. Yes, my name is Alan Frank Parr, and my address  
17 is 23 Glenmore Court, Acworth, Georgia 30101.

18 Q. Do you understand you're here today for the  
19 cross-examination on your reply declaration that you  
20 submitted in IPR 2024-01197?

21 A. Yes, ma'am.

22 Q. And that is relating to what I'll refer to as  
23 the "'729 Patent," correct?

24 A. Yes, ma'am.

25 Q. Have you ever been deposed before?

1           A.    Yes.

2           Q.    And have you had any discussions with anyone  
3 about the process for this deposition?

4           A.    Just with counsel, explaining what was going to  
5 be reviewed, what dates and times, yes.

6           Q.    So I understand you've been deposed before, and  
7 we've been through this process before, but I'm just  
8 going to explain it briefly here, and we'll get going.

9                    So I'm going to be asking you questions today,  
10 and you should answer them to the best of your ability.

11                   And do you understand that you just took an  
12 oath with the court reporter to tell the truth here  
13 today?

14          A.    Yes, ma'am.

15          Q.    Is there any reason why you cannot completely  
16 and truthfully answer my questions today?

17          A.    Not that I'm aware of, no, ma'am.

18          Q.    Do you understand that even if your attorney  
19 objects during the deposition, you must still answer the  
20 question, unless he instructs you not to do so on the  
21 basis of privilege?

22          A.    Yes, ma'am.

23          Q.    And the court reporter cannot record a nod of  
24 the head or other body language. So it's important for  
25 you to give an audible answer.

1 Do you understand that?

2 A. Yes, ma'am.

3 Q. If you don't understand the question, please  
4 let me know; otherwise, we'll assume that you understood  
5 my question; is that fair?

6 A. Yes, ma'am.

7 Q. And we'll try to take breaks every hour, but if  
8 you need a break, just let me know. I just ask that you  
9 don't do so while a question is pending.

10 Do you understand?

11 A. Yes, ma'am.

12 Q. And do you also understand that under the  
13 rules, you're not allowed to speak with any of the  
14 attorneys here about your testimony or anticipated  
15 testimony during breaks?

16 A. Yes, ma'am.

17 Q. And you're not in communication right now with  
18 anyone via text or chat functions of any sort?

19 A. No, ma'am. I left my phone in the other room.

20 Q. Okay. Great.

21 Have you had any discussions with anyone  
22 employed by Dr. Falk about your deposition here today?

23 A. No, ma'am.

24 Q. And have you had any discussions with any  
25 individuals employed by Dr. Falk about the subject matter

1 of your declaration?

2 A. No, ma'am.

3 Q. Okay. Go ahead and open your binder. We're  
4 going to turn to Exhibit 1093. It's the third tab.  
5 They're not quite in order.

6 A. There is nothing behind that tab.

7 Q. There is nothing behind that tab?

8 A. There is something in front of it. Do you --

9 MS. AGARWAL: Do you have the reply declaration  
10 here?

11 MR. LUMAN: Yes, I have it here.

12 MS. AGARWAL: Could you give it to Dr. Parr?

13 MR. LUMAN: Yes, I can get a copy for myself.

14 MS. AGARWAL: Let's go off the record for a  
15 second.

16 (Recess was taken.)

17 BY MS. AGARWAL:

18 Q. Back on the record.

19 So we're at your reply declaration,  
20 Exhibit 1093, correct?

21 A. Yes, ma'am.

22 Q. And if you turn to the last page, that is your  
23 signature, correct?

24 A. Yes, ma'am, it's my electronic signature.

25 Q. And it is dated July 10th, 2025, correct?

1 A. Yes, ma'am.

2 Q. Did you discuss with Dr. Falk's counsel at any  
3 point prior to submitting your reply declaration?

4 A. Can you ask the question again?

5 Q. Sure. Prior to submitting your reply  
6 declaration on July 10th, 2025, but after -- strike that.

7 Prior to submitting your reply declaration, how  
8 many discussions did you have with Dr. Falk's counsel  
9 regarding your reply declaration?

10 A. I have no idea. I don't recall the exact  
11 numbers or number of meetings. I don't know that.

12 Q. But you did discuss with Dr. Falk's counsel  
13 prior to submitting --

14 A. Yes, ma'am.

15 Q. -- your reply declaration. Okay.

16 And if we go to your "List of Materials  
17 Considered," that starts on page Romanette i, correct?

18 A. Yes, ma'am.

19 Q. Go to page Romanette iii. You cite to a number  
20 of exhibits in your reply declaration that you did not  
21 cite to in your opening declaration, correct?

22 A. Yes, ma'am. There are some additional  
23 documents I reviewed.

24 Q. And those would be Exhibits 1073 to 1083, 1085  
25 to 1092, 2007 and Paper 10, correct?

1 A. Yes, ma'am.

2 Q. And who first identified these new exhibits?

3 A. We had discussions and then we -- we did  
4 another search, and those were -- that was done by  
5 Dr. Falk's counsel.

6 Q. So Dr. Falk identified these.

7 A. No, Dr. Falk's counsel.

8 Q. Sorry. Dr. Falk's counsel identified these new  
9 exhibits to you?

10 A. Based on discussions we had, yes.

11 Q. Did you identify any of these new exhibits?

12 A. Not that I'm aware of.

13 Q. Prior to submitting your reply declaration, did  
14 you review any other documents, other than those that are  
15 listed here?

16 A. No, ma'am.

17 Q. You're not relying on any other documentary  
18 evidence to support your reply declaration, correct?

19 A. No, ma'am, just the documents listed here.

20 Q. In preparation for today's deposition, who did  
21 you meet with?

22 A. I met with Mr. Luman, Mr. Minnick and -- I  
23 forgot Eric's last name, a third Falk counsel member.

24 Q. And how long did you meet with them for?

25 A. We met on Thursday and Friday of last week.

1 Q. And did you review any documents during your  
2 preparation?

3 A. We talked about my deposition -- my report and  
4 associated documents.

5 Q. Have you done any further investigation of  
6 documents or other evidence since July 10th, 2025?

7 A. No, ma'am.

8 Q. Have you read Patent Owner's response and its  
9 expert declaration that were filed in this matter?

10 A. If it was one of the documents in this list, I  
11 reviewed it. If it's not in this list, I don't recall  
12 reviewing it.

13 Q. So in this list you have the Declaration of  
14 Dr. Martyn Christopher Davies. That is Exhibit 2007.

15 A. Yes, ma'am.

16 Q. So you reviewed Dr. Davies' expert declaration,  
17 correct?

18 A. Yes, ma'am.

19 Q. And it says here that you are also relying on  
20 the Institution Decision, Paper 10, correct?

21 A. Yes, ma'am.

22 Q. So you've reviewed the Institution Decision.

23 A. I looked at both of those documents, yes,  
24 ma'am.

25 Q. Okay. Let's go to paragraph 23 of your

1 declaration. Here, about halfway through the paragraph,  
2 you state that in your first deposition you testified  
3 that, "I haven't done a literature search on {fast  
4 dissolving lozenges}, so I wasn't aware if there were any  
5 fast-dissolving lozenges in the prior art"; is that  
6 correct?

7 A. Yes, that's what it states.

8 Q. And at the time you had not done a literature  
9 search on fast-dissolving lozenges, correct?

10 A. I did not. In my mind there was no need to do  
11 it, to be able to identify fast-dissolving lozenges, and  
12 it identified the use of its synocrint, and all of that  
13 made perfectly sense to me as a POSA.

14 Q. Turn to page, page 13. Starting in paragraph  
15 24 through paragraph 35, which is on page 18, you go  
16 through a number of exhibits as examples of what you  
17 claim to be fast-dissolving lozenges, correct?

18 A. I go through documents that listed  
19 quick-dissolving lozenges, yes.

20 Q. Just to be clear, Dr. Falk's counsel identified  
21 these examples to you, correct?

22 A. Yes, they did the literature search, because I  
23 don't have access to the appropriate databases.

24 Q. If we go back to paragraph 23, in this  
25 paragraph, you don't define a disintegration time for

1 fast-dissolving lozenges, correct?

2 A. I do not, because I operate under the FDA's.

3 The fast-dissolving is something that dissolves  
4 in a few -- that disintegrates in a few seconds, within a  
5 few seconds or 30 seconds, based on the USP apparatus.

6 Q. Let's turn to paragraph 24. Here you cite to  
7 Exhibit 1075, McEntee, correct?

8 A. Yes, ma'am.

9 Q. And you insert a quote from McEntee, the first  
10 sentence states. "Fast melt formulations are typically  
11 in the form of tablets or lozenges that dissolve or  
12 disperse in a patient's mouth within a minute without the  
13 need of water or chewing," correct?

14 A. Yes, ma'am.

15 Q. And you don't cite to any disintegration or  
16 dissolution data for the lozenge from McEntee, correct?

17 A. No. That's a complete repeat of what was in  
18 that patent or that document.

19 Q. Let's go to Exhibit 1075, which is McEntee.  
20 This is the exhibit that you relied on, correct?

21 A. Yes, ma'am.

22 Q. And the quote that I just read to you comes  
23 from page 3, lines 20 to 28 in that paragraph, the second  
24 sentence there, correct?

25 A. Yes, ma'am.

1 Q. Okay. And you just stated that this sentence  
2 encompasses what is in the document, correct?

3 MR. LUMAN: Objection. Form; mischaracterizes  
4 his testimony.

5 THE WITNESS: It -- it is a reproduction of  
6 what is in this document.

7 BY MS. AGARWAL:

8 Q. Could you explain further what you mean by  
9 that.

10 A. Well, if you -- if you look at the sentence in  
11 the document, I believe it lines up with what's in --  
12 what I highlighted. I can confirm that just to make  
13 sure. But -- to view what I highlighted in paragraph 24  
14 what is written in this reference.

15 Q. Okay. Let me ask my question a different way.  
16 You don't cite to anything else in  
17 Exhibit 1075, correct? You only cite to this quote.

18 A. Well, that's correct. It's just documented  
19 there was a lozenge.

20 Q. So you don't cite to any of -- you don't cite  
21 to any data that might be in Exhibit 1075, correct?

22 A. No, I -- I just cited that -- that particular  
23 sentence that indicated there was -- there does exist a  
24 fast-dissolving lozenge.

25 Q. And you don't cite to any definition in

1 Exhibit 1075 that would indicate a disintegration time,  
2 correct?

3 A. Again, I -- I operate as any POSA would under  
4 the FDA guidance document around what an ODT is.

5 Q. And staying in Exhibit 1075, this portion that  
6 you quoted in your reply declaration, this is the only  
7 reference of a lozenge in this reference, correct?

8 A. I have to go back and re-read it to -- to see  
9 if that's the only spot. I don't -- I can't -- I don't  
10 memorize it. So I don't know. I'd have to re-read the  
11 document to confirm that.

12 Q. Well, if there were other references of  
13 lozenges in this reference, presumably you would put it  
14 in your reply declaration, correct?

15 A. I -- I don't know. This -- this made -- my --  
16 this sentence made the point I was making that there was  
17 a fast-dissolving lozenge.

18 So, again, I can re-read the document and  
19 confirm whether that's the only spot, but I don't -- from  
20 memory, I can't confirm that.

21 Q. Let's go to page 20 of Exhibit 1075. Oh, I'm  
22 sorry. Page 24.

23 McEntee discloses -- sorry.

24 Exhibit 1075 discloses a number of examples  
25 starting on page 24, correct?

1                   MR. LUMAN: Objection. Mischaracterizes the  
2 document.

3 BY MS. AGARWAL:

4           Q.    I'm sorry. I think it starts on page 23. It  
5 goes to page 40.

6           A.    Yes, it lists 21 examples.

7           Q.    You didn't cite to any of these examples in  
8 your reply declaration, correct?

9           A.    I did not.

10          Q.    Okay.

11          A.    Again, the statement was to show that there  
12 were fast-dissolving lozenges, and that sentence  
13 indicated that.

14          Q.    Let's go back to your reply declaration.

15                   If you want to pop it out of the binder, that  
16 might be easier as well. We'll be going back to it a  
17 bunch.

18                   MR. LUMAN: I have a stapled one if you want to  
19 switch. That way you can --

20                   THE WITNESS: Okay. I'll take this one.

21 BY MS. AGARWAL:

22          Q.    In paragraphs 25 to 26 of your reply  
23 declaration you cite to Exhibit 1076 to Martin, correct?

24          A.    Yes, ma'am.

25          Q.    And you specifically cite to paragraphs 60, 67,

1 and 64 of Martin, correct?

2 A. Yes, ma'am.

3 Q. Let's go to Exhibit 1076. This is the exhibit  
4 that you're citing to in paragraphs 25 and 26, correct?

5 A. Yes, ma'am.

6 Q. Let's go to paragraph 60, page 22.

7 This paragraph describes a sublingual tablet  
8 wafer, pellet, or lozenge, i.e., a tablet wafer, pellet,  
9 or a lozenge, correct?

10 A. Yeah. The sentence goes on with additional  
11 words, but that's what it says, yes, ma'am.

12 Q. And the last sentence of this paragraph states:  
13 "Generally, a sublingual tablet, wafer, pellet or lozenge  
14 should dissolve or disintegrate quickly, allowing the  
15 analgesic to be rapidly absorbed," correct?

16 A. Yes, ma'am.

17 Q. And is paragraph 25 of your reply declaration  
18 you cite to that last sentence, correct, that last  
19 paragraph of Exhibit 60 of Exhibit 1076.

20 A. Yes, ma'am.

21 Q. This paragraph does not give a reference of  
22 time for "quickly," correct?

23 A. Again, a POA would look at it knowing it is a  
24 ODT and -- and would follow the FDA guidance around  
25 orally disintegrating tablets or dosage forms.

1           Q.    Let's turn to paragraph 67 in Exhibit 1076.  
2           You quote this paragraph, paragraph 67, of Exhibit 1076,  
3           in paragraph 25 of your reply declaration, correct?

4           A.    Yes.

5           Q.    The second sentence states that: "In certain  
6           embodiments, the orally disintegrating tablets, wafers,  
7           pellets, or lozenges of the present invention dissolve  
8           completely over a period of about 10 seconds to about 120  
9           seconds, about 10 seconds to about 90 seconds, about 10  
10          seconds to about 60 seconds, about 10 seconds to about 30  
11          seconds, or about 20 seconds to about 60 seconds when  
12          placed into human saliva or a solution that mimics human  
13          saliva," correct?

14          A.    Yes, ma'am.

15          Q.    And these time frames that are given refer to  
16          the orally disintegrating tablets, wafers, pellets, or  
17          lozenges, correct?

18          A.    Yes, ma'am.

19          Q.    And this reference does not -- this reference  
20          doesn't relate the specific time frames to a particular  
21          dosage form, correct?

22          A.    I -- I'm not sure I agree with that. It says,  
23          "In certain embodiments, the orally disintegrating  
24          tablets, wafers, pellets, or lozenges dissolve," and it  
25          gives the timing. So a POSA would look at that and give

1 those timings that are associated with any of those  
2 dosage forms.

3 Q. Let's go to Exhibit 1005 in your binder.

4 You rely on Exhibit 1005 in your grounds for  
5 obviousness?

6 A. Yes, ma'am.

7 Q. Could you please read the title on the first  
8 page.

9 A. "Guidance for Industrial -- "Guidance for  
10 Industry - Orally Disintegrating Tablets."

11 Q. If we go to -- if we go to page 2 of this  
12 exhibit --

13 MR. LUMAN: Is that page 2 on the bottom page  
14 number?

15 MS. AGARWAL: Yes.

16 MR. LUMAN: Okay.

17 THE WITNESS: Yes.

18 BY MS. AGARWAL:

19 Q. The last paragraph states that -- the last  
20 paragraph, second sentence states: "Based on the  
21 original product rationale and Agency experience, we  
22 recommend that, in addition to the original definition,  
23 ODTs be considered solid oral preparations that  
24 disintegrate rapidly in the oral cavity, with an in-vitro  
25 disintegration time of approximately 30 seconds or less,

1 when based on the United States Pharmacopeia  
2 disintegration test method or alternative."

3 Do you see that?

4 A. Yes, ma'am.

5 Q. So in Exhibit 1076, where the reference  
6 provides a range of about 10 to 30 seconds, you would  
7 understand that to apply to ODTs, correct?

8 A. It is a time frame within the ODTs, yes. It  
9 doesn't use the -- it doesn't state whether it uses the  
10 USP to determine that. It just gives those ranges.

11 Q. And the time frame from 10 to about 120  
12 seconds, according to the FDA definition, would not be an  
13 ODT, correct?

14 A. Let me -- can I go back to that original  
15 document?

16 Q. Yes. It was Exhibit 1076.

17 A. 1076.

18 Q. In paragraph 67.

19 A. Okay. We have a difference here. In this it  
20 talks about releases the analgesic content over those  
21 time periods. That defines dissolution.

22 The US- -- the FDA talks about disintegration.  
23 The dosage form has to disintegrate first before it can  
24 dissolve.

25 So, in this case, where they're talking about

1 dissolution, disintegration occurs before these times  
2 they have here, and, I believe, would meet what the FDA  
3 defines as rapidly disintegrating in approximately 30  
4 seconds.

5 Again, the FDA says using the USP method. It  
6 doesn't state what that method is in this one.

7 At least I didn't see it, anyway.

8 Q. The second sentence, however, refers to  
9 dissolving completely.

10 A. Uh-huh.

11 Q. Correct?

12 A. Correct.

13 Q. And that would be what the FDA guidance is  
14 discussing, correct?

15 A. The FDA guidance discusses disintegration, and  
16 disintegration has to occur before dissolution. So if  
17 these dosage forms are dissolving within that 10 seconds  
18 or that 120 seconds, they would have clearly  
19 disintegrated before that time period.

20 Q. So an ODT could dissolve in 120 seconds,  
21 according to Exhibit 1076.

22 A. Yeah, it -- it -- present invention is all  
23 completely over a period of 10 seconds to 120 seconds.  
24 Right? That's dissolving. It would have disintegrated  
25 much sooner than that, because it has to disintegrate

1 before the drug can dissolve.

2 Q. And in the first sentence where it states that:  
3 "The orally disintegrating tablets, wafers, pellets, or  
4 lozenges release their analgesic contents to about 120  
5 seconds," that would have to occur prior to dissolving at  
6 120 seconds?

7 A. Well, the word -- a POSA would look at the word  
8 as content as the drug dissolving. And so the dosage  
9 form has to disintegrate first, and then once it  
10 disintegrates, then it can start to dissolve the drug.

11 And so content would be -- a POSA would look at  
12 that as meaning dissolved.

13 Q. So in this context, then, would release and  
14 dissolve be synonymous to a POSA?

15 MR. LUMAN: Objection. Form.

16 THE WITNESS: It -- this talks about dissolve  
17 in the timings that you mentioned previously. So that's  
18 the drug being in solution.

19 For a drug to be in solution -- if it's in a  
20 dosage form, a tablet, a wafer, or a lozenge, that dosage  
21 form has to first disintegrate to make the drug available  
22 to be dissolved.

23 So if it dissolves within 10 to 120 seconds, it  
24 would have had to have disintegrated long before that for  
25 the drug to be dissolved.

1 BY MS. AGARWAL:

2 Q. Okay. We can move on.

3 Let's go back to your reply declaration,  
4 paragraphs 27 to 28. You cite to a reference called  
5 Mezaache. Exhibit 1077, correct?

6 A. Yes, ma'am.

7 Q. And in your reply declaration you cite to  
8 paragraphs 2, 3, 40, and 10 of Exhibit 1077, correct?

9 A. Yes, ma'am.

10 Q. Let's go to Exhibit 1077, to Mezaache, and this  
11 is the exhibit you referred to, cite to, in your reply  
12 declaration.

13 A. Yes, ma'am, it appears to be.

14 Q. Let's go to paragraph 2 of Exhibit 1077. The  
15 first sentence of paragraph 2 states: "The invention  
16 relates to compressible compositions and dosage forms  
17 based thereon, such as tablets and lozenges which, when  
18 invested, quickly dissolve in the mouth, but which  
19 effectively mask the taste of unpleasant active agent(s)  
20 therein," correct?

21 A. Yes, ma'am.

22 Q. And you quote that in your declaration in  
23 paragraph 27, correct? It spans pages 14 to 15.

24 A. Yes, ma'am.

25 Q. This actually relates to taste-masking,

1 correct?

2 A. It relates to rapidly-dissolving dosage forms,  
3 which includes lozenges that -- and it also relates to  
4 taste-masking, yes, ma'am.

5 Q. Paragraph 2 of Exhibit 1077 does not define  
6 "quickly dissolve," correct?

7 A. Again, it doesn't, but a POA would be aware  
8 that the definition of "quickly dissolve" was defined in  
9 the FDA guidance document around ODTs.

10 Q. And the FDA guidance you're referring to is the  
11 one we just looked at, Exhibit 1005, correct?

12 A. Yes, ma'am.

13 Q. That FDA guidance doesn't ever refer to  
14 lozenges, correct?

15 A. Can we go back to that document?

16 Q. Yes.

17 A. I think it was 1005.

18 Q. Yes.

19 A. It refers to a solid dosage form. It doesn't  
20 limit itself to tablets, capsules, lozenges. It says a  
21 solid dosage form, which disintegrates rapidly in a matter  
22 of seconds. So the document doesn't limit us to tablets,  
23 capsules, or lozenges.

24 Q. But this guidance is specifically for orally  
25 disintegrated tablets, correct?

1           A.    The -- the title indicates that, but, as you  
2    read the document, a POSA would understand a solid oral  
3    dosage form can contain tablets, capsules, lozenges. It  
4    doesn't limit itself by that definition.

5           And the only thing the guidance did was it  
6    added on to that sentence that the testing should be done  
7    with this type of apparatus.

8           So while the title might say "tablets," ODT is  
9    a general term, that, as this statement says, encompasses  
10   all dosage forms.

11          Q.    Okay. Let's turn back to Exhibit 1077. And if  
12   we go to paragraph 3 of Exhibit 1077, the middle of the  
13   paragraph, it states: "One aspect associated with  
14   ameliorating the effects of ingesting molecules that are  
15   generally unpalatable is to provide the drug in dosage  
16   forms, such as tablets and lozenges, which, when  
17   ingested, quickly dissolve in the mouth."

18          Do you see that?

19          A.    Yes, I do.

20          Q.    And you quoted this sentence in your reply  
21   declaration, correct, in paragraph 27?

22          A.    Let's see here. 27.

23          Q.    It is the first full quote there.

24          A.    Right. Yes, ma'am.

25          Q.    This paragraph, paragraph 3, does not define

1 "quickly dissolve," correct?

2 A. Again, it does not, but, again, a POSA would be  
3 aware of the FDA guidance that we just discussed with the  
4 definition of a rapidly-dissolving dosage form.

5 Q. If we go to the next sentence in paragraph 3 of  
6 Exhibit 1077, it defines tablets. It states: "Tablets  
7 may be defined as solid dosage pharmaceutical forms  
8 containing drug substances with or without suitable  
9 fillers."

10 Do you see that?

11 A. Yes, ma'am.

12 Q. Exhibit 1077 does not define lozenges anywhere,  
13 correct?

14 A. I'd have to -- I don't -- didn't put that down  
15 to memory. I'd have to read the whole document to  
16 determine whether it does. It does identify  
17 fast-dissolving lozenges, which was the reason I  
18 referenced this document.

19 Q. Let's go to paragraph 40 of Exhibit 1077.

20 The last sentence of paragraph 40 states:  
21 "Tablets and other dosage forms, e.g., lozenges, made  
22 therefrom rapidly dissolve when placed in the mouth,  
23 generally less than 30 seconds."

24 Do you see that?

25 A. Yes, ma'am.

1           Q.    And you quote this in your reply declaration,  
2 correct?

3           A.    Yes, ma'am.

4           Q.    This is the third and last reference to a  
5 lozenge in this Exhibit 1077, correct?

6           A.    I would have to go back and re-read the whole  
7 document. I didn't count the number of times "lozenge"  
8 was used, so I can't say if it is or it isn't.

9           Q.    If there are any other references to a lozenge  
10 in Exhibit 1077, you would have put them in your reply  
11 declaration, correct?

12          A.    Not necessarily. I -- I think the arguments  
13 were substantial where the document has already shown --  
14 talked about rapidly-dissolving lozenges, and I've  
15 identified it twice. I'm not so sure if a third or  
16 fourth time would have made any difference.

17                The document clearly shows that -- indicates a  
18 rapidly-dissolving lozenge.

19          Q.    And going back to your reply declaration,  
20 Exhibit 1093, the only other citation you have to  
21 Exhibit 1077 is paragraph 10, correct?

22          A.    Yes, ma'am.

23          Q.    You don't cite to any examples disclosed in  
24 Exhibit 1077, correct?

25          A.    I do not.

1           Q.    Then going to paragraph -- paragraphs 29 and 30  
2 of your reply declaration, you cite to Exhibit 1078,  
3 Augsburger, correct?

4           A.    Yes, ma'am.

5           Q.    And in paragraph 29, you cite to paragraph 143  
6 of Augsburger, correct, and paragraph 43?

7           A.    Yes, ma'am. I cite paragraph 43 and 143. I  
8 think I also cite 83 to 84.

9           Q.    Yes.

10          A.    And 79 and 85.

11          Q.    Let's turn to Exhibit 1078. This is the  
12 reference that you cite to in your reply declaration,  
13 correct?

14          A.    Yes, ma'am.

15          Q.    And in your reply declaration, you don't cite  
16 to any time frames for lozenges which have a rapid  
17 disintegration rate, correct, in paragraphs -- in  
18 paragraph 29, your reply declaration?

19          A.    I do not cite any times. It just indicates  
20 rapidly disintegration rates, which, again, a POSA would  
21 be familiar with what that means according to the FDA  
22 guidance.

23          Q.    And going back to Exhibit 1078, paragraph 43,  
24 the first sentence states: "The invention still further  
25 relates to methods for preparing rapidly-disintegrating

1 dosage forms comprising active cushioning components of  
2 the invention."

3 Do you see that?

4 A. Yes, ma'am.

5 Q. And the end of the second sentence refers to  
6 tablets or lozenges which have rapid disintegration  
7 rates.

8 Do you see that?

9 A. Yes, ma'am.

10 Q. What is the time frame that the lozenge, which  
11 has a rapid disintegration rate, would dissolve in?

12 A. Again, a POSA would look at it based on -- it  
13 says rapidly-dissolving. So a POSA would look at it in  
14 relationship to the FDA guidance.

15 Q. Go to paragraph 143, page 9. This states: "In  
16 another embodiment, the present invention relates to a  
17 rapidly disintegrating lozenge."

18 Do you see that?

19 A. Yes, ma'am.

20 Q. What is the time frame that the rapidly  
21 disintegrating lozenge dissolves in paragraph 143?

22 A. Again, a POSA would look at that in  
23 relationship to the FDA guidance that we discussed  
24 previously.

25 Q. So Exhibit 1078 doesn't disclose a time frame

1 for when the lozenge is dissolved, correct?

2 A. I'd have to re-read the document. I didn't put  
3 that down to memory. It may be in there. I don't  
4 recall.

5 Q. If there was a time frame for a lozenge to be  
6 dissolved in, you would put it in your reply declaration,  
7 though, correct?

8 A. Possibly. Again, the goal was to identify  
9 rapidly-dissolving lozenges, which this document and  
10 those references did.

11 Q. And let's go to paragraph 61 of Exhibit 1078,  
12 page 4.

13 A. I'm -- I'm sorry. Which?

14 Q. Paragraph 61 of Exhibit 1078.

15 A. Paragraph 61. Okay. I'm sorry.

16 Q. There are a lot of numbers.

17 A. Yeah. Okay.

18 Q. Paragraph 61 states: "As used herein, the  
19 phrase 'fast-disintegrating tablet' encompasses a tablet  
20 having a disintegration time on the tongue without the  
21 addition of liquid beyond that normally available in the  
22 mouth due to salivation of between zero to due to 60  
23 seconds with the most preferred disintegration time of  
24 zero to 20 seconds."

25 Do you see that?

1 A. Yes, ma'am.

2 Q. This reference doesn't have a similar  
3 definition for a rapidly disintegrating tablet, correct?  
4 Or -- sorry, a rapidly disintegrating lozenge.

5 A. Again, I think the POSA would look at this  
6 as -- a fast disintegrating tablet as a general term, and  
7 that encompasses anything that is labeled as a fast  
8 disintegrating tablet. So that would include tablets,  
9 lozenges, capsules; whatever the inventor in this case  
10 indicated, that it's a fast-dissolving lozenge.

11 Q. Going back to your reply declaration, in  
12 paragraph 31, you cite to Exhibit 1079 to Tang, correct?

13 A. In paragraph 31?

14 Q. Yes.

15 A. Yes, ma'am, I do.

16 Q. Let's go Exhibit 1079. This is the reference  
17 that you cite to in your reply declaration, correct?

18 A. Yes, ma'am, it is.

19 Q. And if we go to column 14 of Exhibit 1079, in  
20 your reply declaration you quote from Tang, column 14,  
21 lines 9 to 13, correct?

22 A. Yes.

23 Q. That states: "In another embodiment, the  
24 invention provides 'fast melt' formulation. Such fast  
25 melt formulations are typically in the form of a tablet

1 or lozenge that dissolve or disperse in a patient's mouth  
2 in a minute without the need of water or chewing,"  
3 correct?

4 A. Yes, ma'am.

5 Q. If you look at Exhibit 1079, the next sentence  
6 after that sentence states: "Such fast melt formulations  
7 are described in WO 03/074029."

8 Do you see that?

9 A. Yes, ma'am.

10 Q. This reference, WO 03/074029, is the McEntee  
11 reference that you cite to in your reply declaration as  
12 Exhibit 1075, correct?

13 A. Yes, ma'am, it is.

14 Q. And the portion that you cite to from Tang from  
15 Exhibit 1075 -- excuse me -- Exhibit 1079 in your reply  
16 declaration is identical to the portion you quote from  
17 McEntee in your reply declaration, correct?

18 A. I'd have to check that.

19 Q. So we can compare paragraph 24 of your reply  
20 declaration, paragraph 21 of your reply declaration,  
21 starting with "such fast melt formulations" and "fast  
22 melt formulations."

23 A. Yeah. In paragraph 24, I don't see "such --" I  
24 don't see the same thing. I don't see "such fast melt  
25 formulations are typically" -- that. I don't see that in

1 paragraph 24.

2 Q. So after the word "such," starting in paragraph  
3 31, starting with "fast melt formulations are typically  
4 in the form of a tablet or lozenge that dissolve or  
5 disperse in a patient's mouth within a minute without the  
6 need of water or chewing," that is the same as the first  
7 sentence of the quote in paragraph 24, correct?

8 MR. LUMAN: Mischaracterizes the document.

9 THE WITNESS: The words are the same, but you  
10 could find that statement in any number of documents.

11 Now, whether it came specifically from that  
12 document, I can't say, because it is not verbatim with  
13 what's in the McEntee.

14 So if it was word for word, I would agree with  
15 you, but it is not word for word.

16 So is that verbiage similar to what is in  
17 there? The answer is it is. Did it come from there? I  
18 can't confirm that.

19 BY MS. AGARWAL:

20 Q. You do agree that the sentence in Exhibit 1079  
21 after the portion you quote, "Such fast melt  
22 formulations," starting with, "Such fast melt  
23 formulations," refers to the McEntee reference, correct.

24 A. Yeah, that does refer to the McEntee reference,  
25 yes.

1           Q.    And you don't cite to anything else from  
2   Exhibit 1079 in your reply declaration, correct?

3           A.    No.  That's the only thing I state to --  
4   because, again, I was -- the purpose was to identify the  
5   existence of fast-dissolving lozenges, and that paragraph  
6   did that.

7           Q.    And you don't cite to any definition of fast  
8   melt formulations or dissolution data from Exhibit 1079,  
9   correct?

10          A.    I did not.  I don't know if the document  
11   identified what the definition of rapidly disintegrating  
12   was, but it may be in there.  I don't recall it by  
13   memory.

14          Q.    If it were in the reference, you would have put  
15   it in your reply declaration, correct?

16          A.    Not necessarily.  Again, I think the statement  
17   was -- it was selected to show that a fast-dissolving  
18   lozenge does exist, and that document I selected does  
19   indicate that.

20          Q.    Okay.  And if you turn to column 17 of  
21   Exhibit 1079, starting at line 19 and going to column 19,  
22   line 44, 45, Exhibit 1079 discloses a number of examples,  
23   correct?

24          A.    Yes, ma'am, it shows eight examples.

25          Q.    You don't cite to any of these examples in your

1       reply declaration, correct?

2           A.    I do not.

3           Q.    Let's go back to your reply declaration.

4                In paragraph 32, you cite to Exhibit 1080 to  
5 Singh, correct?

6           A.    Yes, ma'am.

7           Q.    And you cite to paragraphs 57 and claim 11 in  
8 paragraph 32, and in paragraph 33 you cite to paragraph  
9 61 and 83 of Exhibit 1080, correct?

10          A.    Yes, ma'am.

11          Q.    And in paragraph 32, you quote portions of  
12 Singh, which refer to quick-dissolving tablets or  
13 lozenges, correct?

14          A.    Yes, ma'am.

15          Q.    And you quote, claim 11, which discloses a  
16 quick-dissolving lozenge or tablet, correct?

17          A.    Yes, ma'am.

18          Q.    You don't provide any time frame for  
19 dissolution for the disintegration rate for the  
20 quick-dissolving lozenge.

21          A.    Again, I didn't -- did not, because a POA  
22 would understand what those terms mean based on the FDA  
23 guidance.

24          Q.    And let's go to Exhibit 1080, to Singh. This  
25 is the reference you cite to in your reply declaration,

1 correct?

2 A. Yes, ma'am.

3 Q. Let's go to paragraph 57.

4 And the last sentence of paragraph 57 states:

5 "Preferably, the compositions of the present invention  
6 are formulated as a tablet or lozenge, in particular  
7 quick-dissolving tablets or lozenges, such as those  
8 described in U.S. Patent Publication No. 20050226925,"  
9 correct?

10 A. Yes, ma'am.

11 Q. How quickly does the quick-dissolving tablet or  
12 lozenge in this paragraph disintegrate?

13 A. Again, as a POA reads it, they -- they'd base  
14 that disintegration, it says rapidly disintegrating or  
15 quick-dissolving, they would follow the FDA guidance as  
16 to what that meant.

17 Q. If we go to claim 11, which is the claim you  
18 quoted in your reply declaration, correct?

19 A. Yes, ma'am.

20 Q. This discloses a quick-dissolving lozenge or  
21 tablet, correct?

22 A. Yes, ma'am, it does.

23 Q. How quickly would this quick-dissolving lozenge  
24 or tablet dissolve or disintegrate?

25 A. Again, a POA would know based on the FDA

1 guidance. It would go by the FDA guidance of a  
2 description of a quick-dissolving or an ODT product.

3 Q. If we go to claim 12, claim 12 states: "The  
4 pharmaceutical composition of claim 1, wherein the  
5 composition provides complete dissolution in about 6  
6 minutes or less following administration."

7 Do you see that?

8 A. Yes, ma'am.

9 Q. So would a quick-dissolving lozenge or  
10 tablet -- strike that.

11 Does a quick-dissolving lozenge or tablet  
12 always disintegrate within 60 seconds?

13 A. It depends on -- I would assume it would depend  
14 on the method you used. Based on the FDA guidance, they  
15 indicate 30 seconds using a USP method. So in -- in --

16 You've got two questions there: One is  
17 disintegration and one is dissolution.

18 Disintegration has to occur. Dissolution has  
19 to occur second.

20 So which one would you like me to respond to?

21 Q. So does -- would you understand a  
22 quick-dissolving lozenge, based on the FDA guidance, to  
23 always disintegrate within 60 seconds?

24 A. Their recommendation is -- if I recall, I'd  
25 have to go back and look. Let me check and make sure of

1 the approximately 30 seconds? Let's see. That was 1005,  
2 right? Its definition says "in a matter of seconds." It  
3 doesn't define number of seconds. For example, and it  
4 also says, for example, that talks about 30 seconds in  
5 there.

6 So I guess if you could repeat your question, I  
7 could try to answer it.

8 Q. Would you always expect a quick-dissolving  
9 lozenge to dissolve within 60 seconds?

10 A. Based on the FDA guidance, it talks about  
11 disintegration. It doesn't mention "dissolve." So it  
12 could easily disintegrate much sooner than 60 seconds,  
13 but it could take 60 seconds for it to dissolve.

14 Q. So you would understand a quick-dissolving  
15 lozenge or tablet to disintegrate within 60 seconds  
16 according to the US -- or according to the FDA guidance.

17 A. It -- it talks about disintegration in the  
18 guidance, and it says "seconds," dissolves within  
19 seconds. It doesn't define exactly the number of  
20 seconds, but it would have to disintegrate before it  
21 dissolves.

22 And -- and in 11 it talks about  
23 "quick-dissolving," and you've referenced six minutes, it  
24 talks about dissolving, but that disintegration could  
25 have occurred much sooner than that 6-minute time point.

1           Q.    The FDA guidance does give a time frame,  
2           correct? It adds on 30 seconds, or less, as part of the  
3           disintegration rate for orally disintegrating tablet,  
4           correct?

5           A.    What it does say is: "We surveyed applications  
6           of products submitted to Agency. Completed review in the  
7           laboratory show that although disintegrations did range  
8           from a few seconds to longer than a minute, the majority  
9           of these disintegrate within 30 seconds or less."

10                So that's based on data that they've observed.

11           Q.    And the last paragraph on numbered page 2, in  
12           Exhibit 1005, states that: "The FDA recommended that in  
13           addition to the original definition, ODTs be considered  
14           solid oral preparations that disintegrate rapidly in the  
15           oral cavities with an in vitro disintegration time of  
16           approximately 30 seconds or less," correct?

17           A.    Correct. But, again, it says "approximately 30  
18           seconds." So we've got some leeway there based on the  
19           size of the tablet, the type of disintegration  
20           formulation that was used. I think that's recommended --  
21           that's mentioned in -- if you go to page 3, in, like, the  
22           third paragraph, it talks about additional parameters for  
23           consideration.

24                MS. AGARWAL: We have been going for about an  
25           hour. Do you can want to take a break?

1 THE WITNESS: Sure.

2 (Recess was taken.)

3 BY MS. AGARWAL:

4 Q. Let's go to your reply declaration,  
5 Exhibit 1093, and go to paragraph 34.

6 A. Okay.

7 Q. And in the paragraph 34, you cite to  
8 Exhibit 1081, to Barman, correct?

9 A. Yes, ma'am.

10 Q. And you quote portions of Barman, paragraph 44,  
11 and claims 31 and 33 in Exhibit 1081, correct?

12 A. Yes, ma'am.

13 Q. And in quoting your first quote of Barman, of  
14 Exhibit 1081, you quote, "A fast-dissolving dosage form  
15 such as a tablet, troche, or lozenge," correct?

16 A. Yes, ma'am.

17 Q. And for claims 31 and 33, these claims refer to  
18 a method for preventing oral mucositis comprising the  
19 administration of fast-dissolving lozenge or troche  
20 dissolved in the mouth, correct?

21 A. Yes.

22 Q. You don't provide any time frame for  
23 dissolution or disintegration for the fast-dissolving  
24 lozenge in your reply declaration, correct?

25 A. I do not. Again, a POSA would follow the FDA

1 suggestion or guidance as to determining what that is.

2 Q. Let's go to Exhibit 1081, to Barman. This is  
3 the reference that you cite to in your reply declaration,  
4 correct?

5 A. Yes, ma'am.

6 Q. If we go to paragraph 44, it states: "A  
7 fast-dissolving dosage form, such as a tablet, troche, or  
8 lozenge or dry film, is preferable for delivery of the  
9 beta Glucan containing prophylactic or therapeutic in the  
10 oral space," correct?

11 A. Correct.

12 Q. It's your opinion that a POSA would read the  
13 fast-dissolving dosage form, such as a tablet, troche, or  
14 lozenge, to be according to the FDA guidance, correct?

15 A. Again, if it wanted to be a fast-dissolving  
16 dosage form, yes, ma'am.

17 Q. And does Exhibit 1081 disclose a time frame for  
18 fast-dissolving anywhere?

19 A. I'd have to re-read it, but I didn't -- I don't  
20 recall right offhand whether it does or doesn't.

21 Q. If it did, you would include that in your reply  
22 declaration, correct?

23 A. Again, maybe not. I -- I wouldn't think so,  
24 because, again, the goal was to identify fast-dissolving  
25 lozenges, and paragraph 44 indicates a fast-dissolving

1       lozenge, and a POSA would know based on FDA guidance what  
2       that means.

3             Q.     And if you -- and you don't cite to any  
4       examples of -- in Exhibit 1081, correct?

5             A.     I don't see where it indicates any examples.

6             Q.     Exhibit 1081 doesn't have any examples of a  
7       fast-dissolving lozenge, correct?

8             A.     I don't -- I don't see anything in there. It  
9       just references -- it indicates that the patent covers a  
10      fast-dissolving lozenge.

11            Q.     Let's go back to your reply declaration. In  
12      paragraph 35 you cite to Exhibit 1082 to Than; is that  
13      correct?

14            A.     Yes, ma'am.

15            Q.     And you cite to page 2 of Than which states  
16      that: "Compounding pharmacies can prepare unique routes  
17      of administration, such as a quick-dissolving lozenge, a  
18      lollipop, or a transdermal patch," correct?

19            A.     Yes, ma'am.

20            Q.     In your reply declaration, you don't provide  
21      any time frame for dissolution or disintegration for the  
22      quick-dissolving lozenge disclosed in Than, correct?

23            A.     Again, based on FDA guidance, that term is  
24      defined.

25            Q.     And if we go to Exhibit 1082, to Than, this is

1 the reference that you cite to in your reply declaration,  
2 correct?

3 A. Yes, ma'am.

4 Q. Go to page 2, about a little more than halfway  
5 down the page, where it states: "Prepare unique routes  
6 of administration such as quick-dissolving lozenge,  
7 lollipop, or transdermal patch." That's what you quote  
8 in your reply declaration, correct?

9 A. Yes, ma'am.

10 Q. And it's your opinion that the quick-dissolving  
11 lozenge disclosed here would dissolve or disintegrate  
12 according to the FDA guidance, correct?

13 A. A POSA would -- would read that as  
14 quick-dissolving and put that with the FDA guidance, yes,  
15 ma'am.

16 Q. Let's go back to your reply declaration,  
17 Exhibit 1093, and let's go to paragraph 52. Here in  
18 paragraph 52 you point to examples of solid ODT  
19 formulations that have the same drug dosage amount as the  
20 corresponding liquid formulation, correct?

21 A. Yes, ma'am.

22 Q. And then you list out four examples, correct?

23 A. Yes, ma'am.

24 Q. Those are Claritin, Zofran, Clarinex, and  
25 Pepcid, correct?

1 A. Yes, ma'am.

2 Q. The first example you point to is Claritin ODT  
3 and liquid syrup, which are both dosed at 10 milligrams,  
4 correct?

5 A. Yes, ma'am.

6 Q. Claritin or loratadine, I believe it's  
7 pronounced --

8 A. Uh-huh.

9 Q. -- is absorbed systemically to provide  
10 therapeutic effect, correct?

11 A. Yes, ma'am, it is.

12 Q. And that would be both the ODT and the liquid  
13 syrup, correct?

14 A. Yes, ma'am.

15 Q. And the ODT and liquid syrup are both  
16 administered orally, correct?

17 A. Yes, ma'am.

18 Q. And based on your knowledge, neither the ODT  
19 nor the liquid syrup has a modified release profile,  
20 correct?

21 A. I'd have to re-read the insert, but none of  
22 these would indicate that they -- at least these two  
23 products have a modified release, no, ma'am.

24 Q. So both the ODT and liquid syrup for Claritin  
25 are administered in the same route and have the same

1 release profile, correct?

2 A. They are administered the same route. I'd have  
3 to go back and look at the package inserts to see if  
4 they're bioequivalent or not. That, I don't know.

5 Q. Let's go to Exhibit 1089, which is the Claritin  
6 insert, correct?

7 A. Yes, ma'am.

8 Q. Okay. I apologize. It is very tiny.

9 On page 1, if you go to the third bolded  
10 section header, it says, "Pharmacokinetics Absorption."

11 Do you see that?

12 A. Yes, ma'am.

13 Q. The package insert here states, the second  
14 sentence, it starts with: "Based on a cross-study." I  
15 don't know if you can read that.

16 A. A little bit.

17 Q. Okay. It states: "Based on a cross-study  
18 comparison of single doses of loratadine syrup and  
19 tablets given to healthy adult volunteers, the plasma  
20 concentration profile of decarboethoxy-loratadine for the  
21 two formulations is comparable."

22 Do you see that?

23 A. Yes.

24 Q. This type of cross-study establishes that the  
25 syrup form and the tablet form have comparable plasma

1 concentrations in subjects, correct?

2 A. It does. This says "comparable." It doesn't  
3 say "bioequivalent," but it says "comparable," yes.

4 Q. That would mean the bioavailability of the drug  
5 is comparable or similar, correct?

6 A. Yeah, I don't know what their definition of  
7 "comparable" is, but it says, "comparable."

8 Q. Does the FDA define "bioequivalent"?

9 A. They do.

10 Q. And they define it as "comparable," correct?

11 A. That, I don't know. Bioequivalence has very  
12 defined parameters. I don't know whether "comparable" --  
13 I don't believe the FDA has a definition around  
14 "comparable."

15 Bioequivalence is very clear. They have very  
16 clear criteria.

17 Q. When switching from one dosage form to another,  
18 for example, from an ODT to a liquid, or vice versa, you  
19 would need to ensure that the -- there was  
20 bioequivalence, correct?

21 MR. LUMAN: Objection. Form; incomplete  
22 hypothetical.

23 THE WITNESS: When we go from one formulation  
24 to the next, we would do PK studies, and typically we  
25 would do a pharmacokinetic study, which would be

1 bioequivalence that shows based on bioequivalent --  
2 bioavailability parameters they are equivalent to the  
3 FDA, yes, ma'am.

4 BY MS. AGARWAL:

5 Q. Let's go back to your reply declaration. The  
6 second example you give is for Zofran, correct?

7 A. Yes, ma'am.

8 Q. And the Zofran ODT and the oral solution are  
9 both dosed at either 4 milligrams or 8 milligrams,  
10 correct?

11 A. Yes, ma'am.

12 Q. And you also state that the oral solution and  
13 the ODT are bioequivalent, correct?

14 A. Yes, ma'am.

15 Q. Zofran or -- I believe it's pronounced  
16 ondansetron --

17 A. Very good.

18 Q. -- are systemically acting, correct?

19 A. They are.

20 Q. That would be in both ODT and the oral  
21 solution, they're both systemically acting.

22 A. Correct. I would like to clarify one point.

23 Again, it goes back to disintegration. Whether  
24 a drug acts systemically or locally, it's based on the  
25 drug. It's a far bigger challenge to get a drug absorbed

1 orally than it is to get it to work topically.

2 In both cases, topical or oral, it has to  
3 interact with the GI tract.

4 And in the case of systemic, it has to get  
5 through the GI tract and then to the systemic. In the  
6 case of topical, it just has to interact with the  
7 topical.

8 So the fact that you can -- ODTs and oral  
9 solutions are equivalent systemically means there is  
10 going to be equivalent topically, as well, because  
11 topical interaction is the first step in getting the drug  
12 absorbed to get to the membrane.

13 Q. That wouldn't apply to drugs that are not  
14 systemically available, though, correct?

15 A. I'm not sure I understand the question. Could  
16 you rephrase it?

17 Q. So you described that systemically-acting  
18 drugs, there is the interaction with the GI tract. It  
19 needs to be absorbed.

20 A. Uh-huh.

21 Q. The topically-acting drugs, it's only the site  
22 of action that matters, correct?

23 A. That's actually not true. In the case of  
24 desonide, not only does it interact topically, but it  
25 does get in the systemic, but it's cleared by the liver

1 before it gets to the systemic.

2 So the topical could be local, or it could be  
3 systemic. It's just that it's cleared before it gets to  
4 the bloodstream.

5 But irrespective, topical or systemic, there is  
6 always an interaction with the GI tract, topically or  
7 systemically, for that -- for any drug.

8 Q. When you talk about the absorption of the  
9 budesonide systemically, that's not referring to any  
10 therapeutic effect, correct, because therapeutic effect  
11 of budesonide is topical?

12 A. That's correct. The -- there is a topical  
13 effect with the interaction with the system. The drug  
14 does get absorbed, but it's metabolized by the liver  
15 before it gets to generating any systemic activity.

16 Q. What percentage of budesonide is absorbed?

17 A. You know, I -- I think it's around 10 percent.  
18 I think that was the number that Dr. Davies mentioned in  
19 his reply, but I'm -- it's in -- it's low enough to where  
20 it doesn't generate any systemic effect.

21 Q. I believe we were talking about Zofran in your  
22 example, paragraph 52 of your reply declaration.

23 So based on the discussions that we just had,  
24 and your statement here that the ODT in oral solutions of  
25 Zofran are bioequivalent, that would mean that both the

1 ODT and the oral solution have similar rates of  
2 absorption into the bloodstream, correct?

3 A. Yes, ma'am.

4 Q. Okay.

5 A. Whether you give it as an ODT or an oral  
6 solution, you're going to get the same blood levels.

7 Q. And that's important -- the absorption is  
8 important for therapeutic effect for a drug like Zofran,  
9 correct?

10 A. For that drug, yes, ma'am.

11 Q. The third example, you cite to is Clarinex or  
12 desloratadine, correct?

13 A. Yes, ma'am.

14 Q. And the Clarinex ODT and liquid syrup are both  
15 dosed at 5 milligrams, correct?

16 A. Yes, ma'am.

17 Q. And desloratadine is systemically acting,  
18 correct?

19 A. Yes, ma'am.

20 Q. Let's go to Exhibit 1091. This is the exhibit  
21 you cite to for your Clarinex example, correct?

22 A. Sorry. I phased out. My apologies.

23 Q. Okay. If you turn to page 2, there is a  
24 heading that states, "Pharmacokinetic Absorption,"  
25 correct?

1           A.    Yes, ma'am.

2           Q.    And this section goes from page 2 to page 3,  
3 correct?

4           A.    Yes, ma'am.

5           Q.    And at the top of page 3, the first paragraph  
6 states: "The pharmacokinetic profile of Clarinex syrup  
7 was evaluated in a three-way crossover study in 30 adult  
8 volunteers. A single dose of 5 mls of Clarinex syrup  
9 containing 5 milligrams of desloratadine was  
10 bioequivalent to a single dose of 5 milligrams Clarinex  
11 tablet."

12                   Do you see that?

13          A.    Yes, ma'am.

14          Q.    Are so this type of study establishes that the  
15 syrup form and the tablet form have bioequivalence,  
16 correct?

17          A.    Yes. It means that an ODT that disintegrates  
18 or dissolves in the mouth in a small volume is equivalent  
19 to the bioavailability of, in this case, an oral syrup.  
20 Yes, ma'am.

21          Q.    Corticosteroids, such as budesonide, have very  
22 low bioavailability, correct?

23          A.    I don't know that. I know budesonide and that  
24 there are corticosteroids like Prednisone, Prednisolone,  
25 they're systemically active, but I don't know what

1 percent of bioavailability.

2 Q. A topical corticosteroid, such as budesonide,  
3 has low to no bioavailability, correct?

4 A. No, that's not true. It -- it acts locally.  
5 It gets to the liver, and it's rapidly metabolized to its  
6 inactive form. So it depends on how you define  
7 "absorbed."

8 The FDA defines "absorbed" as to what gets in  
9 the systemic circulation, whether it is active or  
10 metabolized.

11 So in the case of budesonide, I'm assuming that  
12 it's metabolized to an inactive. You may still measure  
13 that, and that's how you use to calculate their overall  
14 bioavailability.

15 Q. The '729 Patent claims topical corticosteroids  
16 with no systemic activity, correct?

17 A. Correct. Right. But, again, as I said  
18 previously, budesonide doesn't have activity, because  
19 it's rapidly metabolized in the liver. So its active  
20 component gets to the systemic circulation in very, very  
21 small amounts.

22 Q. So for the '729 Patent, in topical  
23 corticosteroids, a measure of bioavailability is not  
24 appropriate or relevant to determine the therapeutic  
25 effect of that corticosteroid, correct?

1 MR. LUMAN: Mischaracterizes the document;  
2 incomplete hypothetical.

3 THE WITNESS: The -- if you're asking in those  
4 studies, would you do -- measure blood levels. Is that  
5 what you are asking?

6 BY MS. AGARWAL:

7 Q. I'm asking whether a measure of bioavailability  
8 is relevant to determine the therapeutic effect of a  
9 topical corticosteroid.

10 A. The FDA expects you, even for topical, any  
11 topical, to measure blood levels to determine what  
12 percentage gets there systemically, so that PK analysis  
13 is done.

14 In the case of budesonide, it works locally.  
15 It's rapidly metabolized in the liver, but it's still  
16 going to generate some PKs.

17 So the FDA requires the company to understand  
18 that drug and that process.

19 Does that answer your question?

20 Q. But that's not relevant to therapeutic effect  
21 of budesonide, correct?

22 A. It -- the therapeutic effect is topically, but  
23 you still have to measure that in clinical studies to  
24 ensure that your formulation hasn't changed where you get  
25 a higher bioavailability than in a different formulation.

1 But the efficacy isn't determined -- isn't  
2 determined by PK. It's determined by clinical studies.

3 Q. The fourth example that you give in paragraph  
4 52 is Pepcid or famotidine, correct?

5 A. Famotidine, yes, ma'am.

6 Q. I got three out of four.

7 A. You are doing very well for a non-pharmacist.  
8 You're doing excellent.

9 Q. The Pepcid ODT and oral suspension are both  
10 dosed at 40 milligrams, correct?

11 A. Correct.

12 Q. And the ODT and the oral suspension are  
13 bioequivalent, correct?

14 A. Correct. So this example, along with the other  
15 three, show that -- or two of the three that have  
16 bioequivalence -- that you can take an ODT and get an  
17 equivalent exposure as you do a solution or suspension.

18 In this case, it's a suspension, not a  
19 solution.

20 So -- so, again, it shows a POSA, that going  
21 from a solution or a suspension to an ODT, you don't have  
22 to change the dose, and you're going to get similar  
23 bioavailability systemically, which means you're going to  
24 get similar exposure topically, because you have to give  
25 the same exposure topically to the GI tract to get the

1 same exposure systemically.

2 Q. Where in the GI tract are these systemic drugs  
3 absorbed according to the example?

4 A. I couldn't even begin to tell you.

5 An absorption can occur in the stomach. It can  
6 occur in the early small intestine. It can occur in the  
7 late small intestine. I've developed drugs that had high  
8 absorption in the colon. So I'd have to sit down and  
9 evaluate each drug to figure out where they're absorbed  
10 at. And it could be all the way across those areas.

11 Q. And none of those are in the upper GI tract,  
12 correct?

13 A. I have no idea. The -- the famotidine is used  
14 to treat ulcers. So that could be ulcers in the stomach  
15 and the esophagus, because you have reflux. So at least  
16 famotidine could be to treat ulcers in the lower  
17 esophagus, early small -- which is the early small  
18 intestine, early GI tract, or the stomach.

19 Q. But the famotidine is a systemically-acting  
20 drug, correct?

21 A. It is. But it may have a topical component. I  
22 don't -- I know what the drug is used for. I don't know  
23 if it's just systemic or if it's topical as well.

24 But you asked, these don't work in the upper GI  
25 tract, and the answer is Pepcid does, because it could be

1 the stomach or the esophagus where the ulcers are at.

2 Q. Your reply declaration doesn't cite to any  
3 examples that show a topically-acting corticosteroid in  
4 liquid form that can use the same dose as a  
5 topically-acting drug in an ODT, correct?

6 A. I'm sorry. Rephrase that again.

7 Q. You don't cite to anything in your reply  
8 declaration that shows a topically-acting corticosteroid  
9 in a liquid form that has the same dose as a  
10 topically-acting corticosteroid in an ODT, correct?

11 MR. LUMAN: Objection. Mischaracterizes the  
12 document.

13 THE WITNESS: I don't show specific examples,  
14 but, again, a POSA would realize topically is very easy  
15 to do, because I don't have to get the drug absorbed. So  
16 if I can get the same level of drug with an ODT, as I do  
17 with the syrup or a solution, which these four examples  
18 show, I can do it with a systemic, if I can do it with a  
19 systemic, a POSA would know you can do it topically,  
20 because it has to interact topically before it can go  
21 systemically.

22 So by proving it's a systemic activity, a  
23 priority would prove that it's working topically or -- or  
24 it interacts topically for that topical drug to do what  
25 it needs to do.

1           So that was the purpose of these examples, is  
2   to show -- in particular, topical, I don't need a higher  
3   dose. Systemically, I don't need a higher dose. So,  
4   topically, I shouldn't need a higher dose, either, a POSA  
5   would know that, for the same indication.

6           Now, if you changed medical indications, then  
7   that might change.

8           But for the same indication, you shouldn't need  
9   that if it's an ODT versus a solution or a suspension.

10          MS. AGARWAL: Let's take a five-minute break  
11   before we go on to the next topic.

12          MR. LUMAN: Sure.

13          (Recess was taken.)

14   BY MS. AGARWAL:

15          Q. Let's turn to paragraph 75 of your reply  
16   declaration, and in this paragraph you refer to the '865  
17   Patent, correct?

18          A. Yes, ma'am.

19          Q. That is Exhibit 1085.

20          A. Yes, ma'am.

21          Q. Let's go to Exhibit 1085. This is the patent  
22   you are referring to in your reply declaration, correct?

23          A. Yes, ma'am.

24          Q. Look at the first sentence of the abstract. It  
25   states: "A taste-masked microcapsule composition for

1 administration of the drug is provided," correct?

2 A. Yes, ma'am.

3 Q. If we go to column 4 of the '865 Patent, line  
4 12, 12 or 13, it starts: "The term 'drug'" in quotation  
5 marks.

6 A. Yes, ma'am.

7 Q. Do you see that?

8 A. Yes, ma'am.

9 Q. And so this paragraph defines the term "drug,"  
10 correct?

11 A. It says, "Any therapeutic, or otherwise, active  
12 agents," yes.

13 Q. And it goes on to state: "Drugs useful in  
14 conjunction with the present invention include  
15 antibiotics, antiviral agents," et cetera, and it lists a  
16 bunch of drugs, correct?

17 A. Yes, ma'am.

18 Q. Corticosteroids are not listed in this list of  
19 useful drugs, correct?

20 A. I'd have to quickly peruse it.

21 Q. Okay.

22 A. What I will say is it -- in general, it  
23 indicates antiinflammatory agents, I think on line -- it  
24 must be 19. Corticosteroids are antiinflammatory agents.  
25 So corticosteroids would fall in that general category,

1 as you list general categories.

2 Now, I'll have to look and see it if mentions  
3 corticosteroids specifically.

4 I don't -- I don't see anything in there that  
5 lists necessarily specific drugs. He just lists class of  
6 drugs, and, again, the corticosteroids fall in the area  
7 of antiinflammatory agents.

8 Q. And if you go further down in the paragraph,  
9 around line 28, it states: "Generally, the drugs used in  
10 conjunction with the present methodology are those which  
11 are bitter, or otherwise unpleasant tasting, and thus in  
12 need of taste-masking."

13 Do you see that?

14 A. Yes, ma'am.

15 Q. And if we go to claim 1 of the '865 Patent,  
16 claim 1 claims a taste-masked microcapsule composition,  
17 correct?

18 A. Yes.

19 Q. And it is a microcapsule composition of a  
20 water-soluble drug, correct?

21 A. Yes.

22 Q. And claim 2 claims the taste-masked  
23 microcapsule composition, correct?

24 A. Yes, ma'am.

25 Q. And claim 3 claims the taste-masked

1 microcapsule composition of a water-soluble drug,  
2 correct?

3 A. Yes, ma'am.

4 Q. And budesonide is not a water-soluble drug,  
5 correct?

6 A. In its low dose, it may very well be. I don't  
7 know exactly.

8 Q. Are corticosteroids generally water-soluble?

9 A. It depends on their -- each compound could be  
10 different, and it would depend on their dose. So I  
11 can't -- and I don't know if we're -- I don't exactly  
12 know for any of the compounds. So some of them could be  
13 highly water-soluble -- some could be water-soluble; some  
14 could not.

15 Q. And one last claim I want to point you to,  
16 claim 4 claims the taste masks microcapsule composition,  
17 correct?

18 A. Yes, ma'am.

19 Q. Claims 1, 2, 3, and 4 are directed to  
20 taste-masking, correct?

21 A. They are, but I think if you -- again, look at  
22 my report. The reason I looked at that is while it's  
23 taste-masked, it also says it releases a drug rapidly  
24 once it passes the mouth. So it shows, if I recall  
25 correctly, rather the taste-mask loss is virtually

1 immediately, and shortly thereafter.

2 So, again, it is to show that this taste-mask  
3 could be used in an ODT.

4 I'm not denying that this talks about  
5 taste-masking, but it -- it talks about taste-masking,  
6 but it also says that it allows the virtual immediate  
7 release shortly after it passes through the mouth.

8 Q. So I believe you're referring to paragraph 76  
9 of your reply declaration.

10 A. Yes, ma'am.

11 Q. And you cite to a few places in the '865 Patent  
12 in that paragraph, correct?

13 A. Yes, ma'am.

14 Q. And the first quote that you cite to is what  
15 you're referring to as the virtually immediate release of  
16 the drug, correct?

17 A. Yes, ma'am.

18 Q. You don't define what "immediate release" means  
19 in your reply declaration, correct?

20 A. I do not indicate that. Again, it's -- I think  
21 as you talk about, it does say shortly after -- virtually  
22 immediately and shortly after passage to the mouth. So  
23 it's -- when you say "virtually immediately," it means  
24 very, very short; very, very quick, a POA would  
25 interpret that as.

1           What the time would be? To me "virtually  
2 immediately" is seconds, and I think a POSA would look at  
3 "virtually immediately" as seconds.

4           Q.    If we go back to Exhibit 1085, which is the  
5 '865 Patent, and look at that quote in column 2, line 65  
6 to column 3, line 3, and the end of that sentence in  
7 column 3 states: "Achieving virtually immediate release  
8 of the drug," correct?

9           A.    Correct.

10          Q.    The '865 Patent -- or does the '865 Patent  
11 define "immediate release"?

12          A.    I'd have to read it. I don't remember it at  
13 that level of detail.

14                Again, as a POSA reads, virtually immediate  
15 release would mean a very, very short period of time.

16          Q.    Does the FDA have a definition for immediate  
17 release?

18          A.    They have a rapid releasing -- they do define  
19 different things, and I believe rapid -- very rapid  
20 releasing is -- is 80 percent at 15 minutes. So anything  
21 faster than that is considered very rapid release. I  
22 believe that's the correct number. I might be not quite  
23 right. And so that -- and so that could entertain  
24 anywhere from immediate to within -- you know, 80 percent  
25 within a minute or less to up to 15 minutes. And the FDA

1 considers those equivalent to a solution.

2 Q. If we turn to column 8 of the '865 Patent, line  
3 47, all the way to the end, it starts: "In," going to  
4 the next line, "quantitative terms."

5 Do you see that?

6 A. Yes, ma'am.

7 Q. It states: "In quantitative terms, the  
8 targeted release microcapsules desirably provide  
9 dissolution of at least 75 percent of the drug within 45  
10 minutes when tested according to the United States  
11 pharmacopeia dissolution activity."

12 Do you see that?

13 A. Yes, ma'am.

14 Q. Does this provide any guidance as to what  
15 "immediate release" means in the '865 Patent?

16 A. It -- it doesn't, because it says, at least  
17 or at -- at least about 75 and 45 minutes.

18 I could have 75 percent released in one minute,  
19 and it still meets 75 and 45 minutes.

20 So unless you have a full profile, it can be  
21 anything along that.

22 When I develop a product, I try to get as wide  
23 a dissolution spec as I can so I don't fail batches. So  
24 even if my drug is a very rapidly, and it dissolves  
25 within 5 minutes, I'm shooting for a spec at 75 percent

1 in 45 minutes. Actually, I shoot for 80 percent, because  
2 that's -- that's what the FDA's target is in 45 minutes.  
3 That way, you never have to worry about any batches  
4 failing. So that's a target.

5 That doesn't indicate what the actual release  
6 rate is. I mean a POSA sees "virtually immediately," or  
7 whatever -- yeah, "virtually immediately," they would  
8 think it as much faster than 75 percent at 45 minutes.

9 Q. Let's move on to the second quote that you have  
10 in your reply declaration. The last sentence quoting  
11 from the abstract states: "These high-coating levels  
12 give rise to effective taste-masking, while nevertheless  
13 targeted release of the drug."

14 A. I'm sorry. Can you -- which paragraph are we  
15 on?

16 Q. The second full one.

17 A. "The composition comprises"?

18 Q. Yes. The last sentence of that.

19 A. Uh-huh.

20 Q. "These high-coating levels give rise to  
21 effective taste-masking, while nevertheless allowing  
22 targeted release of drugs so that the drug is released  
23 shortly after passage through the mouth."

24 Do you see that?

25 A. Yes, ma'am.

1           Q.    And that's what you were referring to as the  
2 drug being released shortly after passage through the  
3 mouth.

4           A.    Yes, that's what the cap said. It goes along  
5 with the virtually immediately releasing the drug.

6           Q.    Does the '865 Patent define how long after the  
7 drug passes through the mouth the drug would be released?

8           A.    It doesn't give a time, but it says, "virtually  
9 immediately." So, again, a POSA would look at it going,  
10 that's -- "virtually immediately" is within seconds.

11          Q.    Let's go back to Exhibit 1085, the '865 Patent.  
12 If you turn to column 9, we go to lines 23, 25, it  
13 states: "An ideal taste-masking microcapsule would allow  
14 no dissolution of the drug at all in one minute."

15                Do you see that?

16          A.    Yes, I do.

17          Q.    So the '865 Patent teaches that the drug is not  
18 released at all in one minute, correct?

19          A.    It says, An ideal taste-masking microcapsule  
20 would not -- would allow no dissolution of the drug in  
21 one minute.

22                And then it says, "Thus, the preferred  
23 microcapsule should allow dissolution of considerably  
24 less than 75 percent of the drug in one minute."

25                So they've already -- they right there -- it

1 said "the preferred microcapsule should allow dissolution  
2 of considerably less than 75 percent of the drug in one  
3 minute." So they have already set a limit of 75 percent.

4 Then they go down to 50 percent, 25, and 5.

5 So they've already acknowledged that -- that  
6 there are targets that it could release within one  
7 minute.

8 Q. If you keep going after less than 5 percent, it  
9 says, "Less than 1 percent are still more preferred,"  
10 correct?

11 A. Correct. It does. So, obviously, the lower  
12 the better, but it still says the preferred is less than  
13 75, and it just keeps working its way down.

14 So as a POSA reads that, okay, we could have --  
15 as long as you have less than 75 percent a minute, it  
16 meets one of the embodiments of this patent.

17 Q. And you agree that this reference is directed  
18 towards taste-masking of bitter drugs, correct?

19 A. One facet of this is taste-masking, but it also  
20 continuously stresses that while there it effectively  
21 taste-masks, it allows the drug to work, to be released  
22 virtually immediately, and then -- and that section  
23 implies that it can be used in ODTs.

24 So does it have a taste-masking component?  
25 Absolutely. But it also stresses the value of the patent

1 around virtual immediate release of the drug.

2 Q. Releasing the drug in the mouth would defeat  
3 the purpose of the taste-masking that's disclosed in the  
4 '865 Patent, correct?

5 A. Right. But it says it virtually releases  
6 shortly after passage through the mouth. So it's not  
7 saying -- this patent doesn't say releasing it. It says  
8 it rapidly releases or it virtually immediately releases  
9 it after it leaves the mouth.

10 So the time between when it leaves the mouth  
11 and it gets into the stomach, it could release in the  
12 esophagus.

13 Q. If we go to column 6 of the '865 Patent,  
14 starting at line 56, it states that: "Another preferred  
15 class of drugs are water-soluble H2-antagonists, more  
16 preferably H2-antagonists selected from the group  
17 consisting of ranitidine; famotidine," et cetera.  
18 Correct?

19 A. Yes, ma'am.

20 Q. Then it gives the example of ranitidine.

21 A. Ranitidine, yes, ma'am.

22 Q. And ranitidine is a systemically-acting drug,  
23 correct?

24 A. Yes, ma'am, it is, to the best of my knowledge.  
25 Yes, it is.

1           Q.    So the taste-masking of ranitidine,  
2               specifically, would ensure that the drug is taste-masked  
3               in the mouth, but would not affect bioavailability,  
4               correct?

5           A.    That would be an intent, yes. That would be  
6               taste-masked well enough to mask it, but it would release  
7               the drug virtually immediately, which means early in the  
8               small -- early in the GI tract, so it was available to be  
9               absorbed throughout the whole GI tract.

10               So the patent is really designed, in my mind,  
11               as a POSA would look at, as two things: Taste-masking,  
12               but still being able to -- to achieve a virtual release  
13               of a drug to allow its best chance for being absorbed; or  
14               to work actively, locally within the GI tract.

15           Q.    How long would a drug like ranitidine last in  
16               the stomach or the GI tract while it's being absorbed?

17               MR. LUMAN: Incomplete hypothetical.

18               THE WITNESS: What do you mean? Can you repeat  
19               the question again?

20           BY MS. AGARWAL:

21           Q.    Yes. How -- for how long would a drug like  
22               ranitidine last in the stomach or the GI tract while it's  
23               being absorbed?

24               MR. LUMAN: Incomplete hypothetical.

25               THE WITNESS: What do you mean by "last"?

1 BY MS. AGARWAL:

2 Q. How long would it take for it to be completely  
3 absorbed?

4 MR. LUMAN: Same objection.

5 THE WITNESS: To the best of my knowledge,  
6 ranitidine is not completely absorbed. It has low  
7 bioavailability. I don't recall us doing -- I worked on  
8 the drug, so I don't -- but I don't recall us doing  
9 regional absorption studies. So I don't know exactly  
10 where it is absorbed at. So I can't answer that  
11 question, sorry.

12 BY MS. AGARWAL:

13 Q. How long does it take for a tablet or something  
14 that you swallow to go from the mouth to the stomach?

15 A. It -- it depends on the size of the tablet. It  
16 could be anywhere from -- I'm estimating now -- probably  
17 4 or 5 seconds up to hours. It all depends on the size  
18 of the dosage form. It depends on the surface coating of  
19 the tablet or capsule. Is it tacky? If they're large,  
20 and they're tacky, they can hang up in a sphincter that  
21 connects the esophagus to the stomach, and the patient  
22 never knows that. So it could be anywhere from, like I  
23 said, four to five seconds to hours.

24 Q. An orally disintegrating tablet, an ODT, how  
25 long would it take for an ODT to transverse from the

1 mouth to the stomach?

2 A. I haven't measured those times, but based on  
3 the way they work, I would expect them to be more in the  
4 matter of seconds to minutes, because it is a small  
5 volume, as I indicated in my report.

6 Usually, when you get about 1.1 mls, which is  
7 what's in the literature, 1 to 2 mls, you'll swallow, and  
8 so it's -- but it's going to be a small volume of a few  
9 mls that's going to take its time to work down the  
10 esophagus, or it takes much longer for an ODT than it  
11 would for a standard immediate-release tablet that you  
12 swallow with large amounts of water.

13 Q. Let's go back to your reply declaration.

14 In paragraph 77, you cite to the '865 Patent's  
15 disclosure of a porous structure, correct?

16 A. Yeah, what I -- what I recite from it is it  
17 talks about the polymeric walls and the microcapsule and  
18 the form by coacervation and that they typically have  
19 pores, yes, they do, in 77.

20 Q. And go back to the '865 Patent, Exhibit 1085,  
21 to where you cite to that porous structure. It is column  
22 9, and starting at line 31 of column 9, it states:  
23 "Although the present invention is not limited by any  
24 theory of operation, it is believed that the polymeric  
25 walls of the microcapsules, particularly those formed by

1       coacervation, typically have pores," correct?

2             A.    Yes, ma'am.

3             Q.    And if you go down further to line 41, it  
4       states that: "Another mechanism of release is believed  
5       to occur --" sorry. Let me start again.

6             "Another mechanism of release, which is  
7       believed to occur, is breakage of the coating," correct?

8             A.    Yes, ma'am.

9             Q.    And if we go to column 1 of the '865 Patent,  
10       starting at line 62, it states: "In contrast to prior  
11       microencapsulation techniques, the present invention  
12       makes use of materials and process parameters which  
13       enable preparation of uniform, impervious coatings, and  
14       involves preparation and formulations of having high  
15       coating levels."

16            Do you see that?

17            A.    Yes, ma'am.

18            Q.    "impervious coating" indicates that the drug is  
19       completely coated by the taste-masking coating, correct?

20            A.    Yeah, but if you continue on at paragraph -- up  
21       to 2, it talks -- "taste-masking while providing for  
22       release of drug shortly after the drug passes through the  
23       mouth."

24            So is it impervious? Does it protect  
25       taste-masking? It does. We've discussed that, and I

1 agree with that.

2 But it also discusses that it provides for the  
3 release of the drug shortly after it passes the mouth, so  
4 it passes very quickly, and -- and this inventor  
5 indicated a possible couple of mechanisms by which that  
6 occurs.

7 Q. Impervious would indicate there are no pores,  
8 correct?

9 A. No, not necessarily. Impervious could mean you  
10 can't go through the -- you can't go through the polymer  
11 itself, but you can -- you could go through the pores,  
12 which is how they indicated their mechanism of action --  
13 one of the two mechanisms of actions that they propose.

14 Q. There is no example of the mechanism of action  
15 working in the way that they propose through the pores,  
16 correct, in the '865 Patent?

17 MR. LUMAN: Form.

18 THE WITNESS: They -- they're the authors.  
19 They proposed two possible mechanisms. I think they --  
20 if we go back to -- remind me what that paragraph is.  
21 BY MS. AGARWAL:

22 Q. In column 9.

23 A. They may have indicated there were other ones.  
24 And they say here -- I think they also said somewhere in  
25 there irrespective -- regardless of the reason for these

1 effects, these -- it can be adjusted to adjust the  
2 release rate of the drug.

3 So, again, the patent indicates we can  
4 effectively taste-mask it, but we can have virtually  
5 immediate release of the drug after it leaves the mouth.

6 So, you know, how they define impervious and  
7 then the fact that they can release the drug rapidly  
8 based on these mechanisms is what the patent entails.

9 MS. AGARWAL: I have no further questions.

10 THE WITNESS: Thank you.

11 MR. LUMAN: We have no further question,  
12 either. So we can go off the record.

13 (The deposition adjourned at 11:36 a.m.)

14 \* \* \*

15 I declare under penalty of perjury, under the  
16 laws of the State of California, that the foregoing  
17 testimony, as corrected, is the truth, the whole truth,  
18 and nothing but the truth.

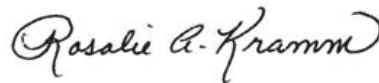
19  
20  
21 \_\_\_\_\_  
22 ALAN PARR, PHARM.D  
23  
24  
25

REPORTER'S CERTIFICATE

I, Rosalie A. Kramm, Certified Shorthand Reporter for the State of California, do hereby certify:

That the witness named in the foregoing deposition was by me duly sworn; that the deposition was then taken before me at the time and place herein set forth; that the testimony and proceedings were reported stenographically by me and were transcribed through computerized transcription by me; that the foregoing is a true record of the testimony and proceedings taken at that time; and that I am not interested in the event of the action.

Witness my hand dated August 28, 2025.



ROSALIE A. KRAMM

CSR 5469, RPR, CRR

1 Nathanael Luman, Esq.

2 nate.luman@knobbe.com

3 August 29, 2025

4 RE: Pharma, Falk GMBH v. Ellodi Pharmaceuticals LP  
5 8/25/2025, Alan Parr , Pharm.D (#7534844)

6 The above-referenced transcript is available for  
7 review.

8 Within the applicable timeframe, the witness should  
9 read the testimony to verify its accuracy. If there are  
10 any changes, the witness should note those with the  
11 reason, on the attached Errata Sheet.

12 The witness should sign the Acknowledgment of  
13 Deponent and Errata and return to the deposing attorney.  
14 Copies should be sent to all counsel, and to Veritext at  
15 cs-midatlantic@veritext.com.

16 Return completed errata within 30 days from  
17 receipt of testimony.

18 If the witness fails to do so within the time  
19 allotted, the transcript may be used as if signed.

20  
21  
22 Yours,

23 Veritext Legal Solutions  
24  
25

Pharma, Falk GMBH v. Ellodi Pharmaceuticals LP  
Alan Parr , Pharm.D (#7534844)

E R R A T A S H E E T

PAGE\_\_\_\_\_ LINE\_\_\_\_\_ CHANGE\_\_\_\_\_

REASON\_\_\_\_\_

PAGE\_\_\_\_\_ LINE\_\_\_\_\_ CHANGE\_\_\_\_\_

REASON\_\_\_\_\_

PAGE\_\_\_\_\_ LINE\_\_\_\_\_ CHANGE\_\_\_\_\_

REASON\_\_\_\_\_

PAGE\_\_\_\_\_ LINE\_\_\_\_\_ CHANGE\_\_\_\_\_

REASON\_\_\_\_\_

PAGE\_\_\_\_\_ LINE\_\_\_\_\_ CHANGE\_\_\_\_\_

REASON\_\_\_\_\_

PAGE\_\_\_\_\_ LINE\_\_\_\_\_ CHANGE\_\_\_\_\_

REASON\_\_\_\_\_

Alan Parr , Pharm.D

Date

Pharma, Falk GMBH v. Ellodi Pharmaceuticals LP

Alan Parr , Pharm.D (#7534844)

ACKNOWLEDGEMENT OF DEPONENT

I, Alan Parr , Pharm.D, do hereby declare that I have read the foregoing transcript, I have made any corrections, additions, or changes I deemed necessary as noted above to be appended hereto, and that the same is a true, correct and complete transcript of the testimony given by me.

\_\_\_\_\_  
Alan Parr , Pharm.D

\_\_\_\_\_  
Date

\*If notary is required

SUBSCRIBED AND SWORN TO BEFORE ME THIS  
\_\_\_\_\_ DAY OF \_\_\_\_\_, 20\_\_\_\_.

\_\_\_\_\_  
NOTARY PUBLIC

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                         |                                                                                                                                                                                              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>0</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>1079</b> 30:12,16<br>30:19 31:5,15<br>32:20 33:2,8<br>33:21,22                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>143</b> 27:5,7<br>28:15,21<br><b>15</b> 22:23 61:20<br>61:25                         | <b>21</b> 15:6 31:20<br><b>22</b> 16:6<br><b>23</b> 4:17 10:25<br>11:24 15:4<br>64:12                                                                                                        |
| <b>03/074029</b> 31:7<br>31:10                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>17</b> 33:20<br><b>18</b> 11:15<br><b>18769</b> 73:19<br><b>19</b> 33:21,21<br>57:24 | <b>24</b> 11:15 12:6<br>13:13 14:22,25<br>31:19,23 32:1<br>32:7                                                                                                                              |
| <b>1</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>1080</b> 34:4,9,24<br><b>1081</b> 39:8,11,14<br>40:2,17 41:4,6<br><b>1082</b> 41:12,25<br><b>1083</b> 3:8 8:24<br><b>1085</b> 3:9 8:24<br>56:19,21 61:4<br>64:11 69:20<br><b>1089</b> 44:5<br><b>1091</b> 3:10<br>49:20<br><b>1092</b> 3:11 8:25<br><b>1093</b> 3:12 7:4<br>7:20 26:20<br>39:5 42:17<br><b>10th</b> 7:25 8:6<br>10:6<br><b>11</b> 34:7,15<br>35:17 37:22<br><b>11:36</b> 72:13<br><b>12</b> 36:3,3 57:4<br>57:4<br><b>120</b> 17:8 19:11<br>20:18,20,23<br>21:4,6,23<br><b>1299</b> 2:17<br><b>13</b> 11:14 30:21<br>57:4<br><b>14</b> 22:23 30:19<br>30:20 | <b>2</b>                                                                                | <b>25</b> 1:12 4:1<br>15:22 16:4,17<br>17:3 64:12<br>65:4<br><b>26</b> 15:22 16:4<br><b>27</b> 22:4,23<br>24:21,22<br><b>28</b> 12:23 22:4<br>58:9 73:16<br><b>29</b> 27:1,5,18<br>74:3      |
| <b>1</b> 36:4 44:9<br>58:15,16 59:19<br>65:9 69:7 70:9<br><b>1.1</b> 69:6<br><b>10</b> 8:25 10:20<br>17:8,9,9,10<br>19:6,11 20:17<br>20:23 21:23<br>22:8 26:21<br>43:3 48:17<br><b>1005</b> 3:7 18:3,4<br>23:11,17 37:1<br>38:12<br><b>1073</b> 3:8 8:24<br><b>1075</b> 12:7,19<br>13:17,21 14:1<br>14:5,21,24<br>31:12,15<br><b>1076</b> 15:23<br>16:3,19 17:1,2<br>19:5,16,17<br>20:21<br><b>1077</b> 22:5,8,10<br>22:14 23:5<br>24:11,12 25:6<br>25:12,19 26:5<br>26:10,21,24<br><b>1078</b> 27:2,11,23<br>28:25 29:11,14 | <b>2</b> 18:11,13 22:8<br>22:14,15 23:5<br>38:11 41:15<br>42:4 49:23<br>50:2 58:22<br>59:19 61:5<br>69:7 70:21<br><b>20</b> 12:23 14:21<br>17:11 29:24<br>76:15<br><b>20004-2400</b><br>2:18<br><b>20050226925</b><br>35:8<br><b>2007</b> 3:13 8:25<br>10:14<br><b>202.776.2102</b><br>2:19<br><b>2024-01197</b><br>4:20<br><b>2025</b> 1:12 4:1<br>7:25 8:6 10:6<br>73:16 74:3                                                                                                                                                                                                | <b>3</b>                                                                                | <b>3</b> 12:23 22:8<br>24:12,25 25:5<br>38:21 50:2,5<br>58:25 59:19<br>61:6,6,7<br><b>30</b> 12:5 17:10<br>18:25 19:6<br>20:3 25:23<br>27:1 36:15<br>37:1,4 38:2,9<br>38:16,17 50:7<br>74:16 |

|                       |                        |                       |                        |
|-----------------------|------------------------|-----------------------|------------------------|
| <b>300</b> 2:7        | <b>5469</b> 1:14 4:4   | <b>8</b>              | <b>absolutely</b>      |
| <b>30101</b> 4:17     | 73:21                  | <b>8</b> 46:9 62:2    | 65:25                  |
| <b>31</b> 30:12,13    | <b>56</b> 66:14        | <b>8,771,729</b> 1:7  | <b>absorbed</b> 16:15  |
| 32:3 39:11,17         | <b>57</b> 34:7 35:3,4  | <b>8/25/2025</b> 74:5 | 43:9 46:25             |
| 69:22                 | <b>6</b>               | <b>80</b> 61:20,24    | 47:12,19 48:14         |
| <b>32</b> 34:4,8,11   | <b>6</b> 36:5 37:25    | 63:1                  | 48:16 51:7,8           |
| <b>33</b> 34:8 39:11  | 66:13                  | <b>83</b> 27:8 34:9   | 54:3,9 55:15           |
| 39:17                 | <b>60</b> 15:25 16:6   | <b>84</b> 27:8        | 67:9,13,16,23          |
| <b>34</b> 39:5,7      | 16:19 17:10,11         | <b>85</b> 27:10       | 68:3,6,10              |
| <b>35</b> 11:15 41:12 | 29:22 36:12,23         | <b>858.707.4000</b>   | <b>absorption</b>      |
| <b>3579</b> 2:7       | 37:9,12,13,15          | 2:9                   | 44:10 48:8             |
| <b>4</b>              | <b>61</b> 29:11,14,15  | <b>865</b> 56:16 57:3 | 49:2,7,24 54:5         |
| <b>4</b> 3:4 29:12    | 29:18 34:9             | 58:15 60:11           | 54:8 68:9              |
| 46:9 57:3             | <b>62</b> 70:10        | 61:5,10,10            | <b>abstract</b> 56:24  |
| 59:16,19 68:17        | <b>64</b> 16:1         | 62:2,15 64:6          | 63:11                  |
| <b>40</b> 15:5 22:8   | <b>65</b> 61:5         | 64:11,17 66:4         | <b>access</b> 11:23    |
| 25:19,20 53:10        | <b>67</b> 15:25 17:1,2 | 66:13 69:14,20        | <b>accuracy</b> 74:9   |
| <b>41</b> 70:3        | 19:18                  | 70:9 71:16            | <b>achieve</b> 67:12   |
| <b>43</b> 27:6,7,23   | <b>7</b>               | <b>9</b>              | <b>achieving</b> 61:7  |
| <b>44</b> 33:22 39:10 | <b>700</b> 2:17        | <b>9</b> 28:15 30:21  | <b>acknowledged</b>    |
| 40:6,25               | <b>729</b> 4:23 51:15  | 64:12 69:22,22        | 65:5                   |
| <b>45</b> 33:22 62:9  | 51:22                  | 71:22                 | <b>acknowledge...</b>  |
| 62:17,19 63:1         | <b>75</b> 56:15 62:9   | <b>90</b> 17:9        | 76:3                   |
| 63:2,8                | 62:17,18,19,25         | <b>92130</b> 2:8      | <b>acknowledg...</b>   |
| <b>47</b> 62:3        | 63:8 64:24             | <b>9:02</b> 4:1       | 74:12                  |
| <b>5</b>              | 65:2,3,13,15           | <b>a</b>              | <b>acting</b> 46:18,21 |
| <b>5</b> 49:15 50:8,9 | <b>7534844</b> 74:5    | <b>a.m.</b> 4:1 72:13 | 47:17,21 49:17         |
| 50:10 62:25           | 75:2 76:2              | <b>ability</b> 5:10   | 54:19 55:3,5,8         |
| 65:4,8 68:17          | <b>76</b> 60:8         | <b>able</b> 11:11     | 55:10 66:22            |
| <b>50</b> 65:4        | <b>77</b> 69:14,19     | 67:12                 | <b>action</b> 47:22    |
| <b>52</b> 42:17,18    | <b>79</b> 27:10        | <b>above</b> 74:6     | 71:12,14 73:15         |
| 48:22 53:4            |                        | 76:7                  | <b>actions</b> 71:13   |
|                       |                        |                       | <b>active</b> 22:19    |
|                       |                        |                       | 28:1 50:25             |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 51:9,19 57:11<br><b>actively</b> 67:14<br><b>activity</b> 48:15<br>51:16,18 55:22<br>62:11<br><b>acts</b> 46:24 51:4<br><b>actual</b> 63:5<br><b>actually</b> 22:25<br>47:23 63:1<br><b>acworth</b> 4:17<br><b>added</b> 24:6<br><b>addition</b> 18:22<br>29:21 38:13<br><b>additional</b> 8:22<br>16:10 38:22<br><b>additions</b> 76:6<br><b>address</b> 4:15,16<br><b>adds</b> 38:2<br><b>adjourned</b><br>72:13<br><b>adjust</b> 72:1<br><b>adjusted</b> 72:1<br><b>administered</b><br>43:16,25 44:2<br><b>administration</b><br>36:6 39:19<br>41:17 42:6<br>57:1<br><b>adult</b> 44:19<br>50:7<br><b>affect</b> 67:3<br><b>agarwal</b> 2:15<br>3:4 4:10 7:9,12<br>7:14,17 13:7 | 15:3,21 18:15<br>18:18 22:1<br>32:19 38:24<br>39:3 46:4 52:6<br>56:10,14 67:20<br>68:1,12 71:21<br>72:9<br><b>agency</b> 18:21<br>38:6<br><b>agent</b> 22:19<br><b>agents</b> 57:12,15<br>57:23,24 58:7<br><b>agree</b> 17:22<br>32:14,20 65:17<br>71:1<br><b>ahead</b> 7:3<br><b>alan</b> 1:11 4:6<br>4:16 72:22<br>74:5 75:2,24<br>76:2,4,12<br><b>allotted</b> 74:19<br><b>allow</b> 64:13,20<br>64:23 65:1<br>67:13<br><b>allowed</b> 6:13<br><b>allowing</b> 16:14<br>63:21<br><b>allows</b> 60:6<br>65:21<br><b>alternative</b><br>19:2<br><b>ameliorating</b><br>24:14 | <b>amount</b> 42:19<br><b>amounts</b> 51:21<br>69:12<br><b>analgesic</b> 16:15<br>19:20 21:4<br><b>analysis</b> 52:12<br><b>answer</b> 5:10,16<br>5:19,25 32:17<br>37:7 52:19<br>54:25 68:10<br><b>antagonists</b><br>66:15,16<br><b>antibiotics</b><br>57:15<br><b>anticipated</b><br>6:14<br><b>antiinflamm...</b><br>57:23,24 58:7<br><b>antiviral</b> 57:15<br><b>anyway</b> 20:7<br><b>apologies</b> 49:22<br><b>apologize</b> 44:8<br><b>apparatus</b> 12:5<br>24:7<br><b>appeal</b> 1:2<br><b>appearances</b><br>2:1<br><b>appears</b> 22:13<br><b>appended</b> 76:7<br><b>applicable</b> 74:8<br><b>applications</b><br>38:5<br><b>apply</b> 19:7<br>47:13 | <b>appropriate</b><br>11:23 51:24<br><b>approximately</b><br>18:25 20:3<br>37:1 38:16,17<br><b>area</b> 58:6<br><b>areas</b> 54:10<br><b>arguments</b><br>26:12<br><b>art</b> 11:5<br><b>asked</b> 54:24<br><b>asking</b> 5:9 52:3<br>52:5,7<br><b>aspect</b> 24:13<br><b>associated</b> 10:4<br>18:1 24:13<br><b>assume</b> 6:4<br>36:13<br><b>assuming</b> 51:11<br><b>attached</b> 3:15<br>74:11<br><b>attorney</b> 5:18<br>74:13<br><b>attorneys</b> 6:14<br><b>audible</b> 5:25<br><b>augsburger</b><br>27:3,6<br><b>august</b> 1:12 4:1<br>73:16 74:3<br><b>authors</b> 71:18<br><b>available</b> 21:21<br>29:21 47:14<br>67:8 74:6 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>avenue</b> 2:17<br><b>aware</b> 5:17<br>9:12 11:4 23:7<br>25:3                                                                                                                                                                                                                                                                                                                                                                                                                  | <b>believe</b> 13:11<br>20:2 43:6<br>45:13 46:15<br>48:21 60:8<br>61:19,22                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>bloodstream</b><br>48:4 49:2<br><b>board</b> 1:2<br><b>body</b> 5:24<br><b>bolded</b> 44:9<br><b>bottom</b> 18:13<br><b>break</b> 6:8 38:25<br>56:10<br><b>breakage</b> 70:7<br><b>breaks</b> 6:7,15<br><b>briefly</b> 5:8<br><b>budesonide</b><br>48:9,11,16<br>50:21,23 51:2<br>51:11,18 52:14<br>52:21 59:4<br><b>bunch</b> 15:17<br>57:16 | <b>cases</b> 47:2<br><b>categories</b> 58:1<br><b>category</b> 57:25<br><b>cavities</b> 38:15<br><b>cavity</b> 18:24<br><b>centre</b> 2:7<br><b>certain</b> 17:5,23<br><b>certificate</b> 73:1<br><b>certified</b> 73:3<br><b>certify</b> 73:5<br><b>cetera</b> 57:15<br>66:17<br><b>challenge</b> 46:25<br><b>chance</b> 67:13<br><b>change</b> 53:22<br>56:7 75:4,7,10<br>75:13,16,19<br><b>changed</b> 52:24<br>56:6<br><b>changes</b> 74:10<br>76:6<br><b>chat</b> 6:18<br><b>check</b> 31:18<br>36:25<br><b>chewing</b> 12:13<br>31:2 32:6<br><b>christopher</b><br>10:14<br><b>circulation</b><br>51:9,20<br><b>citation</b> 26:20<br><b>cite</b> 8:19,21<br>12:6,15 13:16<br>13:17,20,20,25 |
| <b>b</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>believed</b> 69:24<br>70:4,7<br><b>best</b> 5:10 66:24<br>67:13 68:5<br><b>beta</b> 40:9<br><b>better</b> 65:12<br><b>beyond</b> 29:21<br><b>bigger</b> 46:25<br><b>binder</b> 7:3<br>15:15 18:3<br><b>bioavailability</b><br>45:4 46:2<br>50:19,22 51:1<br>51:3,14,23<br>52:7,25 53:23<br>67:3 68:7<br><b>bioequivalence</b><br>45:11,15,20<br>46:1 50:15<br>53:16<br><b>bioequivalent</b><br>44:4 45:3,8<br>46:1,13 48:25<br>50:10 53:13<br><b>bit</b> 44:16<br><b>bitter</b> 58:11<br>65:18<br><b>blood</b> 49:6 52:4<br>52:11 | <b>c</b>                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>b2</b> 1:7<br><b>back</b> 7:18<br>11:24 14:8<br>15:14,16 19:14<br>22:3 23:15<br>24:11 26:6,19<br>27:23 30:11<br>34:3 36:25<br>41:11 42:16<br>44:3 46:5,23<br>61:4 64:11<br>69:13,20 71:20<br><b>barman</b> 39:8<br>39:10,13 40:2<br><b>base</b> 35:13<br><b>based</b> 9:10 12:5<br>18:20 19:1<br>22:17 28:12<br>34:22 35:25<br>36:14,22 37:10<br>38:10,18 41:1<br>41:23 43:18<br>44:14,17 46:1<br>46:24 48:23<br>69:2 72:8<br><b>basis</b> 5:21<br><b>batches</b> 62:23<br>63:3 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <b>calculate</b> 51:13<br><b>california</b> 2:8<br>4:1,4 72:16<br>73:4<br><b>called</b> 22:4<br><b>cap</b> 64:4<br><b>capsule</b> 68:19<br><b>capsules</b> 23:20<br>23:23 24:3<br>30:9<br><b>case</b> 1:5 19:25<br>30:9 47:4,6,23<br>50:19 51:11<br>52:14 53:18                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 15:7,23,25<br>16:18 22:4,7<br>22:11 26:23<br>27:2,5,7,8,12<br>27:15,19 30:12<br>30:17 31:11,14<br>33:1,7,25 34:4<br>34:7,8,25 39:7<br>40:3 41:3,12<br>41:15 42:1<br>49:11,21 55:2<br>55:7 60:11,14<br>69:14,21<br><b>cited</b> 13:22<br><b>citing</b> 16:4<br><b>claim</b> 11:17<br>34:7,15 35:17<br>35:17 36:3,3,4<br>58:15,16,22,25<br>59:15,16<br><b>claims</b> 39:11,17<br>39:17 51:15<br>58:16,22,25<br>59:16,19<br><b>clarify</b> 46:22<br><b>clarinex</b> 42:24<br>49:11,14,21<br>50:6,8,10<br><b>claritin</b> 42:24<br>43:2,6,24 44:5<br><b>class</b> 58:5<br>66:15<br><b>clear</b> 11:20<br>45:15,16 | <b>cleared</b> 47:25<br>48:3<br><b>clearly</b> 20:18<br>26:17<br><b>clinical</b> 52:23<br>53:2<br><b>coacervation</b><br>69:18 70:1<br><b>coated</b> 70:19<br><b>coating</b> 63:11<br>63:20 68:18<br>70:7,15,18,19<br><b>coatings</b> 70:13<br><b>colon</b> 54:8<br><b>column</b> 30:19<br>30:20 33:20,21<br>57:3 61:5,6,7<br>62:2 64:12<br>66:13 69:21,22<br>70:9 71:22<br><b>come</b> 32:17<br><b>comes</b> 12:22<br><b>communication</b><br>6:17<br><b>company</b> 52:17<br><b>comparable</b><br>44:21,25 45:2<br>45:3,5,7,7,10<br>45:12,14<br><b>compare</b> 31:19<br><b>comparison</b><br>44:18<br><b>complete</b> 12:17<br>36:5 76:8 | <b>completed</b> 38:6<br>74:16<br><b>completely</b><br>5:15 17:8 20:9<br>20:23 68:2,6<br>70:19<br><b>component</b><br>51:20 54:21<br>65:24<br><b>components</b><br>28:1<br><b>composition</b><br>36:4,5 56:25<br>58:16,19,23<br>59:1,16 63:17<br><b>compositions</b><br>22:16 35:5<br><b>compound</b> 59:9<br><b>compounding</b><br>41:16<br><b>compounds</b><br>59:12<br><b>compressible</b><br>22:16<br><b>comprises</b><br>63:17<br><b>comprising</b><br>28:1 39:18<br><b>computerized</b><br>73:11<br><b>concentration</b><br>44:20<br><b>concentrations</b><br>45:1 | <b>confirm</b> 13:12<br>14:11,19,20<br>32:18<br><b>conjunction</b><br>57:14 58:10<br><b>connects</b> 68:21<br><b>considerably</b><br>64:23 65:2<br><b>consideration</b><br>38:23<br><b>considered</b><br>8:17 18:23<br>38:13 61:21<br><b>considers</b> 62:1<br><b>consisting</b><br>66:17<br><b>contain</b> 24:3<br><b>containing</b> 25:8<br>40:9 50:9<br><b>content</b> 19:20<br>21:8,11<br><b>contents</b> 21:4<br><b>context</b> 21:13<br><b>continue</b> 70:20<br><b>continuously</b><br>65:20<br><b>contrast</b> 70:10<br><b>cooley</b> 2:14<br><b>cooley.com</b><br>2:20,21<br><b>copies</b> 74:14<br><b>copy</b> 7:13<br><b>correct</b> 4:23<br>7:20,23,25 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8:17,21,25<br>9:18 10:17,20<br>11:6,9,17,21<br>12:1,7,13,16,20<br>12:24 13:2,17<br>13:18,21 14:2<br>14:7,14,25<br>15:8,23 16:1,4<br>16:9,15,18,22<br>17:3,13,17,21<br>19:7,13 20:11<br>20:12,14 22:5<br>22:8,20,23<br>23:1,6,11,14,25<br>24:21 25:1,13<br>26:2,5,11,21,24<br>27:3,6,13,17<br>29:1,7 30:3,12<br>30:17,21 31:3<br>31:12,17 32:7<br>32:23 33:2,9<br>33:15,23 34:1<br>34:5,9,13,16<br>35:1,9,18,21<br>38:2,4,16,17<br>39:8,11,15,20<br>39:24 40:4,10<br>40:11,14,22<br>41:4,7,13,18,22<br>42:2,8,12,20,22<br>42:25 43:4,10<br>43:13,16,20<br>44:1,6 45:1,5<br>45:10,20 46:6 | 46:10,13,18,22<br>47:14,22 48:10<br>48:12 49:2,9<br>49:12,15,18,21<br>49:25 50:3,16<br>50:22 51:3,16<br>51:17,25 52:21<br>53:4,10,11,13<br>53:14 54:12,20<br>55:5,10 56:17<br>56:22 57:1,10<br>57:16,19 58:17<br>58:20,23 59:2<br>59:5,17,20<br>60:12,16,19<br>61:8,9,22<br>64:18 65:10,11<br>65:18 66:4,18<br>66:23 67:4<br>69:15 70:1,7<br>70:19 71:8,16<br>76:8<br><b>corrected</b> 72:17<br><b>corrections</b><br>76:6<br><b>correctly</b> 59:25<br><b>corresponding</b><br>42:20<br><b>corticosteroid</b><br>51:2,25 52:9<br>55:3,8,10<br><b>corticosteroids</b><br>50:21,24 51:15<br>51:23 57:18,24 | 57:25 58:3,6<br>59:8<br><b>counsel</b> 5:4 8:2<br>8:8,12 9:5,7,8<br>9:23 11:20<br>74:14<br><b>count</b> 26:7<br><b>couple</b> 71:5<br><b>court</b> 4:17 5:12<br>5:23<br><b>cousin</b> 2:16<br><b>covers</b> 41:9<br><b>criteria</b> 45:16<br><b>cross</b> 4:19<br>44:14,17,24<br><b>crossover</b> 50:7<br><b>crr</b> 1:14 73:21<br><b>cs</b> 74:15<br><b>csr</b> 1:14 4:4<br>73:21<br><b>cushioning</b><br>28:1<br><b>d</b><br><b>d</b> 3:1<br><b>data</b> 12:16<br>13:21 33:8<br>38:10<br><b>databases</b><br>11:23<br><b>date</b> 75:24<br>76:12<br><b>dated</b> 7:25<br>73:16 | <b>dates</b> 5:5<br><b>davies</b> 10:14,16<br>48:18<br><b>day</b> 76:15<br><b>days</b> 74:16<br><b>dc</b> 2:18<br><b>decarboethoxy</b><br>44:20<br><b>decision</b> 10:20<br>10:22<br><b>declaration</b><br>4:19 7:1,9,19<br>8:3,6,7,9,15,20<br>8:21 9:13,18<br>10:9,13,16<br>11:1 14:6,14<br>15:8,14,23<br>16:17 17:3<br>22:3,7,12,22<br>24:21 26:1,11<br>26:19 27:2,12<br>27:15,18 29:6<br>30:11,17,20<br>31:11,16,17,20<br>31:20 33:2,15<br>34:1,3,25<br>35:18 39:4,24<br>40:3,22 41:11<br>41:20 42:1,8<br>42:16 46:5<br>48:22 55:2,8<br>56:16,22 60:9<br>60:19 63:10<br>69:13 |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>declare</b> 72:15<br>76:4<br><b>deemed</b> 76:6<br><b>defeat</b> 66:2<br><b>define</b> 11:25<br>23:5 24:25<br>25:12 37:3,19<br>45:8,10 51:6<br>60:18 61:11,18<br>64:6 72:6<br><b>defined</b> 23:8<br>25:7 41:24<br>45:12<br><b>defines</b> 19:21<br>20:3 25:6 51:8<br>57:9<br><b>definition</b><br>13:25 18:22<br>19:12 23:8<br>24:4 25:4 30:3<br>33:7,11 37:2<br>38:13 45:6,13<br>61:16<br><b>delivery</b> 40:8<br><b>denying</b> 60:4<br><b>depend</b> 36:13<br>59:10<br><b>depends</b> 36:13<br>51:6 59:9<br>68:15,17,18<br><b>deponent</b> 74:13<br>76:3<br><b>deposed</b> 4:25<br>5:6 | <b>deposing</b> 74:13<br><b>deposition</b> 1:11<br>5:3,19 6:22<br>9:20 10:3 11:2<br>72:13 73:7,8<br><b>described</b> 31:7<br>35:8 47:17<br><b>describes</b> 16:7<br><b>description</b><br>36:2<br><b>designed</b> 67:10<br><b>desirably</b> 62:8<br><b>desloratadine</b><br>49:12,17 50:9<br><b>desonide</b> 47:24<br><b>detail</b> 61:13<br><b>determine</b><br>19:10 25:16<br>51:24 52:8,11<br><b>determined</b><br>53:1,2,2<br><b>determining</b><br>40:1<br><b>develop</b> 62:22<br><b>developed</b> 54:7<br><b>diego</b> 2:8 4:1<br><b>difference</b><br>19:19 26:16<br><b>different</b> 13:15<br>52:25 59:10<br>61:19<br><b>directed</b> 59:19<br>65:17 | <b>disclose</b> 28:25<br>40:17<br><b>disclosed</b> 26:23<br>41:22 42:11<br>66:3<br><b>discloses</b> 14:23<br>14:24 33:22<br>34:15 35:20<br><b>disclosure</b><br>69:15<br><b>discuss</b> 8:2,12<br><b>discussed</b> 25:3<br>28:23 70:25<br><b>discusses</b> 20:15<br>71:2<br><b>discussing</b><br>20:14<br><b>discussions</b> 5:2<br>6:21,24 8:8 9:3<br>9:10 48:23<br><b>disintegrate</b><br>16:14 18:24<br>19:23 20:25<br>21:9,21 35:12<br>35:24 36:12,23<br>37:12,15,20<br>38:9,14 42:11<br><b>disintegrated</b><br>20:19,24 21:24<br>23:25<br><b>disintegrates</b><br>12:4 21:10<br>23:21 50:17 | <b>disintegrating</b><br>16:25 17:6,16<br>17:23 18:10<br>20:3 21:3<br>27:25 28:17,21<br>29:19 30:3,4,6<br>30:8 33:11<br>35:14 38:3<br>68:24<br><b>disintegration</b><br>11:25 12:15<br>14:1 18:25<br>19:2,22 20:1<br>20:15,16 27:17<br>27:20 28:6,11<br>29:20,23 34:19<br>35:14 36:17,18<br>37:11,17,24<br>38:3,15,19<br>39:23 41:21<br>46:23<br><b>disintegrations</b><br>38:7<br><b>disperse</b> 12:12<br>31:1 32:5<br><b>dissolution</b><br>12:16 19:21<br>20:1,16 33:8<br>34:19 36:5,17<br>36:18 39:23<br>41:21 62:9,11<br>62:23 64:14,20<br>64:23 65:1 |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>dissolve</b> 12:11<br>16:14 17:7,24<br>19:24 20:20<br>21:1,10,14,16<br>22:18 23:6,8<br>24:17 25:1,22<br>28:11 31:1<br>32:4 35:24<br>37:9,11,13<br>42:11<br><b>dissolved</b> 21:12<br>21:22,25 29:1<br>29:6 39:20<br><b>dissolves</b> 12:3<br>21:23 28:21<br>37:18,21 50:18<br>62:24<br><b>dissolving</b> 11:4<br>11:5,9,11,17,19<br>12:1,3 13:24<br>14:17 15:12<br>20:9,17,24<br>21:5,8 23:2<br>25:4,17 26:14<br>26:18 28:13<br>29:9 30:10<br>33:5,17 34:12<br>34:16,20 35:7<br>35:11,15,20,23<br>36:2,9,11,22<br>37:8,14,23,24<br>39:14,19,23<br>40:7,13,15,18<br>40:24,25 41:7 | 41:10,17,22<br>42:6,10,14<br><b>document</b><br>12:18 13:2,6<br>13:11 14:4,11<br>14:18 15:2<br>19:15 23:9,15<br>23:22 24:2<br>25:15,18 26:7<br>26:13,17 29:2<br>29:9 32:8,12<br>33:10,18 52:1<br>55:12<br><b>documentary</b><br>9:17<br><b>documented</b><br>13:18<br><b>documents</b><br>8:23 9:14,19<br>10:1,4,6,10,23<br>11:18 32:10<br><b>doing</b> 53:7,8<br>68:7,8<br><b>dosage</b> 16:25<br>17:21 18:2<br>19:23 20:17<br>21:8,20,20<br>22:16 23:2,19<br>23:21 24:3,10<br>24:15 25:4,7<br>25:21 28:1<br>39:14 40:7,13<br>40:16 42:19<br>45:17 68:18 | <b>dose</b> 50:8,10<br>53:22 55:4,9<br>56:3,3,4 59:6<br>59:10<br><b>dosed</b> 43:3 46:9<br>49:15 53:10<br><b>doses</b> 44:18<br><b>dr</b> 1:4 2:3 4:11<br>6:22,25 7:12<br>8:2,8,12 9:5,6,7<br>9:8 10:14,16<br>11:20 48:18<br><b>drive</b> 2:7<br><b>drug</b> 21:1,8,10<br>21:18,19,21,25<br>24:15 25:8<br>42:19 45:4<br>46:24,25,25<br>47:11 48:7,13<br>49:8,10 52:18<br>54:9,20,22<br>55:5,15,16,24<br>57:1,4,9 58:20<br>59:1,4,23<br>60:16 61:8<br>62:9,24 63:13<br>63:22 64:2,5,7<br>64:7,14,17,20<br>64:24 65:2,21<br>66:1,2,22 67:2<br>67:7,13,15,21<br>68:8 70:18,22<br>70:22 71:3<br>72:2,5,7 | <b>drugs</b> 47:13,18<br>47:21 54:2,7<br>57:13,16,19<br>58:5,6,9 63:22<br>65:18 66:15<br><b>dry</b> 40:8<br><b>due</b> 29:22,22<br><b>duly</b> 4:7 73:7<br><b>e</b><br><b>e</b> 3:1 75:3,3,3<br><b>e.g.</b> 25:21<br><b>early</b> 54:6,17<br>54:17,18 67:7<br>67:8<br><b>easier</b> 15:16<br><b>easily</b> 37:12<br><b>easy</b> 55:14<br><b>effect</b> 43:10<br>48:10,10,13,20<br>49:8 51:25<br>52:8,20,22<br><b>effective</b> 63:12<br>63:21<br><b>effectively</b><br>22:19 65:20<br>72:4<br><b>effects</b> 24:14<br>72:1<br><b>efficacy</b> 53:1<br><b>eight</b> 33:24<br><b>either</b> 46:9 56:4<br>72:12 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>electronic</b> 7:24<br><b>ellodi</b> 1:7 2:13<br>74:4 75:1 76:1<br><b>embodiment</b><br>28:16 30:23<br><b>embodiments</b><br>17:6,23 65:16<br><b>employed</b> 6:22<br>6:25<br><b>enable</b> 70:13<br><b>encompasses</b><br>13:2 24:9<br>29:19 30:7<br><b>ensure</b> 45:19<br>52:24 67:2<br><b>entails</b> 72:8<br><b>entertain</b> 61:23<br><b>equivalent</b> 46:2<br>47:9,10 50:18<br>53:17 62:1<br><b>eric's</b> 9:23<br><b>errata</b> 74:11,13<br>74:16<br><b>esophagus</b><br>54:15,17 55:1<br>66:12 68:21<br>69:10<br><b>esq</b> 2:5,6,15<br>74:1<br><b>establishes</b><br>44:24 50:14<br><b>estimating</b><br>68:16 | <b>et</b> 57:15 66:17<br><b>evaluate</b> 54:9<br><b>evaluated</b> 50:7<br><b>event</b> 73:15<br><b>evidence</b> 9:18<br>10:6<br><b>exact</b> 8:10<br><b>exactly</b> 37:19<br>59:7,11 68:9<br><b>examination</b><br>3:3 4:9,19<br><b>example</b> 37:3,4<br>43:2 45:18<br>46:6 48:22<br>49:11,21 53:3<br>53:14 54:3<br>66:20 71:14<br><b>examples</b> 11:16<br>11:21 14:24<br>15:6,7 26:23<br>33:22,24,25<br>41:4,5,6 42:18<br>42:22 55:3,13<br>55:17 56:1<br><b>excellent</b> 53:8<br><b>excuse</b> 31:15<br><b>exhibit</b> 3:7,8,9<br>3:10,11,12,13<br>7:4,20 10:14<br>12:7,19,20<br>13:17,21 14:1<br>14:5,21,24<br>15:23 16:3,3<br>16:19,19 17:1 | 17:2 18:3,4,12<br>19:5,16 20:21<br>22:5,8,10,11,14<br>23:5,11 24:11<br>24:12 25:6,12<br>25:19 26:5,10<br>26:20,21,24<br>27:2,11,23<br>28:25 29:11,14<br>30:12,16,19<br>31:5,12,15,15<br>32:20 33:2,8<br>33:21,22 34:4<br>34:9,24 38:12<br>39:5,8,11,14<br>40:2,17 41:4,6<br>41:12,25 42:17<br>44:5 49:20,20<br>56:19,21 61:4<br>64:11 69:20<br><b>exhibits</b> 3:6,15<br>8:20,24 9:2,9<br>9:11 11:16<br><b>exist</b> 13:23<br>33:18<br><b>existence</b> 33:5<br><b>expect</b> 37:8<br>69:3<br><b>expects</b> 52:10<br><b>experience</b><br>18:21<br><b>expert</b> 10:9,16<br><b>explain</b> 5:8<br>13:8 | <b>explaining</b> 5:4<br><b>exposure</b> 53:17<br>53:24,25 54:1<br><b>f</b><br><b>facet</b> 65:19<br><b>fact</b> 47:8 72:7<br><b>fail</b> 62:23<br><b>failing</b> 63:4<br><b>fails</b> 74:18<br><b>fair</b> 6:5<br><b>falk</b> 1:4 2:3<br>6:22,25 9:6,23<br>74:4 75:1 76:1<br><b>falk's</b> 8:2,8,12<br>9:5,7,8 11:20<br><b>fall</b> 57:25 58:6<br><b>familiar</b> 27:21<br><b>famotidine</b><br>53:4,5 54:13<br>54:16,19 66:17<br><b>far</b> 46:25<br><b>fast</b> 11:3,5,9,11<br>11:17 12:1,3<br>12:10 13:24<br>14:17 15:12<br>25:17 29:19<br>30:6,7,10,24,24<br>31:6,21,21,24<br>32:3,21,22<br>33:5,7,17<br>39:14,19,23<br>40:7,13,15,18<br>40:24,25 41:7 |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 41:10<br><b>faster</b> 61:21<br>63:8<br><b>fda</b> 14:4 16:24<br>19:12,22 20:2<br>20:5,13,15<br>23:9,10,13<br>25:3 27:21<br>28:14,23 34:22<br>35:15,25 36:1<br>36:14,22 37:10<br>37:16 38:1,12<br>39:25 40:14<br>41:1,23 42:12<br>42:14 45:8,13<br>46:3 51:8<br>52:10,17 61:16<br>61:25<br><b>fda's</b> 12:2 63:2<br><b>figure</b> 54:9<br><b>filed</b> 10:9<br><b>fillers</b> 25:9<br><b>film</b> 40:8<br><b>find</b> 32:10<br><b>first</b> 4:7 9:2<br>11:2 12:9 18:7<br>19:23 21:2,9<br>21:21 22:15<br>24:23 27:24<br>32:6 39:13<br>43:2 47:11<br>50:5 56:24<br>60:14 | <b>five</b> 56:10<br>68:23<br><b>follow</b> 16:24<br>35:15 39:25<br><b>following</b> 36:6<br><b>follows</b> 4:7<br><b>foregoing</b><br>72:16 73:6,12<br>76:5<br><b>forgot</b> 9:23<br><b>form</b> 12:11<br>13:3 17:21<br>19:23 21:9,15<br>21:20,21 23:19<br>23:21 24:3<br>25:4 30:25<br>32:4 39:14<br>40:7,13,16<br>44:25,25 45:17<br>45:21 50:15,15<br>51:6 55:4,9<br>68:18 69:18<br>71:17<br><b>formed</b> 69:25<br><b>forms</b> 16:25<br>18:2 20:17<br>22:16 23:2<br>24:10,16 25:7<br>25:21 28:1<br><b>formulated</b><br>35:6<br><b>formulation</b><br>30:24 38:20<br>42:20 45:23 | 52:24,25<br><b>formulations</b><br>12:10 30:25<br>31:6,21,22,25<br>32:3,22,23<br>33:8 42:19<br>44:21 70:14<br><b>forth</b> 73:9<br><b>four</b> 42:22 53:6<br>55:17 68:23<br><b>fourth</b> 26:16<br>53:3<br><b>frame</b> 19:8,11<br>28:10,20,25<br>29:5 34:18<br>38:1 39:22<br>40:17 41:21<br><b>frames</b> 17:15<br>17:20 27:16<br><b>frank</b> 4:16<br><b>friday</b> 9:25<br><b>front</b> 7:8<br><b>full</b> 24:23 62:20<br>63:16<br><b>functions</b> 6:18<br><b>further</b> 10:5<br>13:8 27:24<br>58:8 70:3 72:9<br>72:11 | <b>generally</b> 16:13<br>24:15 25:23<br>58:9 59:8<br><b>generate</b> 48:20<br>52:16<br><b>generating</b><br>48:15<br><b>georgia</b> 4:17<br><b>getting</b> 47:11<br><b>gi</b> 47:3,5,18<br>48:6 53:25<br>54:2,11,18,24<br>67:8,9,14,16,22<br><b>give</b> 5:25 7:12<br>16:21 17:25<br>38:1 46:6 49:5<br>53:3,24 63:12<br>63:20 64:8<br><b>given</b> 17:15<br>44:19 76:9<br><b>gives</b> 17:25<br>19:10 66:20<br><b>glenmore</b> 4:17<br><b>glucan</b> 40:9<br><b>gmb</b> 2:3<br><b>gmbh</b> 1:4 74:4<br>75:1 76:1<br><b>go</b> 7:3,14 8:16<br>8:19 10:25<br>11:15,18,24<br>12:19 14:8,21<br>15:14 16:3,6<br>18:3,11,11<br>19:14 22:3,10 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <b>g</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <b>general</b> 24:9<br>30:6 57:22,25<br>58:1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 22:14 23:15<br>24:12 25:5,19<br>26:6 28:15<br>29:11 30:16,19<br>34:3,24 35:3<br>35:17 36:1,3<br>36:25 38:21<br>39:4,5 40:2,6<br>41:11,25 42:4<br>42:16,17 44:3<br>44:5,9 45:23<br>46:5 49:20<br>55:20 56:11,21<br>57:3 58:8,15<br>61:4 64:11,12<br>65:4 66:13<br>68:14 69:13,20<br>70:3,9 71:10<br>71:10,11,20<br>72:12<br><b>goal</b> 29:8 40:24<br><b>goes</b> 15:5 16:10<br>46:23 50:2<br>57:13 64:4<br><b>going</b> 5:4,8,9<br>7:4 15:16<br>26:19 27:1,23<br>30:11 33:21<br>38:24 47:10<br>49:6 52:16<br>53:20,22,23<br>62:3 64:9 65:8<br>69:8,9 | <b>good</b> 4:12<br>46:17<br><b>great</b> 6:20<br><b>grounds</b> 18:4<br><b>group</b> 66:16<br><b>guess</b> 37:6<br><b>guidance</b> 14:4<br>16:24 18:9,9<br>20:13,15 23:9<br>23:10,13,24<br>24:5 25:3<br>27:22 28:14,23<br>34:23 35:15<br>36:1,1,14,22<br>37:10,16,18<br>38:1 40:1,14<br>41:1,23 42:12<br>42:14 62:14<br><b>h</b><br><b>h</b> 75:3<br><b>h2</b> 66:15,16<br><b>halfway</b> 11:1<br>42:4<br><b>hand</b> 73:16<br><b>hang</b> 68:20<br><b>head</b> 5:24<br><b>header</b> 44:10<br><b>heading</b> 49:24<br><b>healthy</b> 44:19<br><b>hereto</b> 76:7<br><b>hi</b> 4:11<br><b>high</b> 54:7 63:11<br>63:20 70:14 | <b>higher</b> 52:25<br>56:2,3,4<br><b>highlighted</b><br>13:12,13<br><b>highly</b> 59:13<br><b>hour</b> 6:7 38:25<br><b>hours</b> 68:17,23<br><b>huh</b> 20:10 43:8<br>47:20 63:19<br><b>human</b> 17:12<br>17:12<br><b>hypothetical</b><br>45:22 52:2<br>67:17,24<br><b>i</b><br><b>i.e.</b> 16:8<br><b>iagarwal</b> 2:20<br><b>idea</b> 8:10 54:13<br><b>ideal</b> 64:13,19<br><b>identical</b> 31:16<br><b>identified</b> 9:2,6<br>9:8 11:12,20<br>26:15 33:11<br><b>identify</b> 9:11<br>11:11 25:16<br>29:8 33:4<br>40:24<br><b>iii</b> 8:19<br><b>immediate</b> 60:6<br>60:15,18 61:7<br>61:11,14,16,24<br>62:15 66:1<br>69:11 72:5 | <b>immediately</b><br>60:1,22,23<br>61:2,3 63:6,7<br>64:5,9,10<br>65:22 66:8<br>67:7<br><b>impervious</b><br>70:13,18,24<br>71:7,9 72:6<br><b>implies</b> 65:23<br><b>important</b> 5:24<br>49:7,8<br><b>inactive</b> 51:6<br>51:12<br><b>include</b> 30:8<br>40:21 57:14<br><b>includes</b> 23:3<br><b>incomplete</b><br>45:21 52:2<br>67:17,24<br><b>indicate</b> 14:1<br>33:19 36:15<br>43:22 60:20<br>63:5 71:7<br><b>indicated</b> 13:23<br>15:13 30:10<br>69:5 71:5,12<br>71:23<br><b>indicates</b> 24:1<br>26:17 27:19<br>40:25 41:5,9<br>57:23 70:18<br>72:3 |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                             |                                                                                                                                   |                                                    |                                                                                                          |
|---------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|----------------------------------------------------------------------------------------------------------|
| <b>indication</b> 56:5<br>56:8                                                              | <b>inventor</b> 30:9<br>71:4                                                                                                      | 59:7,11,12<br>61:24 68:9<br>72:6                   | <b>limited</b> 69:23                                                                                     |
| <b>indications</b><br>56:6                                                                  | <b>invested</b> 22:18                                                                                                             | <b>knowing</b> 16:23                               | <b>line</b> 33:21,22<br>57:3,23 58:9<br>61:5,6 62:2,4<br>66:14 69:22<br>70:3,10 75:4,7<br>75:10,13,16,19 |
| <b>individuals</b><br>6:25                                                                  | <b>investigation</b><br>10:5                                                                                                      | <b>knowledge</b><br>43:18 66:24<br>68:5            | <b>lines</b> 12:23<br>13:11 30:21<br>64:12                                                               |
| <b>industrial</b> 18:9                                                                      | <b>involves</b> 70:14                                                                                                             | <b>knows</b> 68:22                                 | <b>liquid</b> 29:21<br>42:20 43:3,12<br>43:15,19,24<br>45:18 49:14<br>55:4,9                             |
| <b>industry</b> 18:10                                                                       | <b>ipr</b> 4:20                                                                                                                   | <b>kramm</b> 1:14<br>4:3 73:3,20                   | <b>list</b> 8:16 10:10<br>10:11,13 42:22<br>57:18 58:1                                                   |
| <b>ingested</b> 24:17                                                                       | <b>ipr2024-01197</b><br>1:5                                                                                                       | <b>I</b>                                           | <b>listed</b> 9:15,19<br>11:18 57:18                                                                     |
| <b>ingesting</b> 24:14                                                                      | <b>irrespective</b><br>48:5 71:25                                                                                                 | <b>l.p.</b> 1:7 2:13                               | <b>lists</b> 15:6 57:15<br>58:5,5                                                                        |
| <b>insert</b> 12:9<br>43:21 44:6,13                                                         | <b>isha</b> 2:15                                                                                                                  | <b>labeled</b> 30:7                                | <b>literature</b> 11:3<br>11:8,22 69:7                                                                   |
| <b>inserts</b> 44:3                                                                         | <b>j</b>                                                                                                                          | <b>laboratory</b><br>38:7                          | <b>little</b> 42:4 44:16                                                                                 |
| <b>institution</b><br>10:20,22                                                              | <b>j</b> 2:6                                                                                                                      | <b>language</b> 5:24                               | <b>liver</b> 47:25<br>48:14 51:5,19<br>52:15                                                             |
| <b>instructs</b> 5:20                                                                       | <b>jonathan</b> 2:16                                                                                                              | <b>large</b> 68:19<br>69:12                        | <b>local</b> 48:2                                                                                        |
| <b>intent</b> 67:5                                                                          | <b>jonathan.cou...</b><br>2:21                                                                                                    | <b>late</b> 54:7                                   | <b>locally</b> 46:24<br>51:4 52:14<br>67:14                                                              |
| <b>interact</b> 47:3,6<br>47:24 55:20                                                       | <b>july</b> 7:25 8:6<br>10:6                                                                                                      | <b>laws</b> 72:16                                  | <b>lollipop</b> 41:18<br>42:7                                                                            |
| <b>interaction</b><br>47:11,18 48:6<br>48:13                                                | <b>k</b>                                                                                                                          | <b>leaves</b> 66:9,10<br>72:5                      |                                                                                                          |
| <b>interacts</b> 55:24                                                                      | <b>keep</b> 65:8                                                                                                                  | <b>leeway</b> 38:18                                |                                                                                                          |
| <b>interested</b><br>73:15                                                                  | <b>keeps</b> 65:13                                                                                                                | <b>left</b> 6:19                                   |                                                                                                          |
| <b>interpret</b> 60:25                                                                      | <b>knobbe</b> 2:4                                                                                                                 | <b>legal</b> 74:23                                 |                                                                                                          |
| <b>intestine</b> 54:6,7<br>54:18                                                            | <b>knobbe.com</b><br>2:10,11 74:2                                                                                                 | <b>level</b> 55:16<br>61:13                        |                                                                                                          |
| <b>invention</b> 17:7<br>20:22 22:15<br>27:24 28:2,16<br>30:24 35:5<br>57:14 69:23<br>70:11 | <b>know</b> 6:4,8<br>8:11 14:10,15<br>33:10 35:25<br>41:1 44:4,15<br>45:6,11,12<br>48:17 50:23,23<br>50:25 54:22,22<br>55:19 56:5 | <b>levels</b> 49:6 52:4<br>52:11 63:11,20<br>70:15 |                                                                                                          |
|                                                                                             |                                                                                                                                   | <b>limit</b> 23:20,22<br>24:4 65:3                 |                                                                                                          |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>long</b> 9:24 21:24<br/>64:6 65:15<br/>67:15,21 68:2<br/>68:13,25<br/><b>longer</b> 38:8<br/>69:10<br/><b>look</b> 13:10<br/>16:23 17:25<br/>21:7,11 28:12<br/>28:13,22 30:5<br/>31:5 36:25<br/>44:3 56:24<br/>58:2 59:21<br/>61:2,5 64:9<br/>67:11<br/><b>looked</b> 10:23<br/>23:11 59:22<br/><b>loratadine</b> 43:6<br/>44:18,20<br/><b>loss</b> 59:25<br/><b>lot</b> 29:16<br/><b>low</b> 48:19<br/>50:22 51:3<br/>59:6 68:6<br/><b>lower</b> 54:16<br/>65:11<br/><b>lozenge</b> 12:16<br/>13:19,24 14:7<br/>14:17 16:8,9<br/>16:13 21:20<br/>26:5,7,9,18<br/>28:10,17,21<br/>29:1,5 30:4,10<br/>31:1 32:4</p> | <p>33:18 34:16,20<br/>35:6,12,20,23<br/>36:9,11,22<br/>37:9,15 39:15<br/>39:19,24 40:8<br/>40:14 41:1,7<br/>41:10,17,22<br/>42:6,11<br/><b>lozenges</b> 11:4,5<br/>11:9,11,17,19<br/>12:1,11 14:13<br/>15:12 17:7,17<br/>17:24 21:4<br/>22:17 23:3,14<br/>23:20,23 24:3<br/>24:16 25:12,17<br/>25:21 26:14<br/>27:16 28:6<br/>29:9 30:9 33:5<br/>34:13 35:7<br/>40:25<br/><b>lp</b> 74:4 75:1<br/>76:1<br/><b>luman</b> 2:5 7:11<br/>7:13 9:22 13:3<br/>15:1,18 18:13<br/>18:16 21:15<br/>32:8 45:21<br/>52:1 55:11<br/>56:12 67:17,24<br/>68:4 71:17<br/>72:11 74:1</p> | <p><b>m</b><br/><b>ma'am</b> 4:21,24<br/>5:14,17,22 6:2<br/>6:6,11,16,19,23<br/>7:2,21,24 8:1<br/>8:14,18,22 9:1<br/>9:16,19 10:7<br/>10:15,18,21,24<br/>12:8,14,21,25<br/>15:24 16:2,5<br/>16:11,16,20<br/>17:14,18 18:6<br/>19:4 22:6,9,13<br/>22:21,24 23:4<br/>23:12 24:24<br/>25:11,25 26:3<br/>26:22 27:4,7<br/>27:14 28:4,9<br/>28:19 30:1,15<br/>30:18 31:4,9<br/>31:13 33:24<br/>34:6,10,14,17<br/>35:2,10,19,22<br/>36:8 39:9,12<br/>39:16 40:5,16<br/>41:14,19 42:3<br/>42:9,15,21,23<br/>43:1,5,11,14,17<br/>43:23 44:7,12<br/>46:3,7,11,14<br/>49:3,10,13,16<br/>49:19 50:1,4<br/>50:13,20 53:5</p> | <p>56:18,20,23<br/>57:2,6,8,17<br/>58:14,24 59:3<br/>59:18 60:10,13<br/>60:17 62:6,13<br/>63:25 66:19,21<br/>66:24 70:2,8<br/>70:17<br/><b>made</b> 11:13<br/>14:15,16 25:21<br/>26:16 76:5<br/><b>majority</b> 38:8<br/><b>make</b> 13:12<br/>21:21 36:25<br/><b>makes</b> 70:12<br/><b>making</b> 14:16<br/><b>marked</b> 3:6,15<br/><b>marks</b> 57:5<br/><b>martens</b> 2:4<br/><b>martin</b> 15:23<br/>16:1<br/><b>martyn</b> 10:14<br/><b>mask</b> 22:19<br/>59:25 60:2<br/>67:6 72:4<br/><b>masked</b> 56:25<br/>58:16,22,25<br/>59:23 67:2,6<br/><b>masking</b> 22:25<br/>23:4 58:12<br/>59:20 60:5,5<br/>63:12,21 64:13<br/>64:19 65:18,19<br/>65:24 66:3</p> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 67:1,11 70:19<br>70:21,25<br><b>masks</b> 59:16<br>65:21<br><b>materials</b> 8:16<br>70:12<br><b>matter</b> 6:25<br>10:9 23:21<br>37:2 69:4<br><b>matters</b> 47:22<br><b>mcentee</b> 12:7,9<br>12:16,19 14:23<br>31:10,17 32:13<br>32:23,24<br><b>mean</b> 13:8<br>34:22 45:4<br>48:25 61:15<br>63:6 67:18,25<br>71:9<br><b>meaning</b> 21:12<br><b>means</b> 27:21<br>41:2 47:9<br>50:17 53:23<br>60:18,23 62:15<br>67:7<br><b>meant</b> 35:16<br><b>measure</b> 51:12<br>51:23 52:4,7<br>52:11,23<br><b>measured</b> 69:2<br><b>mechanism</b><br>70:4,6 71:12<br>71:14 | <b>mechanisms</b><br>71:5,13,19<br>72:8<br><b>medical</b> 56:6<br><b>meet</b> 9:21,24<br>20:2<br><b>meetings</b> 8:11<br><b>meets</b> 62:19<br>65:16<br><b>melt</b> 12:10<br>30:24,25 31:6<br>31:21,22,24<br>32:3,21,22<br>33:8<br><b>member</b> 9:23<br><b>membrane</b><br>47:12<br><b>memorize</b><br>14:10<br><b>memory</b> 14:20<br>25:15 29:3<br>33:13<br><b>mention</b> 37:11<br><b>mentioned</b><br>21:17 38:21<br>48:18<br><b>mentions</b> 58:2<br><b>met</b> 9:22,25<br><b>metabolized</b><br>48:14 51:5,10<br>51:12,19 52:15<br><b>method</b> 19:2<br>20:5,6 36:14<br>36:15 39:18 | <b>methodology</b><br>58:10<br><b>methods</b> 27:25<br><b>mezaache</b> 22:5<br>22:10<br><b>microcapsule</b><br>56:25 58:16,19<br>58:23 59:1,16<br>64:13,19,23<br>65:1 69:17<br><b>microcapsules</b><br>62:8 69:25<br><b>microencaps...</b><br>70:11<br><b>midatlantic</b><br>74:15<br><b>middle</b> 24:12<br><b>milligrams</b><br>43:3 46:9,9<br>49:15 50:9,10<br>53:10<br><b>mimics</b> 17:12<br><b>mind</b> 11:10<br>67:10<br><b>minnick</b> 2:6<br>9:22<br><b>minute</b> 12:12<br>31:2 32:5<br>37:25 38:8<br>56:10 61:25<br>62:18 64:14,18<br>64:21,24 65:3<br>65:7,15 | <b>minutes</b> 36:6<br>37:23 61:20,25<br>62:10,17,19,25<br>63:1,2,8 69:4<br><b>mischaracteri...</b><br>13:3 15:1 32:8<br>52:1 55:11<br><b>mls</b> 50:8 69:6,7<br>69:9<br><b>modified</b> 43:19<br>43:23<br><b>molecules</b><br>24:14<br><b>monday</b> 4:1<br><b>morning</b> 4:12<br><b>mouth</b> 12:12<br>22:18 24:17<br>25:22 29:22<br>31:1 32:5<br>39:20 50:18<br>59:24 60:7,22<br>63:23 64:3,7<br>66:2,6,9,10<br>67:3 68:14<br>69:1 70:23<br>71:3 72:5<br><b>move</b> 22:2 63:9<br><b>mucositis</b> 39:18<br><br><b>n</b><br><br><b>n</b> 3:1<br><b>name</b> 4:3,15,16<br>9:23 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                    |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>named</b> 73:6<br><b>nate.luman</b><br>2:10 74:2<br><b>nathanael</b> 2:5<br>74:1<br><b>necessarily</b><br>26:12 33:16<br>58:5 71:9<br><b>necessary</b> 76:6<br><b>need</b> 6:8 11:10<br>12:13 31:2<br>32:6 45:19<br>56:2,3,4,8<br>58:12<br><b>needs</b> 47:19<br>55:25<br><b>neither</b> 43:18<br><b>never</b> 63:3<br>68:22<br><b>nevertheless</b><br>63:12,21<br><b>new</b> 9:2,8,11<br><b>nice</b> 4:13<br><b>nod</b> 5:23<br><b>non</b> 53:7<br><b>normally</b> 29:21<br><b>notary</b> 76:13<br>76:19<br><b>note</b> 74:10<br><b>noted</b> 76:7<br><b>number</b> 8:11<br>8:19 11:16<br>14:24 18:14<br>26:7 32:10 | 33:22 37:3,19<br>48:18 61:22<br><b>numbered</b><br>38:11<br><b>numbers</b> 8:11<br>29:16<br><b>nw</b> 2:17                                                                                                                                                                                                                                                                                                                                   | 50:17 53:9,12<br>53:16,21 55:5<br>55:10,16 56:9<br>60:3 68:24,25<br>69:10<br><b>odts</b> 18:23 19:7<br>19:8 23:9<br>38:13 47:8<br>65:23<br><b>offhand</b> 40:20<br><b>office</b> 1:1<br><b>oh</b> 14:21<br><b>okay</b> 6:20 7:3<br>8:15 10:25<br>13:1,15 15:10<br>15:20 18:16<br>19:19 22:2<br>24:11 29:15,17<br>33:20 39:6<br>44:8,17 49:4<br>49:23 57:21<br>65:14<br><b>once</b> 21:9 59:24<br><b>ondansetron</b><br>46:16<br><b>ones</b> 71:23<br><b>open</b> 7:3<br><b>opening</b> 8:21<br><b>operate</b> 12:2<br>14:3<br><b>operation</b><br>69:24<br><b>opinion</b> 40:12<br>42:10 | <b>oral</b> 18:23,24<br>24:2 38:14,15<br>39:18 40:10<br>46:8,12,20<br>47:2,8 48:24<br>49:1,5 50:19<br>53:9,12<br><b>orally</b> 16:25<br>17:6,16,23<br>18:10 21:3<br>23:24 38:3<br>43:16 47:1<br>68:24<br><b>order</b> 7:5<br><b>original</b> 18:21<br>18:22 19:14<br>38:13<br><b>overall</b> 51:13<br><b>owner</b> 1:8 2:13<br><b>owner's</b> 10:8 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>o</b>                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>p</b>                                                                                                                                                                                                                                                                                                                                           |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>oath</b> 5:12<br><b>objection</b> 13:3<br>15:1 21:15<br>45:21 55:11<br>68:4<br><b>objects</b> 5:19<br><b>observed</b> 38:10<br><b>obviously</b><br>65:11<br><b>obviousness</b><br>18:5<br><b>occur</b> 20:16<br>21:5 36:18,19<br>54:5,6,6 70:5,7<br><b>occurred</b> 37:25<br><b>occurs</b> 20:1<br>71:6<br><b>odt</b> 14:4 16:24<br>19:13 20:20<br>24:8 36:2<br>42:18 43:2,12<br>43:15,18,24<br>45:18 46:8,13<br>46:20 48:24<br>49:1,5,14 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>package</b> 44:3<br>44:13<br><b>page</b> 3:3 7:22<br>8:17,19 11:14<br>11:14,15 12:23<br>14:21,22,25<br>15:4,5 16:6<br>18:8,11,13,13<br>28:15 29:12<br>38:11,21 41:15<br>42:4,5 44:9<br>49:23 50:2,2,5                                                                                                                                           |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 75:4,7,10,13,16<br>75:19<br><b>pages</b> 22:23<br><b>paper</b> 8:25<br>10:20<br><b>paragraph</b><br>10:25 11:1,14<br>11:15,24,25<br>12:6,23 13:13<br>16:6,7,12,17,19<br>16:21 17:1,2,2<br>17:3 18:19,20<br>19:18 22:14,15<br>22:23 23:5<br>24:12,13,21,25<br>24:25 25:5,19<br>25:20 26:21<br>27:1,5,5,6,7,18<br>27:23 28:15,21<br>29:11,14,15,18<br>30:12,13 31:19<br>31:20,23 32:1<br>32:2,7 33:5<br>34:4,8,8,8,11<br>35:3,4,12<br>38:11,22 39:5<br>39:7,10 40:6<br>40:25 41:12<br>42:17,18 48:22<br>50:5 53:3<br>56:15,16 57:9<br>58:8 60:8,12<br>63:14 69:14<br>70:20 71:20 | <b>paragraphs</b><br>15:22,25 16:4<br>22:4,8 27:1,17<br>34:7<br><b>parameters</b><br>38:22 45:12<br>46:2 70:12<br><b>parr</b> 1:11 4:6<br>4:11,16 7:12<br>72:22 74:5<br>75:2,24 76:2,4<br>76:12<br><b>part</b> 38:2<br><b>particular</b><br>13:22 17:20<br>35:6 56:2<br><b>particularly</b><br>69:25<br><b>passage</b> 60:22<br>63:23 64:2<br>66:6<br><b>passes</b> 59:24<br>60:7 64:7<br>70:22 71:3,4<br><b>patch</b> 41:18<br>42:7<br><b>patent</b> 1:1,2,6,8<br>2:13 4:23 10:8<br>12:18 35:8<br>41:9 51:15,22<br>56:17,21 57:3<br>58:15 60:11<br>61:5,10,10<br>62:2,15 64:6 | 64:11,17 65:16<br>65:25 66:4,7<br>66:13 67:10<br>69:20 70:9<br>71:16 72:3,8<br><b>patent's</b> 69:14<br><b>patient</b> 68:21<br><b>patient's</b> 12:12<br>31:1 32:5<br><b>pellet</b> 16:8,8,13<br><b>pellets</b> 17:7,16<br>17:24 21:3<br><b>penalty</b> 72:15<br><b>pending</b> 6:9<br><b>pennsylvania</b><br>2:17<br><b>pepcid</b> 42:25<br>53:4,9 54:25<br><b>percent</b> 48:17<br>51:1 61:20,24<br>62:9,18,25<br>63:1,8 64:24<br>65:2,3,4,8,9,15<br><b>percentage</b><br>48:16 52:12<br><b>perfectly</b> 11:13<br><b>period</b> 17:8<br>20:19,23 61:15<br><b>periods</b> 19:21<br><b>perjury</b> 72:15<br><b>peruse</b> 57:20<br><b>petitioner</b> 1:5<br><b>ph.d.</b> 2:5,6,16 | <b>pharm.d</b> 1:11<br>4:6 72:22 74:5<br>75:2,24 76:2,4<br>76:12<br><b>pharma</b> 1:4 2:3<br>74:4 75:1 76:1<br><b>pharmaceutical</b><br>25:7 36:4<br><b>pharmaceutic...</b><br>1:7 2:13 74:4<br>75:1 76:1<br><b>pharmacies</b><br>41:16<br><b>pharmacist</b><br>53:7<br><b>pharmacokin...</b><br>45:25 49:24<br>50:6<br><b>pharmacokin...</b><br>44:10<br><b>pharmacopeia</b><br>19:1 62:11<br><b>phased</b> 49:22<br><b>phillip</b> 2:6<br><b>phillip.minnick</b><br>2:11<br><b>phone</b> 6:19<br><b>phrase</b> 29:19<br><b>pk</b> 45:24 52:12<br>53:2<br><b>pks</b> 52:16<br><b>place</b> 73:9<br><b>placed</b> 17:12<br>25:22 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>places</b> 60:11<br><b>plasma</b> 44:19<br>44:25<br><b>please</b> 4:14 6:3<br>18:7<br><b>point</b> 8:3 14:16<br>37:25 42:18<br>43:2 46:22<br>59:15<br><b>polymer</b> 71:10<br><b>polymeric</b><br>69:17,24<br><b>pop</b> 15:15<br><b>pores</b> 69:19<br>70:1 71:7,11<br>71:15<br><b>porous</b> 69:15<br>69:21<br><b>portion</b> 14:5<br>31:14,16 32:21<br><b>portions</b> 34:11<br>39:10<br><b>posa</b> 11:13 14:3<br>16:23 17:25<br>21:7,11,14<br>23:7 24:2 25:2<br>27:20 28:12,13<br>28:22 30:5<br>34:21 35:13,25<br>39:25 40:12<br>41:1 42:13<br>53:20 55:14,19<br>56:4 60:24<br>61:2,14 63:6 | 64:9 65:14<br>67:11<br><b>possible</b> 71:5<br>71:19<br><b>possibly</b> 29:8<br><b>prednisolone</b><br>50:24<br><b>prednisone</b><br>50:24<br><b>preferable</b> 40:8<br><b>preferably</b> 35:5<br>66:16<br><b>preferred</b><br>29:23 64:22<br>65:1,9,12<br>66:14<br><b>preparation</b><br>9:20 10:2<br>70:13,14<br><b>preparations</b><br>18:23 38:14<br><b>prepare</b> 41:16<br>42:5<br><b>preparing</b><br>27:25<br><b>present</b> 17:7<br>20:22 28:16<br>35:5 57:14<br>58:10 69:23<br>70:11<br><b>presumably</b><br>14:13<br><b>preventing</b><br>39:18 | <b>previously</b> 3:6<br>21:17 28:24<br>51:18<br><b>prior</b> 8:3,5,7,13<br>9:13 11:5 21:5<br>70:10<br><b>priority</b> 55:23<br><b>privilege</b> 5:21<br><b>probably</b> 68:16<br><b>proceedings</b><br>73:10,13<br><b>process</b> 5:3,7<br>52:18 70:12<br><b>product</b> 18:21<br>36:2 62:22<br><b>products</b> 38:6<br>43:23<br><b>profile</b> 43:19<br>44:1,20 50:6<br>62:20<br><b>pronounced</b><br>43:7 46:15<br><b>prophylactic</b><br>40:9<br><b>propose</b> 71:13<br>71:15<br><b>proposed</b> 71:19<br><b>protect</b> 70:24<br><b>prove</b> 55:23<br><b>provide</b> 24:15<br>34:18 39:22<br>41:20 43:9<br>62:8,14 | <b>provided</b> 57:1<br><b>provides</b> 19:6<br>30:24 36:5<br>71:2<br><b>providing</b><br>70:21<br><b>proving</b> 55:22<br><b>public</b> 76:19<br><b>publication</b><br>35:8<br><b>purpose</b> 33:4<br>56:1 66:3<br><b>put</b> 14:13 25:14<br>26:10 29:2,6<br>33:14 42:14        |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>q</b>                                                                                                                                                                                                                                                                         |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>quantitative</b><br>62:4,7<br><b>question</b> 5:20<br>6:3,5,9 8:4<br>13:15 37:6<br>47:15 52:19<br>67:19 68:11<br>72:11<br><b>questions</b> 5:9<br>5:16 36:16<br>72:9<br><b>quick</b> 11:19<br>34:12,16,20<br>35:7,11,15,20<br>35:23 36:2,9<br>36:11,22 37:8<br>37:14,23 41:17 |

|                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 41:22 42:6,10<br>42:14 60:24<br><b>quickly</b> 16:14<br>16:22 22:18<br>23:6,8 24:17<br>25:1 35:11,23<br>57:20 71:4<br><b>quite</b> 7:5 61:22<br><b>quotation</b> 57:4<br><b>quote</b> 12:9,22<br>13:17 17:2<br>22:22 24:23<br>26:1 30:20<br>31:16 32:7,21<br>34:11,15 39:10<br>39:13,14 42:7<br>60:14 61:5<br>63:9<br><b>quoted</b> 14:6<br>24:20 35:18<br><b>quoting</b> 39:13<br>63:10 | <b>rapidly</b> 16:15<br>18:24 20:3<br>23:2,21 25:4<br>25:22 26:14,18<br>27:20,25 28:13<br>28:17,20 29:9<br>30:3,4 33:11<br>35:14 38:14<br>51:5,19 52:15<br>59:23 62:24<br>66:8 72:7<br><b>rate</b> 27:17<br>28:11 34:19<br>38:3 63:6 72:2<br><b>rates</b> 27:20<br>28:7 49:1<br><b>rather</b> 59:25<br><b>rationale</b> 18:21<br><b>read</b> 10:8 12:22<br>14:8,10,18<br>18:7 24:2<br>25:15 26:6<br>29:2 40:12,19<br>42:13 43:21<br>44:15 61:12<br>74:9 76:5<br><b>reads</b> 35:13<br>61:14 65:14<br><b>realize</b> 55:14<br><b>really</b> 67:10<br><b>reason</b> 5:15<br>25:17 59:22<br>71:25 74:11<br>75:6,9,12,15,18 | 75:21<br><b>recall</b> 8:10<br>10:11 29:4<br>33:12 36:24<br>40:20 59:24<br>68:7,8<br><b>receipt</b> 74:17<br><b>recess</b> 7:16<br>39:2 56:13<br><b>recite</b> 69:16<br><b>recommend</b><br>18:22<br><b>recommendat...</b><br>36:24<br><b>recommended</b><br>38:12,20<br><b>record</b> 4:14<br>5:23 7:14,18<br>72:12 73:13<br><b>refer</b> 4:22<br>17:15 23:13<br>32:24 34:12<br>39:17 56:16<br><b>reference</b> 13:14<br>14:7,7,13<br>16:21 17:19,19<br>19:5 22:4 26:4<br>27:12 30:2,16<br>31:10,11 32:23<br>32:24 33:14<br>34:25 40:3<br>42:1 65:17<br><b>referenced</b><br>25:18 37:23 | 74:6<br><b>references</b><br>14:12 26:9<br>29:10 41:9<br><b>referred</b> 3:6<br>22:11<br><b>referring</b> 23:10<br>48:9 56:22<br>60:8,15 64:1<br><b>refers</b> 20:8<br>23:19 28:5<br>32:23<br><b>reflux</b> 54:15<br><b>regarding</b> 8:9<br><b>regardless</b><br>71:25<br><b>regional</b> 68:9<br><b>relate</b> 17:20<br><b>relates</b> 22:16<br>22:25 23:2,3<br>27:25 28:16<br><b>relating</b> 4:22<br><b>relationship</b><br>28:14,23<br><b>release</b> 21:4,13<br>43:19,23 44:1<br>60:7,15,18<br>61:7,11,15,17<br>61:21 62:8,15<br>63:5,13,22<br>65:6 66:1,11<br>67:6,12 69:11<br>70:4,6,22 71:3<br>72:2,5,7 |
| <b>r</b>                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>r</b> 2:5 75:3,3<br><b>range</b> 19:6 38:7<br><b>ranges</b> 19:10<br><b>ranitidine</b><br>66:17,20,21,22<br>67:1,15,22<br>68:6<br><b>rapid</b> 27:16<br>28:6,11 61:18<br>61:19,19,21                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>released</b> 62:18<br>63:22 64:2,7<br>64:18 65:21<br><b>releases</b> 19:20<br>59:23 66:5,8,8<br><b>releasing</b> 61:18<br>61:20 64:5<br>66:2,7<br><b>relevant</b> 51:24<br>52:8,20<br><b>relied</b> 12:20<br><b>rely</b> 18:4<br><b>relying</b> 9:17<br>10:19<br><b>remember</b><br>61:12<br><b>remind</b> 71:20<br><b>repeat</b> 12:17<br>37:6 67:18<br><b>rephrase</b> 47:16<br>55:6<br><b>reply</b> 4:19 7:9<br>7:19 8:3,5,7,9<br>8:15,20 9:13<br>9:18 14:6,14<br>15:8,14,22<br>16:17 17:3<br>22:3,7,11<br>24:20 26:1,10<br>26:19 27:2,12<br>27:15,18 29:6<br>30:11,17,20<br>31:11,15,17,19<br>31:20 33:2,15 | 34:1,3,25<br>35:18 39:4,24<br>40:3,21 41:11<br>41:20 42:1,8<br>42:16 46:5<br>48:19,22 55:2<br>55:7 56:15,22<br>60:9,19 63:10<br>69:13<br><b>report</b> 10:3<br>59:22 69:5<br><b>reported</b> 1:14<br>73:10<br><b>reporter</b> 4:3<br>5:12,23 73:4<br><b>reporter's</b> 73:1<br><b>reproduction</b><br>13:5<br><b>required</b> 76:13<br><b>requires</b> 52:17<br><b>respond</b> 36:20<br><b>response</b> 10:8<br><b>return</b> 74:13,16<br><b>review</b> 9:14<br>10:1 38:6 74:7<br><b>reviewed</b> 5:5<br>8:23 10:11,16<br>10:22<br><b>reviewing</b><br>10:12<br><b>right</b> 6:17<br>20:24 24:24<br>37:2 40:20<br>51:17 61:23 | 64:25 66:5<br><b>rise</b> 63:12,20<br><b>romanette</b> 8:17<br>8:19<br><b>room</b> 6:19<br><b>rosalie</b> 1:14 4:3<br>73:3,20<br><b>route</b> 43:25<br>44:2<br><b>routes</b> 41:16<br>42:5<br><b>rpr</b> 1:14 73:21<br><b>rules</b> 6:13<br><br>s<br>s 22:19 75:3<br><b>saliva</b> 17:12,13<br><b>salivation</b><br>29:22<br><b>san</b> 2:8 4:1<br><b>saying</b> 66:7<br><b>says</b> 10:19<br>16:11 17:22<br>20:5 23:20<br>24:9 28:13<br>35:14 37:2,4<br>37:18 38:17<br>44:10 45:2,3,7<br>57:11 59:23<br>60:6 62:16<br>64:8,19,22<br>65:9,12 66:5,7<br><b>search</b> 9:4 11:3<br>11:9,22 | <b>second</b> 7:15<br>12:23 17:5<br>18:20 20:8<br>28:5 36:19<br>44:13 46:6<br>63:9,16<br><b>seconds</b> 12:4,5<br>12:5 17:8,9,9,9<br>17:10,10,10,11<br>17:11,11 18:25<br>19:6,12 20:4<br>20:17,18,20,23<br>20:23 21:5,6<br>21:23 23:22<br>25:23 29:23,24<br>36:12,15,23<br>37:1,2,3,4,9,12<br>37:13,15,18,19<br>37:20 38:2,8,9<br>38:16,18 61:2<br>61:3 64:10<br>68:17,23 69:4<br><b>section</b> 44:10<br>50:2 65:22<br><b>see</b> 4:13 14:8<br>19:3 20:7<br>24:18,22 25:10<br>25:24 28:3,8<br>28:18 29:25<br>31:8,23,24,24<br>31:25 36:7<br>37:1 41:5,8<br>44:3,11,22<br>50:12 57:7 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 58:2,4,13 62:5<br>62:12 63:24<br>64:15 70:16<br><b>sees</b> 63:6<br><b>selected</b> 33:17<br>33:18 66:16<br><b>sense</b> 11:13<br><b>sent</b> 74:14<br><b>sentence</b> 12:10<br>12:24 13:1,10<br>13:23 14:16<br>15:12 16:10,12<br>16:18 17:5<br>18:20 20:8<br>21:2 22:15<br>24:6,20 25:5<br>25:20 27:24<br>28:5 31:5,6<br>32:7,20 35:4<br>44:14 56:24<br>61:6 63:10,18<br><b>set</b> 65:3 73:9<br><b>sheet</b> 74:11<br><b>shoot</b> 63:1<br><b>shooting</b> 62:25<br><b>short</b> 60:24<br>61:15<br><b>shorthand</b> 73:3<br><b>shortly</b> 60:1,7<br>60:21,22 63:23<br>64:2 66:6<br>70:22 71:3<br><b>show</b> 15:11<br>33:17 38:7 | 53:15 55:3,13<br>55:18 56:2<br>60:2<br><b>shown</b> 26:13<br><b>shows</b> 26:17<br>33:24 46:1<br>53:20 55:8<br>59:24<br><b>sign</b> 74:12<br><b>signature</b> 7:23<br>7:24 73:19<br><b>signed</b> 74:19<br><b>similar</b> 30:2<br>32:16 45:5<br>49:1 53:22,24<br><b>singh</b> 34:5,12<br>34:24<br><b>single</b> 44:18<br>50:8,10<br><b>sit</b> 54:8<br><b>site</b> 47:21<br><b>six</b> 37:23<br><b>size</b> 38:19<br>68:15,17<br><b>small</b> 50:18<br>51:21 54:6,7<br>54:17,17 67:8<br>69:4,8<br><b>sold</b> 23:21<br><b>solid</b> 18:23<br>23:19 24:2<br>25:7 38:14<br>42:18 | <b>soluble</b> 58:20<br>59:1,4,8,13,13<br>66:15<br><b>solution</b> 17:12<br>21:18,19 46:8<br>46:12,21 49:1<br>49:6 53:17,19<br>53:21 55:17<br>56:9 62:1<br><b>solutions</b> 47:9<br>48:24 74:23<br><b>sooner</b> 20:25<br>37:12,25<br><b>sorry</b> 9:8 14:22<br>14:23 15:4<br>29:13,15 30:4<br>49:22 55:6<br>63:14 68:11<br>70:5<br><b>sort</b> 6:18<br><b>space</b> 40:10<br><b>spans</b> 22:23<br><b>speak</b> 6:13<br><b>spec</b> 62:23,25<br><b>specific</b> 17:20<br>55:13 58:5<br><b>specifically</b><br>15:25 23:24<br>32:11 58:3<br>67:2<br><b>sphincter</b> 68:20<br><b>spot</b> 14:9,19<br><b>standard</b> 69:11 | <b>stapled</b> 15:18<br><b>start</b> 21:10<br>70:5<br><b>starting</b> 11:14<br>14:25 31:21<br>32:2,3,22<br>33:21 66:14<br>69:22 70:10<br><b>starts</b> 8:17 15:4<br>44:14 57:4<br>62:3<br><b>state</b> 4:14 11:2<br>19:9 20:6 33:3<br>46:12 57:13<br>72:16 73:4<br><b>stated</b> 13:1<br><b>statement</b><br>15:11 24:9<br>32:10 33:16<br>48:24<br><b>states</b> 1:1 11:7<br>12:10 16:12<br>17:5 18:19,20<br>19:1 21:2<br>22:15 24:13<br>25:6,20 27:24<br>28:15 29:18<br>30:23 31:6<br>35:4 36:3<br>38:12 40:6<br>41:15 42:5<br>44:13,17 49:24<br>50:6 56:25<br>58:9 61:7 62:7 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 62:10 63:11<br>64:13 66:14<br>69:22 70:4,10<br><b>staying</b> 14:5<br><b>stenographic...</b><br>73:10<br><b>step</b> 47:11<br><b>stomach</b> 54:5<br>54:14,18 55:1<br>66:11 67:16,22<br>68:14,21 69:1<br><b>stresses</b> 65:20<br>65:25<br><b>strike</b> 8:6 36:10<br><b>structure</b> 69:15<br>69:21<br><b>studies</b> 45:24<br>52:4,23 53:2<br>68:9<br><b>study</b> 44:14,17<br>44:24 45:25<br>50:7,14<br><b>subject</b> 6:25<br><b>subjects</b> 45:1<br><b>sublingual</b> 16:7<br>16:13<br><b>submitted</b> 4:20<br>38:6<br><b>submitting</b> 8:3<br>8:5,7,13 9:13<br><b>subscribed</b><br>76:14<br><b>substances</b><br>25:8 | <b>substantial</b><br>26:13<br><b>suggestion</b> 40:1<br><b>suitable</b> 25:8<br><b>suite</b> 2:7,17<br><b>support</b> 9:18<br><b>sure</b> 8:5 13:13<br>17:22 26:15<br>36:25 39:1<br>47:15 56:12<br><b>surface</b> 68:18<br><b>surveyed</b> 38:5<br><b>suspension</b><br>53:9,12,17,18<br>53:21 56:9<br><b>swallow</b> 68:14<br>69:7,12<br><b>switch</b> 15:19<br><b>switching</b><br>45:17<br><b>sworn</b> 4:7 73:7<br>76:14<br><b>synocrint</b> 11:12<br><b>synonymous</b><br>21:14<br><b>syrup</b> 43:3,13<br>43:15,19,24<br>44:18,25 49:14<br>50:6,8,15,19<br>55:17<br><b>system</b> 48:13<br><b>systemic</b> 47:4,5<br>47:25 48:1,3,5<br>48:15,20 51:9 | 51:16,20 54:2<br>54:23 55:18,19<br>55:22<br><b>systemically</b><br>43:9 46:18,21<br>46:24 47:9,14<br>47:17 48:7,9<br>49:17 50:25<br>52:12 53:23<br>54:1,19 55:21<br>56:3 66:22                                                                                                                                                                                      | 35:7 44:19<br><b>tacky</b> 68:19,20<br><b>take</b> 6:7 15:20<br>37:13 38:25<br>53:16 56:10<br>68:2,13,25<br>69:9<br><b>taken</b> 7:16 39:2<br>56:13 73:8,14<br><b>takes</b> 69:10<br><b>talk</b> 48:8 60:21<br><b>talked</b> 10:3<br>26:14<br><b>talking</b> 19:25<br>48:21<br><b>talks</b> 19:20,22<br>21:16 37:4,10<br>37:17,22,24<br>38:22 60:4,5<br>69:17 70:21<br><b>tang</b> 30:12,20<br>31:14<br><b>target</b> 63:2,4<br><b>targeted</b> 62:8<br>63:13,22<br><b>targets</b> 65:6<br><b>taste</b> 22:19,25<br>23:4 56:25<br>58:12,16,22,25<br>59:16,20,23,25<br>60:2,5,5 63:12<br>63:21 64:13,19<br>65:18,19,21,24<br>66:3 67:1,2,6 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>t</b>                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>t</b> 75:3,3<br><b>tab</b> 7:4,6,7<br><b>tablet</b> 16:7,8,13<br>21:20 29:19,19<br>30:3,6,8,25<br>32:4 34:16<br>35:6,11,21,24<br>36:10,11 37:15<br>38:3,19 39:15<br>40:7,13 44:25<br>50:11,15 68:13<br>68:15,19,24<br>69:11<br><b>tablets</b> 12:11<br>16:25 17:6,16<br>17:24 18:10<br>21:3 22:17<br>23:20,22,25<br>24:3,8,16 25:6<br>25:6,21 28:6<br>30:8 34:12 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 67:11 70:19,21<br>70:25 72:4<br><b>tasting</b> 58:11<br><b>teaches</b> 64:17<br><b>techniques</b><br>70:11<br><b>tell</b> 5:12 54:4<br><b>term</b> 24:9 30:6<br>41:23 57:4,9<br><b>terms</b> 34:22<br>62:4,7<br><b>test</b> 19:2<br><b>tested</b> 62:10<br><b>testified</b> 4:7<br>11:2<br><b>testimony</b> 6:14<br>6:15 13:4<br>72:17 73:9,13<br>74:9,17 76:8<br><b>testing</b> 24:6<br><b>text</b> 6:18<br><b>thank</b> 72:10<br><b>theory</b> 69:24<br><b>therapeutic</b><br>40:9 43:10<br>48:10,10 49:8<br>51:24 52:8,20<br>52:22 57:11<br><b>therefrom</b><br>25:22<br><b>thereon</b> 22:17<br><b>thing</b> 24:5<br>31:24 33:3 | <b>things</b> 61:19<br>67:11<br><b>think</b> 15:4<br>23:17 26:12<br>27:8 30:5<br>33:16 38:20<br>40:23 48:17,18<br>57:23 59:21<br>60:20 61:2<br>63:8 71:19,24<br><b>third</b> 7:4 9:23<br>26:4,15 38:22<br>44:9 49:11<br><b>three</b> 50:7 53:6<br>53:15,15<br><b>thursday</b> 9:25<br><b>time</b> 11:8,25<br>14:1 16:22<br>17:15,20 18:25<br>19:8,11,21<br>20:19 26:16<br>27:16 28:10,20<br>28:25 29:5,20<br>29:23 34:18<br>37:25 38:1,15<br>39:22 40:17<br>41:21 61:1,15<br>64:8 66:10<br>69:9 73:8,14<br>74:18<br><b>timeframe</b> 74:8<br><b>times</b> 5:5 20:1<br>26:7 27:19<br>69:2 | <b>timing</b> 17:25<br><b>timings</b> 18:1<br>21:17<br><b>tiny</b> 44:8<br><b>title</b> 18:7 24:1,8<br><b>today</b> 4:18 5:9<br>5:13,16 6:22<br><b>today's</b> 9:20<br><b>tongue</b> 29:20<br><b>took</b> 5:11<br><b>top</b> 50:5<br><b>topic</b> 56:11<br><b>topical</b> 47:2,6,7<br>47:11 48:2,5<br>48:11,12 51:2<br>51:15,22 52:9<br>52:10,11 54:21<br>54:23 55:24<br>56:2<br><b>topically</b> 47:1<br>47:10,21,24<br>48:6 52:22<br>53:24,25 55:3<br>55:5,8,10,14,19<br>55:20,23,24<br>56:4<br><b>towards</b> 65:18<br><b>tract</b> 47:3,5,18<br>48:6 53:25<br>54:2,11,18,25<br>67:8,9,14,16,22<br><b>trademark</b> 1:1<br><b>transcribed</b><br>73:11 | <b>transcript</b> 74:6<br>74:19 76:5,8<br><b>transcription</b><br>73:12<br><b>transdermal</b><br>41:18 42:7<br><b>transverse</b><br>68:25<br><b>treat</b> 54:14,16<br><b>trial</b> 1:2<br><b>troche</b> 39:15,19<br>40:7,13<br><b>true</b> 47:23 51:4<br>73:13 76:8<br><b>truth</b> 5:12<br>72:17,17,18<br><b>truthfully</b> 5:16<br><b>try</b> 6:7 37:7<br>62:22<br><b>turn</b> 7:4,22<br>11:14 12:6<br>17:1 24:11<br>27:11 33:20<br>49:23 56:15<br>62:2 64:12<br><b>twice</b> 26:15<br><b>two</b> 36:16<br>43:22 44:21<br>53:15 67:11<br>71:13,19<br><b>type</b> 24:7 38:19<br>44:24 50:14<br><b>typically</b> 12:10<br>30:25 31:25 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 32:3 45:24<br>69:18 70:1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <b>used</b> 26:8 29:18<br>36:14 38:20<br>54:13,22 58:9<br>60:3 65:23<br>74:19                                                                                                                                                                                                                                                                                                                       | 63:6,7 64:5,8<br>64:10 65:22<br>66:5,8 67:7<br>72:4                                                                                                                                                                                                                                                                                                                | <b>we've</b> 5:7 38:18<br>70:25                                                                                                                                                                                                                                                    |
| <b>u</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <b>useful</b> 57:13,19<br><b>uses</b> 19:9<br><b>using</b> 20:5<br>36:15<br><b>usp</b> 12:5 19:10<br>20:5 36:15<br><b>usually</b> 69:6                                                                                                                                                                                                                                                              | <b>vitro</b> 18:24<br>38:15<br><b>volume</b> 50:18<br>69:5,8<br><b>volunteers</b><br>44:19 50:8<br><b>vs</b> 1:6                                                                                                                                                                                                                                                   | <b>week</b> 9:25<br><b>wide</b> 62:22<br><b>witness</b> 13:5<br>15:20 18:17<br>21:16 32:9<br>39:1 45:23<br>52:3 55:13<br>67:18,25 68:5<br>71:18 72:10<br>73:6,16 74:8<br>74:10,12,18                                                                                               |
| <b>u.s.</b> 1:6 35:8<br><b>uh</b> 20:10 43:8<br>47:20 63:19<br><b>ulcers</b> 54:14,14<br>54:16 55:1<br><b>under</b> 6:12<br>12:2 14:3<br>72:15,15<br><b>understand</b><br>4:18 5:6,11,18<br>6:1,3,10,12<br>19:7 24:2<br>34:22 36:21<br>37:14 47:15<br>52:17<br><b>understood</b> 6:4<br><b>uniform</b> 70:13<br><b>unique</b> 41:16<br>42:5<br><b>united</b> 1:1 19:1<br>62:10<br><b>unpalatable</b><br>24:15<br><b>unpleasant</b><br>22:19 58:11<br><b>upper</b> 54:11,24<br><b>use</b> 11:12 19:9<br>51:13 55:4<br>70:12 | <b>v</b> 74:4 75:1<br>76:1<br><b>valley</b> 2:7<br><b>value</b> 65:25<br><b>verbatim</b> 32:12<br><b>verbiage</b> 32:16<br><b>verify</b> 74:9<br><b>veritext</b> 74:14<br>74:23<br><b>veritext.com.</b><br>74:15<br><b>versa</b> 45:18<br><b>versus</b> 56:9<br><b>vice</b> 45:18<br><b>view</b> 13:13<br><b>virtual</b> 60:6<br>66:1 67:12<br><b>virtually</b> 59:25<br>60:15,21,23<br>61:1,3,7,14 | <b>w</b><br><b>wafer</b> 16:8,8,13<br>21:20<br><b>wafers</b> 17:6,16<br>17:24 21:3<br><b>walls</b> 69:17,25<br><b>want</b> 15:15,18<br>38:25 59:15<br><b>wanted</b> 40:15<br><b>washington</b><br>2:18<br><b>water</b> 12:13<br>31:2 32:6<br>58:20 59:1,4,8<br>59:13,13 66:15<br>69:12<br><b>way</b> 13:15<br>15:19 50:7<br>54:10 62:3<br>63:3 65:13<br>69:3 71:15 | <b>wo</b> 31:7,10<br><b>word</b> 21:7,7<br>32:2,14,14,15<br>32:15<br><b>words</b> 16:11<br>32:9<br><b>work</b> 47:1<br>54:24 65:21<br>67:14 69:3,9<br><b>worked</b> 68:7<br><b>working</b> 55:23<br>65:13 71:15<br><b>works</b> 52:14<br><b>worry</b> 63:3<br><b>written</b> 13:14 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                    | <b>x</b>                                                                                                                                                                                                                                                                           |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                    | <b>x</b> 3:1                                                                                                                                                                                                                                                                       |

| y                                                                           |
|-----------------------------------------------------------------------------|
| <b>yeah</b> 16:10<br>20:22 29:17<br>31:23 32:24<br>45:6 63:7<br>69:16 70:20 |
| z                                                                           |
| <b>zero</b> 29:22,24<br><b>zofran</b> 42:24<br>46:6,8,15<br>48:21,25 49:8   |

Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate.

The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS

COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

Veritext Legal Solutions is committed to maintaining the confidentiality of client and witness information, in accordance with the regulations promulgated under the Health Insurance Portability and Accountability Act (HIPAA), as amended with respect to protected health information and the Gramm-Leach-Bliley Act, as amended, with respect to Personally Identifiable Information (PII). Physical transcripts and exhibits are managed under strict facility and personnel access controls. Electronic files of documents are stored in encrypted form and are transmitted in an encrypted

fashion to authenticated parties who are permitted to access the material. Our data is hosted in a Tier 4 SSAE 16 certified facility.

Veritext Legal Solutions complies with all federal and State regulations with respect to the provision of court reporting services, and maintains its neutrality and independence regardless of relationship or the financial outcome of any litigation. Veritext requires adherence to the foregoing professional and ethical standards from all of its subcontractors in their independent contractor agreements.

Inquiries about Veritext Legal Solutions' confidentiality and security policies and practices should be directed to Veritext's Client Services Associates indicated on the cover of this document or at [www.veritext.com](http://www.veritext.com).