

1 UNITED STATES DISTRICT COURT  
2 SOUTHERN DISTRICT OF FLORIDA  
3 WEST PALM BEACH DIVISION

4 CASE NO. 20-md-02924-ROSENBERG

5 **IN RE: ZANTAC (RANITIDINE)** .  
6 **PRODUCTS LIABILITY** . West Palm Beach, FL  
7 **LITIGATION.** . August 26, 2021  
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10 DISCOVERY CONFERENCE (through Zoom)  
11 BEFORE THE HONORABLE BRUCE REINHART  
12 UNITED STATES MAGISTRATE JUDGE

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1           *THE COURT:* It is 4:00 o'clock, sorry, we are starting  
2 a few minutes late, but this is case number 20-2924, In re:  
3 Zantac Ranitidine Product Liability. We are here for a PTO 32  
4 discovery hearing.

5           Let me have appearances. I'll start with counsel for  
6 the Plaintiff.

7           *MR. NIGH:* Your Honor, this is Daniel Nigh from the  
8 for law firm of Levin Papantonio on behalf of the Plaintiffs.

9           *THE COURT:* Good afternoon, Mr. Nigh. On behalf of  
10 GSK.

11          *MR. SACHSE:* Good afternoon, your Honor, this is Will  
12 Sachse on behalf of GSK.

13          *THE COURT:* Good afternoon. I understand we do have  
14 people for Sanofi and BI. If I could ask counsel for Sanofi to  
15 make an appearance.

16          *MR. BEROUKHIM:* Good afternoon, your Honor, Alex  
17 Beroukhim of Arnold & Porter for the Sanofi parties.

18          *THE COURT:* Good afternoon. On behalf of Boehringer  
19 Ingelheim.

20          *MR. SENTENAC:* Good afternoon, your Honor, Mark  
21 Sentenac, on behalf of Boehringer Ingelheim Pharmaceuticals,  
22 Inc.

23          *THE COURT:* Good afternoon. This was originally  
24 noticed as a PTO 32 hearing for all three Defendants. My  
25 understanding from the special master is that BI and Sanofi

1 have reached agreements with the Plaintiffs, so whatever  
2 discovery issues the parties had intended to bring before the  
3 Court this afternoon for those two Defendants are now moot.

4 Am I correct, Mr. Sentenac?

5 MR. SENTENAC: That's my understanding, your Honor,  
6 that's correct.

7 THE COURT: At least as to BI, Mr. Nigh, is that  
8 correct, you have an agreement?

9 MR. NIGH: On behalf of the Plaintiffs, yes, that is  
10 correct.

11 THE COURT: Mr. Beroukhim, on behalf of Sanofi, do you  
12 understand that we have an agreement on the disputed issues?

13 MR. BEROUKHIM: Yes, your Honor.

14 THE COURT: Mr. Nigh, you can confirm that as well?

15 MR. NIGH: Yes, your Honor.

16 THE COURT: Great. All right. Thank you, Mr.  
17 Beroukhim and Mr. Sentenac. I will excuse you from the camera  
18 if you'd like to be.

19 MR. SENTENAC: Thank you very much, your Honor.

20 THE COURT: I understand we still have a dispute with  
21 GSK, which is fine.

22 So, I guess, Mr. Nigh -- I did have a chance to read  
23 the submissions that the parties sent earlier today, but if you  
24 would like to summarize or make any further argument, I am  
25 happy to hear from you. I did read them, but there's a lot of

1     acronyms and a lot of science in there, so don't short change  
2     yourself. Feel free to explain to me anything you think I need  
3     to know.

4             *MR. NIGH:* Thank you, your Honor. I will try to be  
5     brief with my argument seeing that you already read the papers.

6             I'll say with GSK we have had numerous meet and  
7     confers with Mr. Sachse regarding their product and it appears  
8     that they have been forthcoming with the product that they have  
9     had on hand worldwide. They have given us a lot of detail in  
10    terms of the product that they had, and I know that it was  
11    likely a gargantuan task on their behalf and we received a lot  
12    of detail.

13            We have had the pleasure of that back and forth meet  
14    and confer with them, and I think what we have here today is a  
15    narrowing of the issues that we are presenting to your Honor  
16    here.

17            We have narrowed the scope of what we have requested  
18    to only the product that contains the Zantac API that made its  
19    way into finished products that was distributed into the U.S.  
20    While GSK was selling Zantac in the U.S. their product used  
21    Jurong API, which is also API's known active ingredient  
22    manufactured in Jurong, and Dr. Reddy's API, which is the  
23    active ingredient manufactured by Dr. Reddy's, also called DRL  
24    API.

25            So the active ingredient makes its way into the

1 finished products and often times the active ingredient is  
2 where we will see issues in terms of contamination and/or  
3 degradation, stability issues. GSK --

4 *THE COURT:* I'm sorry, Mr. Nigh, I apologize for  
5 interrupting you, but for my sake and for the court reporter's  
6 sake, when you talk about the first API, the one that GSK  
7 manufactured itself, what did you call that, the Jurong API?

8 *MR. NIGH:* Yes, Jurong, that's spelled J-E-R-O-N-G  
9 API. Maybe I have the spelling wrong, it might be J-U-R-O-N-G.  
10 Is that right, Will?

11 *MR. SACHSE:* Yes, it's J-U-R-O-N-G.

12 *THE COURT:* Okay. J-U-R-O-N-G, and that is the one  
13 that GSK made itself, and then they later contracted out with  
14 Dr. Reddy, so that is the DRL, Dr. Reddy Lab API?

15 *MR. NIGH:* Correct.

16 *THE COURT:* Thank you for clarifying the terminology  
17 for me.

18 *MR. NIGH:* To further along this, GSK's top brass, Dr.  
19 Andrew Searle and Michael Urquhart, have asserted that the type  
20 of Zantac API used and the crystallization of that API, along  
21 with other factors of that API, will affect how much NDMA forms  
22 in Zantac.

23 GSK's assertion is that product using GSK Jurong API  
24 will degrade the least of the APIs that they looked at and they  
25 published a scientific article making this assertion. That is

1 the F. J. King article that we attached.

2 Plaintiffs dispute this finding and Plaintiffs have  
3 the right to test the GSK Jurong API and the DRL API product  
4 that were both tested in that F. J. King article, and product  
5 utilizing DRL API to test their assertion.

6 First, GSK asserts that it should not have to produce  
7 any of its Jurong API because all the GSK Jurong product that  
8 they now have is expired. Our experts maintain that expired  
9 for human consumption does not equate to testing of expired  
10 product having no probative value, they are two different  
11 things. Rather, our experts tell us it is extremely relevant  
12 for numerous reasons, and we believe GSK knows this as well.

13 In that same F. J. King scientific publication that we  
14 attached GSK tested expired API of its competitors in  
15 demonstrating the differences and the rate of degradation  
16 between their Jurong and Dr. Reddy's API and the Saraca API.  
17 They also looked at these expired API products under a  
18 microscope to compare their competitors' products'  
19 crystallization and other issues compared to Jurong and Dr.  
20 Reddy's.

21 Our experts maintain that examining GSK Jurong's API  
22 and Dr. Reddy's API for these tests, and possibly others, goes  
23 to the heart of this litigation and is extremely probative.

24 And I will also remind opposing counsel that they are  
25 still free to argue any issues with the API upon our exempts to

1 admit into evidence our testing of that API.

2 We also believe our requests that we have made to Mr.  
3 Sachse are proportional. We have requested two and a half  
4 kilograms out of the 50 kilograms of GSK Jurong API that they  
5 have. We have requested 500 grams of the 11 kilograms of DRL  
6 API that they have. We have requested a small percentage of  
7 the finished product that GSK has that used DRL API. We  
8 believe our requests are proportional.

9 For these reasons we ask the Court to compel GSK to  
10 produce to us the GSK Jurong API, the DRL API, and the finished  
11 product using DRL API that we specifically requested from GSK,  
12 and that these be shipped to us by August 31st.

13 Thank you, your Honor.

14 *THE COURT:* Thank you very much. Again, the ask is,  
15 you want samples of the DRL API, you want samples of the Jurong  
16 API, and then you want samples of finished product that was  
17 manufactured using DRL. Am I correct?

18 *MR. NIGH:* That is correct, and we gave specific  
19 amounts of samples that we need because that is the amount that  
20 our experts tell us may be needed to carry out all the tests  
21 they need to do on the products.

22 Thank you, Your Honor.

23 *THE COURT:* Thank you. I see that on page three of  
24 your submission.

25 Mr. Sachse, let me turn to you. You and I have done

1 this dance before, so I will ask you, first, is your objection  
2 that it is not relevant, that it is not proportional, that it  
3 is unduly burdensome, or some combination thereof?

4 MR. SACHSE: I think it is a little bit of both --  
5 well, I guess there were three options there, so it's a little  
6 bit of option one and option two. I can kind of walk through  
7 because I think, depending on what we are talking about, the  
8 answer shifts a little bit. But I think the core argument that  
9 we have here is one of relevance.

10 So, let me start and kind of first agree broadly with  
11 Mr. Nigh's kind of characterization of the history, the product  
12 history, which is important to keep in mind for purposes of  
13 this dispute. He is correct, Mr. Nigh is correct that GSK once  
14 made its own API at the Jurong Singapore facility, and in 2010  
15 GSK got regulatory approval to start using Dr. Reddy's API in  
16 GSK's finished products.

17 That transition happened over the next few years so  
18 that by the end of 2014, GSK no longer made its own API at  
19 Jurong and was only getting Zantac or Ranitidine API from Dr.  
20 Reddy's, and then later on they actually added a few other  
21 suppliers. You may have seen in our papers a reference to  
22 Saraca, Orchev, SMS, those were other APIs acquired.

23 So, in essence, as of December 2014, GSK is out of the  
24 Ranitidine API manufacturing business.

25 So, what we are talking about here -- and I agree also



1 with Mr. Nigh, there are three discrete categories of items.  
2 One is expired API, and that kind of comes in two flavors. It  
3 is what I think is a very extensive request for samples of  
4 expired Jurong API, and then a less extensive request for  
5 500 grams of expired Dr. Reddy's API. So, that is the first  
6 category, is expired API.

7 The second category is expired finished product, not a  
8 lot of requests here, so I am not going to argue burden at all,  
9 it's only a handful of requests. This is a straight relevance  
10 argument.

11 And then similarly, the third category is returned  
12 finished product, so these are returned tablets, returned  
13 syrup, injections, etc., again, only making really a relevance  
14 argument because they have only asked for a handful of those  
15 products.

16 To kind of come back to your first question, Judge,  
17 when we think about prong one, expired API, that is where we  
18 have relevance and kind of a proportionality flavor. The  
19 expired finished product, returned finished product, the  
20 proportionality is not really as significant or significant at  
21 all, it is really all about relevance.

22 So, let me just talk a little bit about the Root Cause  
23 Analysis, which I think is a bit of the elephant in the room  
24 here. Sometimes I might slip and I apologize in advance if I  
25 call it the RCA, it has become kind of the lingo of the case.

1           The Root Cause Analysis essentially was an analysis  
2 GSK undertook at the request of regulators in 2019 to test  
3 hundreds of samples of API and finished product in all  
4 different formulations, tablets, EFFERdose, injections, syrup,  
5 suspension, and in essence, GSK was trying to figure out, sort  
6 of like what it says on the tin, they are trying to figure out  
7 the root cause of these reports of NDMA formation with  
8 Ranitidine.

9           After a few months of extensive testing of these  
10 hundreds of samples, and it was not just GSK API, but as Mr.  
11 Nigh mentioned, it was API from GSK's other suppliers, so  
12 Saraca, Dr. Reddy's, SMS, it was also finished product made  
13 with API from Dr. Reddy's, Saraca, the others.

14           There was a very, very, very small amount of finished  
15 product made with Jurong API, but for the most part, the  
16 testing that was done looked at product that GSK had on hand  
17 that was unexpired, again, hundreds and hundreds of samples  
18 tested. And the conclusion -- and this is actually I think  
19 another area where Mr. Nigh and I agree. The conclusion is  
20 Ranitidine does degrade, can degrade over time to form low  
21 levels of NDMA. Heat can affect that rate of degradation,  
22 humidity can affect that rate of degradation.

23           Maybe where we disagree, and this is something that is  
24 a little bit new to me, is in the question of the structure,  
25 the morphology, the shape.

1           So, one of the findings of the Root Cause Analysis as  
2 GSK looked at all of these different samples and they put them  
3 under electron microscopes, they found that the columnar  
4 morphology, which is kind of what it sounds like, it is a  
5 column. Exactly. I think if you look at the published article  
6 that we included with our submissions you will see there is  
7 actually a good picture that I thought made it come alive for  
8 me.

9           So, columnar seems to degrade at a much slower rate  
10 than what I call the lumpy morphology, which is certainly not  
11 the accurate chemical term, but the columnar morphology -- and  
12 this is important because the Jurong API was made with a  
13 process that led to columnar morphology. And so, when GSK  
14 tested its API, its own API, this is -- again, we are in  
15 September, October of 2019.

16           I mentioned that GSK's API business shut down for  
17 Ranitidine in December of 2014, so we are coming up on the end  
18 of the five-year period, the five year expiry for that API.  
19 GSK tests its own Jurong API, sees very, very low levels. 10  
20 out of 11 batches, or samples test below the acceptable daily  
21 limit that we have been talking about in this litigation. The  
22 11th is just a little bit above.

23           When GSK compares those results to figure out, well,  
24 why is that different from what we are seeing with other  
25 batches that we are testing, they land on this columnar

1 morphology as a potential explanation.

2 That gets all kind of wrapped up in an extensive --  
3 this was over the course of months, the testing -- an extensive  
4 submission both to the EMA, the Europeans, and the FDA, and  
5 ultimately, as you know, your Honor, there was a submission --  
6 sorry, a publication, peer reviewed, and that is what we are  
7 calling the King article which we both attached to our  
8 submissions.

9 So, that is kind of the state of play with the Root  
10 Cause Analysis.

11 The Plaintiffs have all of this. The Plaintiffs have  
12 all of the submissions to the regulators, they have all of the  
13 testing results, they have the publication. As Mr. Nigh  
14 mentioned, they took the depositions of Mr. Searle, the  
15 chemist, and Mr. or Dr. Urquhart, I forget, another chemist  
16 involved in the root cause. They have got all of this  
17 evidence.

18 What we are talking about now is that the Plaintiffs  
19 want to go further and they want to do their own testing, but  
20 the conundrum -- and I will say from a GSK perspective, we wish  
21 we had unexpired Jurong API. If we had unexpired Jurong API I  
22 don't think we would be here because we'd say, here it is, and  
23 we'd cut the same deal that BI cut and say, have our unexpired  
24 API, but forget our expired stuff. Unfortunately, we can't do  
25 that because all we have left is expired.

1           So, talking about the expired API, let's start with  
2 what we have. We have a small amount of expired API per batch  
3 that we retained in Jurong. Originally this was a regulatory  
4 requirement. Now, because of the litigation, it's a litigation  
5 hold requirement, but we have these little 30-gram vials. They  
6 are sealed, they are kept in controlled conditions, and they  
7 are just sort of sitting there and getting older.

8           The Plaintiffs have asked for 246 10-gram samples  
9 ranging from 2000 -- date of manufacture of 2010 to 2014. So,  
10 what that means is, if you apply the five-year expiry, all of  
11 these batches would have expired between 2015 and 2019. When  
12 you look at actually the distribution, most of the batches that  
13 the Plaintiffs are requesting, about 80 percent, are from the  
14 2010, 2011 period, so the oldest stuff.

15           So, what we find ourselves facing here is the  
16 question, what is the relevance of testing expired API? We  
17 have been, as Mr. Nigh mentioned, going back and forth on this  
18 for months. We, GSK, have been pretty dug in on the notion  
19 that expired API is not relevant and we've been sort of  
20 searching for an explanation for what exactly -- why Mr. Nigh  
21 and his colleagues think it is relevant, and essentially the  
22 answer we've gotten is our experts say it is relevant, they  
23 want to do stuff with it, trust us, work product.

24           I think that the experts want to do something with  
25 this, and trust us, this is work product, isn't really a

1 discovery standard. I think we are entitled to know, broadly  
2 speaking, well, what is the relevance. I think we heard some  
3 of that from Mr. Nigh today, a little bit, but what it really  
4 comes down to I think is, GSK, you tested expired API, so we  
5 want to test expired API, too.

6 On that front, I want to just be very clear because I  
7 am not sure this came through in the papers.

8 Yes, GSK did test expired API. There was one batch  
9 from 2010, that would have expired in 2015, that GSK tested in  
10 2019. There were a handful of batches, I think it's something  
11 like 18 -- I should say samples, a handful of samples, 18 that  
12 had expired within a few months before testing.

13 So, when we talk about the 18 or so samples that had  
14 just recently expired, that is not what the Plaintiffs -- it's  
15 a different situation from what the Plaintiffs are asking for  
16 here. What they are asking for is well expired API. Really  
17 the only well expired API that they can point to is that one  
18 batch from 2010.

19 Why did GSK test that, that one batch? It was for a  
20 completely different reason than what we are doing here in this  
21 litigation. First of all, it was a response to a regulatory  
22 request for testing; and second of all, it was to search for  
23 and confirm what we have been talking about, the root cause of  
24 this NDMA degradation. This was not about trying to figure out  
25 what level was in that particular batch so that if somebody

1 took that batch, that was how much NDMA they were exposed to,  
2 nothing like that, completely different scientific input.

3 So the question is, if it is not just we want to do it  
4 because you did it, and we only did one batch of expired --  
5 what I will call well expired product, and here it is sort of  
6 exactly backwards, the Plaintiffs want to test 245, 246 batches  
7 of expired product. If that doesn't get them there, then I  
8 think some of what we heard from Mr. Nigh today shows what is  
9 really going on here.

10 They want to cast doubt on GSK's testing, and I  
11 understand that because I don't think that GSK's testing helps  
12 them one lick, but there are a lot of problems with that.

13 The first problem is the threshold, this is apples to  
14 oranges, so they are testing expired product when GSK -- when  
15 it tested its Jurong API, did not test expired Jurong API. So  
16 now we are talking about testing expired API two years later.  
17 In fact, we are talking about testing some API that is six  
18 years past expiry. Presumably this is so that the Plaintiffs  
19 can say, look, now it is higher levels.

20 I think that is exactly what we would expect to see  
21 because, as I have said, we all, I think, agree that Ranitidine  
22 degrades over time. So, if you add two years or six years to a  
23 timeline you are going to presumably see more NDMA formation in  
24 the API.

25 So, that doesn't add anything, to test expired API,

1 when there is no allegation in this case and no evidence in  
2 this case that expired API ever made its way into product.  
3 There is just no probative value of testing this, and in fact,  
4 I submit, and I think this is what we said in our papers, I  
5 think there is a real high likelihood of confusion.

6 We are going to get these competing testing results  
7 that are completely at odds, apples to oranges, and it is going  
8 to just cause confusion and it is going to be inefficient and  
9 ultimately, we submit, their testing will be wholly irrelevant  
10 because it is not answering a question that is pertinent to  
11 this litigation, which is what amount of NDMA, if any, was in  
12 unexpired API that made its way into unexpired product that a  
13 Plaintiff could have taken.

14 So, that is kind of the -- in a nutshell the Jurong  
15 piece.

16 The one thing I want to come back to is, I do think --  
17 I mentioned that when you look at the scales here, and you look  
18 at the request for API, you see that it is so heavily weighted  
19 to that earlier period, 2010, 2011. This is not like an equal  
20 distribution across 2010 to 2014, so this isn't about like  
21 trying to figure out a trend or anything like that. I would  
22 submit that a trend of expired API from two years expired to  
23 six years expired is again irrelevant, since no Plaintiff would  
24 have taken product made with an API that was that expired or  
25 expired at all.



1 But in any event, I think that what that request  
2 really shows us is what is going on here, which is, this is  
3 just about trying to get numbers as high as possible, it's  
4 about trying to muddy the waters, and so for all of those  
5 reasons on Jurong API, we think that there should be no  
6 provision of product for testing.

7 I don't know if you want to address questions on that  
8 before I move on. The rest of it is going to be quick.

9 *THE COURT:* That is fine, take as much time as you  
10 need.

11 My question on that is this -- and I think Mr. Nigh  
12 touched on this in his remarks -- what does it mean that it was  
13 expired, expired for what purpose? Does the molecule  
14 suddenly -- it's good today and the day after tomorrow it is  
15 bad? What does it mean to say that it is expired? And why is  
16 that material to whether it provides an accurate, or  
17 potentially accurate analytical tool for purposes of this  
18 litigation?

19 *MR. SACHSE:* What it means sort of very, very  
20 basically, if API is expired it is no longer within regulatory  
21 specifications, it can no longer be used to formulate finished  
22 product, so that there is no instance where somebody would --  
23 some company would -- let me stick with what I know.

24 There is no instance where GSK would have taken  
25 expired Ranitidine API, whether it is by a day, a year, five

1 years, and put that into a finished product and put that out on  
2 the market.

3 So, then -- it is a great question, Judge. I think  
4 this is really THE question. Is there some other value to  
5 testing expired API? This is what I was kind of noodling  
6 around with and I think I touched on this a little bit earlier.

7 Maybe what they are going to do -- I don't know  
8 because they are not really telling us. Maybe what they are  
9 going to do is they are going to say, okay, let's take it from  
10 2010 all the way up, trace through 2014, get levels, and maybe  
11 they are going to try to draw some kind of curve and say, now  
12 we can see what the degradation rate is, and now we can sort of  
13 back fill and speculate on what the degradation rate would look  
14 like when the product was unexpired. I don't know. Maybe that  
15 is what they are doing.

16 That is problematic because they are starting from  
17 expired, they are finishing expired. All you are going to  
18 learn about is an expired API degradation rate, and as we all  
19 agree, time matters. So, when you are talking about starting  
20 two years past expiry to six years past expiry, we don't know  
21 how much degradation would have happened in the interim between  
22 expiry and those first two years, and we certainly can't draw  
23 any reliable conclusions about zero to five years.

24 So I think that --

25 *THE COURT:* Why doesn't that all arguably go to

1 Daubert and possibly admissibility and weight, not to  
2 discovery?

3 *MR. SACHSE:* Look, I think that obviously, and I will  
4 say to make sure we are clear on the record, we, of course,  
5 would reserve all of the arguments and make all those arguments  
6 at a later point, but the issue here, it is this kind of --  
7 well, I guess I will say it. It is the shenanigans rule.

8 I think what we are dealing with here is, we do not  
9 understand the relevance of testing expired product, whether it  
10 is to do this curve that I was just speculating about or  
11 anything else, and it is our position that the only purpose is  
12 to try to undermine testing that was done under very different  
13 conditions.

14 It is going to be completely confusing, and I get that  
15 we can make those arguments later, but right now we are faced  
16 with a request for 246 samples that they want, by the way, in  
17 like five days, and that is just -- it is not proportionate to  
18 what this litigation needs, and we submit it is not relevant.

19 *THE COURT:* Okay, I understand the argument you are  
20 making. Thank you for answering my questions.

21 *MR. NIGH:* Your Honor, can I respond? Do you want a  
22 response from me on what expired means?

23 *THE COURT:* No.

24 *MR. NIGH:* I do have a response.

25 *THE COURT:* I will give you a chance to respond to all

1 of his points. Let's let him finish his whole presentation and  
2 then you have the burden, so I will give you the last word.

3 MR. NIGH: Okay. Thank you, your Honor.

4 MR. SACHSE: Reddy's, real easy, two points on the  
5 Reddy's API. One, I think they have other sources where they  
6 could get unexpired Reddy's API. That seems to be consistent  
7 with the approach they are taking with BI, as I mentioned,  
8 where if you have the unexpired source you go with that instead  
9 of the expired.

10 Second point, and this is going to really kind of  
11 dovetail with the rest of my comments, I am really struggling  
12 to see whether -- I don't think there is a single Plaintiff  
13 that took Reddy's -- let me put it this way: I don't think  
14 there is a single Plaintiff or claimant who took Zantac made by  
15 GSK using Dr. Reddy's API.

16 If you look at the time period, you look at the  
17 sales -- I have been trying to get this information from the  
18 Plaintiffs, I have been trying to get this information from  
19 registry to no success as of now, and maybe that is also  
20 premature, but when I look at it -- and maybe this is a little  
21 bit of a proportionality burden type argument -- I am really  
22 struggling to see the relevance of this Dr. Reddy's product,  
23 and certainly, certainly, I see no relevance to Dr. Reddy's  
24 product that would not have made its way into the U.S.

25 When we look at the requests they have made, they have

1 asked for tablets. Those did go into the U.S., there were GSK  
2 manufactured Zantac tablets made with Dr. Reddy's API that went  
3 the into the U.S. market for a couple years, not many, like 15  
4 batches. There were no EFFERdose tablets that went into the  
5 U.S. market using Dr. Reddy's API. There were no injections,  
6 no syrup, no suspension, and they have asked for samples of all  
7 of that stuff.

8 So, in addition to it is expired, and what is it going  
9 to tell you since it is expired, those formulations really have  
10 nothing to do with this litigation. There is just no claimant  
11 who could have been taking those products.

12 Then the last category, I think this is a pretty easy  
13 one, this is the returned product, and this kind of comes in  
14 two flavors. One is returned unexpired, the other is returned  
15 and expired.

16 I'll just treat it together because the overarching  
17 problem with returned product, besides the points I've already  
18 made about only tablets went into the U.S., the overarching  
19 problem with returned product is we don't know about the  
20 storage conditions once it left GSK's control. We don't know  
21 about the storage conditions as this returned product came back  
22 to GSK.

23 We all agree, I think Mr. Nigh will say absolutely he  
24 agrees storage conditions matter. That is a big theme of their  
25 case, and there is no way you can test that. You can't draw

1 any reliable conclusions testing that returned product.

2 I can tell you the one thing we do know is, for a  
3 significant amount of that product, when it came back to GSK,  
4 for space reasons and for a whole host of other reasons, it is  
5 not in controlled conditions. It is sitting in a warehouse  
6 ambient. So, we know that there is going to be some element of  
7 ambient temperature at play with that returned product.

8 So, in addition to all the other reasons for a  
9 returned product that is kind of a special -- and it is only a  
10 few samples they are asking for, but that one, to me, seems  
11 like a pretty easy no-go. And I think actually in  
12 conversations that we had certainly over the course of many  
13 months, what I think I have heard from Mr. Nigh and his  
14 colleagues is they would much rather have product, what we call  
15 stock, never left our control, because then we know exactly how  
16 it was maintained, we know what temperature it was maintained  
17 at. That is a much more reliable, important type of task that  
18 you could do.

19 With that, unless you have questions, I think I am  
20 done.

21 *THE COURT:* Take a moment and check your notes.

22 *MR. SACHSE:* Yes. Thank you.

23 *THE COURT:* Thank you, Mr. Sachse. I don't have any  
24 other questions. I will turn back to Mr. Nigh and let you  
25 respond in whatever order you would like to, but in particular,

1 I would like you to specifically address the last point Mr.  
2 Sachse was making about the stuff that left everyone's control  
3 and came back. It seems to me, of all the things I have heard  
4 about, that is presumptively the least reliable to use for any  
5 purposes because we just don't know where it was and how it was  
6 handled, and all of that.

7 So, I would like you to address that in particular and  
8 also the issue about product that was never shipped into the  
9 United States, but obviously address whatever else you would  
10 like to address.

11 *MR. NIGH:* So, the first point that I want to address  
12 is, what does it mean to be expired. You heard a regulatory  
13 definition just now, which is completely different from a  
14 scientific chemistry definition. In fact, in the Root Cause  
15 Analysis done by GSK, even though it was almost five years old,  
16 the GSK Jurong, they still needed to test it to see if it was  
17 reliable for the testing purposes that they were going to use.

18 They needed to see whether or not there was a change  
19 between the different API to see whether or not it was still  
20 columnar and stacked. They also needed to see how much of the  
21 active ingredient was there still in that product versus how  
22 much had degraded over time. What they found was, at almost  
23 five years 99.995 percent of the active ingredient in the  
24 product was still there.

25 Their Root Cause Analysis even says something to the

1 degree that they would have a certain amount of -- I am saying  
2 this from the top of my head, but it says something to the  
3 degree of there will be such amount of active product that it  
4 would be useful for testing purposes for hundreds of years,  
5 essentially. From a chemistry standpoint, that is what we care  
6 about, that is what we are looking at.

7 I will say that goes to the heart of the more that  
8 they say that it is stacked, it doesn't degrade, the more you  
9 can actually test it over a long period of time, that it would  
10 be reliable to be able to test it years and years after it is  
11 expired.

12 Their Root Cause Analysis shows that. In fact, they  
13 show that when they are looking at the competitor product that  
14 they decide to test that is expired. You heard 18 lots are  
15 expired, including one that is nine years expired, and in there  
16 they show 90 something percent and they make the conclusion  
17 that there is enough active ingredient there as well that the  
18 testing results are reliable.

19 So, to say the least, if what they are saying is true  
20 about the DRL -- I mean the GSK Jurong product, the amount of  
21 active ingredient that there is going to be the stacked, it is  
22 going to have all sorts of chemistry -- probative value from a  
23 chemistry standpoint. This is not a regulatory question, this  
24 is, is there going to be probative value in testing the  
25 product.



1           So, you know, with that, they have said multiple times  
2 they don't know what we are going to do. I mentioned what we  
3 are going to do already, some of the things that you see in the  
4 Root Cause Analysis, crystallization, being able to see how  
5 tightly stacked it is. Are the representative samples that we  
6 looked at -- we picked 246 for a reason, because they have  
7 hundreds and hundreds of batches. We picked only 246 of the  
8 batches.

9           We have attached a spreadsheet that shows all the GSK  
10 Jurong batches that they said they had on hand and the 246 that  
11 we picked out of those. We picked a small fraction of what  
12 they had and we picked them in such a way, not to front load  
13 them to 2010 or 2011. In fact, you can look at the picks, you  
14 can see that we picked them almost percentage to when they  
15 manufactured those API batches. It lines up almost exactly.  
16 That was our goal, was to get a representative sample.

17          When we look at them, we can look over time what does  
18 the crystallization look like for these products. That is one  
19 thing we can do, but there are many other things that we can  
20 do, several of those tests being in that precise F. J. King  
21 article that we attached.

22          There are going to be others that we are going to  
23 want, too, because that is GSK's thinking, that is the way in  
24 which they are trying to present their case. There are other  
25 things that we are going to want to do that are not just what

1       they have done.

2               I think it is pretty clear that already I have  
3 mentioned several of the tests that could be probative in  
4 testing that product. So that is the GSK Jurong.

5               In fact, I would say that for GSK Jurong that is the  
6 utmost important product that we need, the GSK Jurong API. I  
7 agree with that because that is the product that was used for a  
8 large majority of product that people who were using  
9 prescription GSK, it was using GSK Jurong.

10              Next, I heard the question Zantac made by GSK with Dr.  
11 Reddy's API. You know, first off, tablets would use the Dr.  
12 Reddy's API, and so I don't know that there is any argument in  
13 terms of the relevancy of that product at this point, but  
14 obviously, if they used Dr. Reddy's API, we believe we should  
15 get that regardless of whether or not that specific product was  
16 intended for U.S. sale or another market.

17              The thing that is important is it is finished product  
18 that has DRL API, so we can actually see how does the product  
19 itself react with the DRL API.

20              In terms of returned product, when we look at the list  
21 of product that they have actually produced to us, that they  
22 say they have on hand, we do believe that, generally speaking,  
23 we would like in terms of the amount -- the ability and what we  
24 can get out of the testing, we would like more, but the  
25 packaging is just as important -- maybe as important, it is

1 something we have to test.

2 We don't want to get 5,000 loose pills. That is not  
3 the same thing as 30 bottles that have the pills in them, or  
4 however it is packaged. Packaging is important in this case.  
5 That is an issue that has already been published, it is in many  
6 of the internal documents.

7 So, when we look at this, fortunately a lot of their  
8 unsold product, we don't have as much in the packaging, that is  
9 the way at least it appears as we look at the spreadsheet.  
10 Perhaps I'm wrong when I look at the spreadsheet in some of the  
11 back and forth conversation. That is why we have requested  
12 several of the returned product so we could have product that  
13 was manufactured around the same timeframe, those tablets, even  
14 if it is returned because we don't think the returned product  
15 is not probative.

16 When you measure return product you can get a  
17 baseline. They can argue on what the baseline is in terms of  
18 the amount of nanograms there, but we are going to have a  
19 baseline, and then we can test from there to see what impacts  
20 things can have. So there is a baseline, everyone can see the  
21 baseline. If they want to argue -- we are not coming in with  
22 experts to say this thing has gone out, it is five years old,  
23 we are going to come back and say you have 5,000 nanograms of  
24 NDMA in your product. That would be silly because they would  
25 be so open up to cross-examination by Defense. So, that is the

1 important issue there.

2 In terms of product not shipped in the U.S., the key  
3 here is that it would be similar to the product that was  
4 actually shipped in the U.S.

5 So, if it is using Dr. Reddy's API and it is a  
6 finished product, then it would be similar to the product that  
7 is actually shipped and used in the U.S. by customers over a  
8 long period of time. Just because their product was product  
9 for another market, maybe it was used different excipients, we  
10 don't know that that is a major issue here, the excipients in  
11 the product.

12 We do know the API is a big issue, and the API in the  
13 finished product is a big issue. That is what we need to be  
14 seeing. So, because it is the same product as the product --  
15 or very similar as the product that actually made its way into  
16 the U.S., that is why those products would be relevant.

17 That is it.

18 *THE COURT:* Okay. Thank you, Mr. Nigh.

19 Let me ask you just one other issue. I am going to go  
20 back to Mr. Sachse on this as well because factually there  
21 appears to me to be an inconsistency.

22 That is, you are saying as to the Jurong API that you  
23 are asking for it is less than 5 percent of what they have.  
24 Mr. Sachse has a footnote 4 in his material saying,  
25 essentially, if they give you what you are asking for they

1 won't have any left for anybody else -- I am paraphrasing, of  
2 course -- seeming to suggest that you are asking for a lot more  
3 than 5 percent. What am I missing there? How does that  
4 reconcile?

5 Mr. Nigh, do you have a thought on that?

6 MR. NIGH: I do. I can look at the spreadsheets that  
7 Mr. Sachse gave to us. We have them in row A, row B, row D,  
8 row E, row F, row G, row H. That is the way he presented them  
9 to us. Our understanding is each and every one of these items,  
10 they have 30 kilograms on hand.

11 As I am estimating this, I am looking at thousands, I  
12 think I probably even had the exact number in the brief, but we  
13 request -- when there is 30 -- they may have 30 grams of these  
14 thousands of different API. We are requesting ten of those 30,  
15 but only 246 of those, so the percentage is 5 percent of the  
16 total amount of API that they say they have on hand.

17 THE COURT: So, it is one-third of what is in each of  
18 the 246 vials that you are asking for, but of the global  
19 universe of everything they have is how we get to 5 percent.

20 MR. NIGH: Yes.

21 THE COURT: Okay. I understand that.

22 Mr. Sachse, did you want to respond at all to that  
23 inquiry?

24 MR. SACHSE: Yes, just briefly, Judge, just to make  
25 sure we are talking about the same thing.

1           First of all, Mr. Nigh corrected himself, it is not  
2   30 kilograms per batch, it is 30 grams. So, they are asking  
3   for one-third of what we have left per batch. The concern I  
4   have is, obviously, and I probably don't need to say this, but  
5   there are other players that are maybe not on this Zoom that we  
6   are going to have to go and potentially serially negotiate  
7   with. There are now players in California, Texas, Tennessee,  
8   Illinois, Philadelphia, my hometown.

9           So, I think that our concern is, if we -- whatever is  
10  the outcome here today, we are going to try to shop what  
11  happens here elsewhere, but if there is not enough product to  
12  shop the same deal -- and I am sure Mr. Nigh would say, well,  
13  you can just give them different batches, but now we are  
14  talking about kind of exponentially causing confusion, because  
15  we are going to have this massive testing confusion and  
16  competing tests and competing batches.

17          I will also add that we need -- of course, if the  
18  Plaintiffs are going to be entitled to get this API and test  
19  it, we need to make sure that we retain enough ourselves to --  
20  if we choose to test it, we need to make sure that we have that  
21  capability, too.

22          So, the issue here is -- look, I am sort of reading  
23  the writing on the wall. If you were going to order API to  
24  produce -- for us to produce API, I would just ask -- and maybe  
25  we can have a conversation after about how much do they really

1 need, is it 10 grams, is it 5 grams. Something less than  
2 10 grams I think is absolutely sufficient based on what our  
3 people are telling us. I think that that is really a  
4 conversation that, if you rule against us, we can have.

5 That is the first point.

6 *THE COURT:* Okay.

7 *MR. SACHSE:* The second point, just to make sure that  
8 the factual record is clear, GSK never sold injection, syrup,  
9 suspension, EFFERdose using Dr. Reddy's API in the United  
10 States.

11 So, there will be no Plaintiff in this registry, no  
12 Plaintiff anywhere, I guess, unless they moved from some other  
13 country, who took GSK Zantac made with Dr. Reddy's in those  
14 formulations. So, the probative value of testing that for this  
15 U.S. litigation is zero.

16 *THE COURT:* Thank you very much, very helpful. So --  
17 all right. Here is where I come out on this.

18 The first question is relevance, is it relevant at  
19 all, meaning does it tend to help prove a fact that is an issue  
20 in this lawsuit. Let me start with the expired API.

21 Well, it seems to me the theory of relevance of all of  
22 this is that it goes to general causation, which hopefully is  
23 what is right because that is the discovery we are doing right  
24 now, is general causation discovery, meaning specifically the  
25 theory of general causation is that Ranitidine degrades into

1 NDMA, NDMA in the body is a carcinogen, it causes cancers,  
2 therefore Plaintiffs in this case may have gotten cancers  
3 caused by taking Zantac. That is the general causation theory.

4 It seems to me that is the question, is this relevant  
5 to that general causation analysis. Even if it is expired, I  
6 think it is relevant. I think it is relevant, and at some  
7 level today I do have to give broad berth to the experts.

8 If the experts tell me through Mr. Nigh that there is  
9 testing they can do which they believe will be probative and  
10 allow them to advance their case by arguing that there is  
11 general causation here, then I do have to give some deference  
12 to that. I do think it is relevant as a baseline matter  
13 because it does go to general causation.

14 And the expiration issue, I will use a bad analogy, I  
15 am a baker and if I use milk that is three days past the  
16 expiration date, my cookies taste just fine. So, I tend to  
17 agree with Mr. Nigh, there is a difference between kind of  
18 regulatory expiration and chemical expiration for discovery  
19 purposes.

20 Again, it may very well be that at the end of the day  
21 Mr. Sachse will prevail on his Daubert motion that this is so  
22 unreliable, or his experts say it is so unreliable, and so be it.  
23 That is for another day and that's a different standard. The  
24 standard today is relevance and it is a pretty low standard.

25 So I do think that the fact of expiration, to me, does



1 not move the needle on relevance for that, and so I am going to  
2 order the production -- I also find it to be proportional.

3 I'm sorry. There was a proportionality objection to  
4 the expired API. The standard for proportionality is whether  
5 it is relevant -- I have already found it is relevant -- and  
6 also whether it is proportional considering the importance of  
7 the issues in the litigation, the amount in controversy, the  
8 parties' relative access to the information, resources, the  
9 importance of the discovery in resolving the issues, and  
10 whether the burden or expense outweighs its benefit.

11 I have said all along in this case general causation  
12 is, to me, the most important issue in this case. It is the  
13 most important issue at stake in this litigation. So, that  
14 factor weighs heavily in favor of the Plaintiffs.

15 The amount in controversy in this case is more zeros  
16 than I can add up, so we will pass that one by.

17 The parties' relative access to the relevant  
18 information is one sided, GSK has it and the Plaintiffs don't,  
19 and the Plaintiffs have no other way to get it, so that inures  
20 to the Plaintiffs' benefit.

21 The importance of this particular discovery in  
22 resolving the issue of general causation, I think it is  
23 sufficient, considering all of the other factors, to get over  
24 the proportionality hurdle.

25 I am going to overrule the objection to providing

1 expired API for both Jurong and Dr. Reddy.

2 I hear, Mr. Sachse, your argument that the Dr. Reddy  
3 products -- Dr. Reddy API products were never sold in the U.S.,  
4 and again, I think that goes to weight, but it's a chemical  
5 formulation. If comparing the degradation rates of the DRL API  
6 and the Jurong API was good enough for the FDA and the EMA as a  
7 methodology for at least starting to look at degradation rates,  
8 I think they are entitled to have both products.

9 Again, your argument as to whether that has any  
10 probative value at trial can be resolved at a different time,  
11 so I will overrule that objection for the same reasons I am  
12 going to overrule the objection to providing finished product,  
13 for those reasons.

14 In terms of the returned product, I do think that is a  
15 much closer question. I think, again, given the importance of  
16 this issue to the litigation, given that the experts say they  
17 can make use of it, and there is no burden argument here, the  
18 tipping point goes to the Plaintiffs on this one. So I am  
19 going to overrule the objections.

20 As to the other two questions, though, that I think  
21 are the secondary questions, Mr. Sachse, I hear you in terms of  
22 do they really need as much as they are asking for. I am not  
23 in a position to really rule on that and resolve that. I don't  
24 know that that is fully framed for me today.

25 I have made my ruling that they can have it. Perhaps

1 you and Mr. Nigh can now have a further discussion about do  
2 they really need 10 grams, could they do 8 grams or 6 grams,  
3 how many expired tablets do they want. I will throw that back  
4 to you and if you need me to resolve it, we can do that in a  
5 way that I can have more information as to what is really  
6 needed there.

7 The other issue I suppose is timing, how soon are they  
8 going to get it, which may be tied up with the how much do they  
9 get, but if they are going to get some of it, presumably you  
10 can start giving them some now and get to a point relatively  
11 quickly when we can resolve that.

12 I am not going to rule on a timing today, I don't know  
13 that anyone has put that in front of me. I will throw that  
14 back to you and let you try to resolve it. If you can't, I am  
15 here next week, you can come back and I will resolve it next  
16 week.

17 Not waiving any objections you may have to the rulings  
18 I have made, have I at least addressed all the issues you  
19 wanted to raise today?

20 *MR. NIGH:* You have. I would say timing is of the  
21 essence, but I think your Honor addressed that. So, over the  
22 next week we are going to be trying to work on the comity  
23 question and hopefully we can reach an agreement. If we can't,  
24 we are going to come back to your Honor on that.

25 *THE COURT:* All right. Again, the reason I think I

1 need to defer on that is I would need better information about  
2 why do you need ten and not six. Why is it that GSK can't  
3 provide you with something for three weeks as opposed to one  
4 week? I just don't have a factual basis on which to rule.

5 I am hoping that you two, working with the special  
6 master, can perhaps get over that hurdle.

7 No one is waiving any arguments in that regard, just  
8 like -- and I will adopt what Mr. Sachse said. They have  
9 reserved all Daubert and admissibility arguments for later on.  
10 That is not what I am addressing today.

11 Mr. Sachse, not waiving any objections you may have to  
12 my rulings here today, have I at least ruled on all the issues  
13 you wanted to present?

14 *MR. SACHSE:* Yes, your Honor. All the issues that are  
15 before you I think you have now ruled on, and I share your  
16 confidence, I am sure that Mr. Nigh and I will be able to work  
17 out some kind of agreement to get a product to them as quickly  
18 as possible. We are going to make best efforts. We are going  
19 to have to get it from all over the world, but we will get that  
20 to them promptly, and as you suggest, on a rolling basis for  
21 sure, and then we will have a conversation about the ten grams  
22 versus maybe some lesser amount and we will see where we go  
23 with that.

24 *THE COURT:* Very well. Thank you both very much,  
25 extremely well argued, very well presented. I appreciate the

1 briefing that I received.

2 Mr. Sachse, I know you are on vacation and we have  
3 taken you away from that, so let me excuse the parties and let  
4 you go.

5 Thank you everybody. We will be in recess.

6 MR. SACHSE: Thank you, Judge.

7 MR. NIGH: Thank you.

8 *(Thereupon, the hearing was concluded.)*

9 \* \* \*

10 I certify that the foregoing is a correct transcript  
11 from the record of proceedings in the above matter.

12  
13 Date: August 28, 2021

14 /s/ Pauline A. Stipes, Official Federal Reporter

15 Signature of Court Reporter  
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Pauline A. Stipes, Official Federal Reporter

<b>MR. BEROUKHIM: [2]</b> 2/15 3/12 <b>MR. NIGH: [16]</b> 2/6 3/8 3/14 4/3 5/7 5/14 5/17 7/17 19/20 19/23 20/2 23/10 29/5 29/19 35/19 37/6 <b>MR. SACHSE: [11]</b> 2/10 5/10 8/3 17/18 19/2 20/3 22/21 29/23 31/6 36/13 37/5 <b>MR. SENTENAC: [3]</b> 2/19 3/4 3/18 <b>THE COURT: [29]</b> 1/25 2/8 2/12 2/17 2/22 3/6 3/10 3/13 3/15 3/19 5/3 5/11 5/15 7/13 7/22 17/8 18/24 19/18 19/22 19/24 22/20 22/22 28/17 29/16 29/20 31/5 31/15 35/24 36/23	30309 [1] 1/18 316 [1] 1/11 31st [1] 7/12 32 [2] 2/3 2/24 32502 [1] 1/12 <b>4</b> 4000 [1] 1/16 404-572-4600 [1] 1/19 4059 [1] 1/22 4600 [1] 1/19 4:00 o'clock [1] 2/1 <b>5</b> 5 grams [1] 31/1 5 percent [4] 28/23 29/3 29/15 29/19 5,000 [2] 27/2 27/23 50 kilograms [1] 7/4 500 grams [2] 7/5 9/5 <b>6</b> 6 grams [1] 35/2 <b>7</b> 7013 [1] 1/12 772.467.2337 [1] 1/25 777 [1] 1/21 <b>8</b> 8 grams [1] 35/2 80 [1] 13/13 850-435-7013 [1] 1/12 <b>9</b> 90 [1] 24/16 90017 [1] 1/21 99.995 [1] 23/23 <b>A</b> ability [1] 26/23 able [3] 24/10 25/4 36/16 about [36] 5/6 8/7 8/25 9/17 9/21 9/22 11/21 12/18 13/1 13/13 14/13 14/23 14/24 15/16 15/17 16/20 17/3 17/4 18/18 18/19 18/23 19/10 21/18 21/19 21/21 23/2 23/4 23/8 24/6 24/20 29/25 30/14 30/25 35/1 36/1 36/21 above [2] 11/22 37/11 absolutely [2] 21/23 31/2 acceptable [1] 11/20 access [2] 33/8 33/17 accurate [3] 11/11 17/16 17/17 acquired [1] 8/22 acronyms [1] 4/1 across [1] 16/20 active [9] 4/21 4/23 4/25 5/1 23/21 23/23 24/3 24/17 24/21 actually [11] 8/20 10/18 11/7 13/12 22/11 24/9 26/18 26/21 28/4 28/7 28/15 add [4] 15/22 15/25 30/17 33/16 added [1] 8/20	addition [2] 21/8 22/8 address [6] 17/7 23/1 23/7 23/9 23/10 23/11 addressed [2] 35/18 35/21 addressing [1] 36/10 admissibility [2] 19/1 36/9 admit [1] 7/1 adopt [1] 36/8 advance [2] 9/24 32/10 affect [3] 5/21 10/21 10/22 after [4] 10/9 17/14 24/10 30/25 afternoon [8] 2/9 2/11 2/13 2/16 2/18 2/20 2/23 3/3 again [10] 7/14 9/13 10/17 11/14 16/23 32/20 34/4 34/9 34/15 35/25 against [1] 31/4 agree [8] 8/10 8/25 10/19 15/21 18/19 21/23 26/7 32/17 agreement [4] 3/8 3/12 35/23 36/17 agreements [1] 3/1 agrees [1] 21/24 ALEX [2] 1/20 2/16 alive [1] 11/7 all [48] allegation [1] 16/1 allow [1] 32/10 almost [4] 23/15 23/22 25/14 25/15 along [3] 5/18 5/20 33/11 already [6] 4/5 21/17 25/3 26/2 27/5 33/5 also [13] 4/21 4/23 6/17 6/24 7/2 8/25 10/12 20/19 23/8 23/20 30/17 33/2 33/6 am [27] 3/4 3/24 7/17 9/8 14/7 20/11 20/21 22/19 24/1 28/19 29/1 29/3 29/11 29/11 30/12 30/22 32/15 33/1 33/25 34/11 34/18 34/22 35/12 35/14 36/5 36/10 36/16 ambient [2] 22/6 22/7 amount [14] 7/19 10/14 13/2 16/11 22/3 24/1 24/3 24/20 26/23 27/18 29/16 33/7 33/15 36/22 amount of [1] 24/1 amounts [1] 7/19 analogy [1] 32/14 analysis [10] 9/23 10/1 10/1 11/1 12/10 23/15 23/25 24/12 25/4 32/5 Analysis even [1] 23/25 analytical [1] 17/17 and/or [1] 5/2 Andrew [1] 5/19 Angeles [1] 1/21 another [5] 10/19 12/15 26/16 28/9 32/23 answer [2] 8/8 13/22 answering [2] 16/10 19/20 any [15] 3/24 6/7 6/25 16/11 17/1 18/23 22/1 22/23 23/4 26/12 29/1 34/9 35/17 36/7 36/11 anybody [1] 29/1
/		
/s [1] 37/14		
<b>1</b>		
10 [1] 11/19 10 grams [3] 31/1 31/2 35/2 10-gram [1] 13/8 11 [1] 11/20 11 kilograms [1] 7/5 1180 [1] 1/18 11th [1] 11/22 15 [1] 21/3 1600 [1] 1/18 18 [4] 14/11 14/11 14/13 24/14 19104 [1] 1/15		
<b>2</b>		
20-2924 [1] 2/2 20-md-02924-ROSENBERG [1] 1/3 2000 [1] 13/9 2010 [9] 8/14 13/9 13/14 14/9 14/18 16/19 16/20 18/10 25/13 2011 [3] 13/14 16/19 25/13 2014 [6] 8/18 8/23 11/17 13/9 16/20 18/10 2015 [2] 13/11 14/9 2019 [4] 10/2 11/15 13/11 14/10 2021 [2] 1/5 37/13 213-243-4059 [1] 1/22 215-994-4000 [1] 1/16 245 [1] 15/6 246 [8] 13/8 15/6 19/16 25/6 25/7 25/10 29/15 29/18 26 [1] 1/5 28 [1] 37/13 2924 [1] 2/2 2929 [1] 1/15		
<b>3</b>		
30 [3] 27/3 29/13 29/14 30 grams [2] 29/13 30/2 30 kilograms [2] 29/10 30/2 30-gram [1] 13/5		

<b>A</b> <b>anyone</b> [1] 35/13 <b>anything</b> [4] 4/2 15/25 16/21 19/11 <b>anywhere</b> [1] 31/12 <b>API</b> [110] <b>API's</b> [1] 4/21 <b>APIs</b> [2] 5/24 8/22 <b>apologize</b> [2] 5/4 9/24 <b>appearance</b> [1] 2/15 <b>appearances</b> [1] 2/5 <b>appears</b> [3] 4/7 27/9 28/21 <b>apples</b> [2] 15/13 16/7 <b>apply</b> [1] 13/10 <b>appreciate</b> [1] 36/25 <b>approach</b> [1] 20/7 <b>approval</b> [1] 8/15 <b>Arch</b> [1] 1/15 <b>are</b> [98] <b>area</b> [1] 10/19 <b>arguably</b> [1] 18/25 <b>argue</b> [4] 6/25 9/8 27/17 27/21 <b>argued</b> [1] 36/25 <b>arguing</b> [1] 32/10 <b>argument</b> [11] 3/24 4/5 8/8 9/10 9/14 19/19 20/21 26/12 34/2 34/9 34/17 <b>arguments</b> [5] 19/5 19/5 19/15 36/7 36/9 <b>Arnold</b> [2] 1/20 2/17 <b>around</b> [2] 18/6 27/13 <b>article</b> [6] 5/25 6/1 6/4 11/5 12/7 25/21 <b>as</b> [43] <b>ask</b> [6] 2/14 7/9 7/14 8/1 28/19 30/24 <b>asked</b> [4] 9/14 13/8 21/1 21/6 <b>asking</b> [9] 14/15 14/16 22/10 28/23 28/25 29/2 29/18 30/2 34/22 <b>asserted</b> [1] 5/19 <b>assertion</b> [3] 5/23 5/25 6/5 <b>asserts</b> [1] 6/6 <b>at all</b> [1] 9/8 <b>Atlanta</b> [1] 1/18 <b>attached</b> [5] 6/1 6/14 12/7 25/9 25/21 <b>August</b> [3] 1/5 7/12 37/13 <b>away</b> [1] 37/3	30/3 <b>batches</b> [13] 11/20 11/25 13/11 13/12 14/10 15/6 21/4 25/7 25/8 25/10 25/15 30/13 30/16 <b>Baylen</b> [1] 1/11 <b>be</b> [41] <b>BEACH</b> [3] 1/2 1/5 1/24 <b>because</b> [29] 6/7 7/19 8/7 9/14 11/12 12/22 12/25 13/4 14/6 15/4 15/11 15/21 16/10 18/8 18/16 21/16 22/15 23/5 25/6 25/23 26/7 27/14 27/24 28/8 28/14 28/20 30/14 31/23 32/13 <b>become</b> [1] 9/25 <b>been</b> [10] 4/8 11/21 13/17 13/18 13/19 14/23 20/17 20/18 21/11 27/5 <b>before</b> [6] 1/8 3/2 8/1 14/12 17/8 36/15 <b>behalf</b> [8] 2/8 2/9 2/12 2/18 2/21 3/9 3/11 4/11 <b>being</b> [2] 25/4 25/20 <b>believe</b> [6] 6/12 7/2 7/8 26/14 26/22 32/9 <b>below</b> [1] 11/20 <b>benefit</b> [2] 33/10 33/20 <b>BEROUKHIM</b> [4] 1/20 2/17 3/11 3/17 <b>berth</b> [1] 32/7 <b>besides</b> [1] 21/17 <b>best</b> [1] 36/18 <b>better</b> [1] 36/1 <b>between</b> [5] 6/16 13/11 18/21 23/19 32/17 <b>BI</b> [5] 2/14 2/25 3/7 12/23 20/7 <b>big</b> [3] 21/24 28/12 28/13 <b>bit</b> [10] 8/4 8/6 8/8 9/22 9/23 10/24 11/22 14/3 18/6 20/21 <b>body</b> [1] 32/1 <b>Boehringer</b> [2] 2/18 2/21 <b>both</b> [7] 6/4 8/4 12/4 12/7 34/1 34/8 36/24 <b>bottles</b> [1] 27/3 <b>brass</b> [1] 5/18 <b>brief</b> [2] 4/5 29/12 <b>briefing</b> [1] 37/1 <b>briefly</b> [1] 29/24 <b>bring</b> [1] 3/2 <b>broad</b> [1] 32/7 <b>broad berth</b> [1] 32/7 <b>broadly</b> [2] 8/10 14/1 <b>BRUCE</b> [1] 1/8 <b>burden</b> [5] 9/8 20/2 20/21 33/10 34/17 <b>burdensome</b> [1] 8/3 <b>business</b> [2] 8/24 11/16	<b>came</b> [4] 14/7 21/21 22/3 23/3 <b>camera</b> [1] 3/17 <b>can</b> [44] <b>can't</b> [6] 12/24 18/22 21/25 35/14 35/23 36/2 <b>cancers</b> [2] 32/1 32/2 <b>capability</b> [1] 30/21 <b>carcinogen</b> [1] 32/1 <b>care</b> [1] 24/5 <b>carry</b> [1] 7/20 <b>case</b> [13] 1/3 2/2 9/25 16/1 16/2 21/25 25/24 27/4 32/2 32/10 33/11 33/12 33/15 <b>cast</b> [1] 15/10 <b>categories</b> [1] 9/1 <b>category</b> [4] 9/6 9/7 9/11 21/12 <b>causation</b> [9] 31/22 31/24 31/25 32/3 32/5 32/11 32/13 33/11 33/22 <b>cause</b> [12] 9/22 10/1 10/7 11/1 12/10 12/16 14/23 16/8 23/14 23/25 24/12 25/4 <b>caused</b> [1] 32/3 <b>causes</b> [1] 32/1 <b>causing</b> [1] 30/14 <b>Centre</b> [1] 1/14 <b>certain</b> [1] 24/1 <b>certainly</b> [5] 11/10 18/22 20/23 20/23 22/12 <b>certify</b> [1] 37/10 <b>chance</b> [2] 3/22 19/25 <b>change</b> [2] 4/1 23/18 <b>characterization</b> [1] 8/11 <b>check</b> [1] 22/21 <b>chemical</b> [3] 11/11 32/18 34/4 <b>chemical expiration</b> [1] 32/18 <b>chemist</b> [2] 12/15 12/15 <b>chemistry</b> [4] 23/14 24/5 24/22 24/23 <b>choose</b> [1] 30/20 <b>Cira</b> [1] 1/14 <b>claimant</b> [2] 20/14 21/10 <b>clarifying</b> [1] 5/16 <b>clear</b> [4] 14/6 19/4 26/2 31/8 <b>closer</b> [1] 34/15 <b>colleagues</b> [2] 13/21 22/14 <b>column</b> [1] 11/5 <b>columnar</b> [6] 11/3 11/9 11/11 11/13 11/25 23/20 <b>combination</b> [1] 8/3 <b>come</b> [7] 9/16 11/7 16/16 27/23 31/17 35/15 35/24 <b>comes</b> [3] 9/2 14/4 21/13 <b>coming</b> [2] 11/17 27/21 <b>comity</b> [1] 35/22 <b>comments</b> [1] 20/11 <b>company</b> [1] 17/23 <b>compare</b> [1] 6/18 <b>compared</b> [1] 6/19 <b>compares</b> [1] 11/23 <b>comparing</b> [1] 34/5 <b>compel</b> [1] 7/9 <b>competing</b> [3] 16/6 30/16
<b>B</b> <b>back</b> [16] 4/13 9/16 13/17 16/16 18/13 21/21 22/3 22/24 23/3 27/11 27/23 28/20 35/3 35/14 35/15 35/24 <b>backwards</b> [1] 15/6 <b>bad</b> [2] 17/15 32/14 <b>baker</b> [1] 32/15 <b>based</b> [1] 31/2 <b>baseline</b> [6] 27/17 27/17 27/19 27/20 27/21 32/12 <b>basically</b> [1] 17/20 <b>basis</b> [2] 36/4 36/20 <b>batch</b> [9] 13/2 14/8 14/18 14/19 14/25 15/1 15/4 30/2	<b>C</b> <b>CA</b> [1] 1/21 <b>California</b> [1] 30/7 <b>call</b> [5] 5/7 9/25 11/10 15/5 22/14 <b>called</b> [1] 4/23 <b>calling</b> [1] 12/7	

<b>C</b> <b>competing...</b> [1] 30/16 <b>competitor</b> [1] 24/13 <b>competitors</b> [1] 6/14 <b>competitors'</b> [1] 6/18 <b>completely</b> [5] 14/20 15/2 16/7 19/14 23/13 <b>concern</b> [2] 30/3 30/9 <b>concluded</b> [1] 37/8 <b>conclusion</b> [3] 10/18 10/19 24/16 <b>conclusions</b> [2] 18/23 22/1 <b>conditions</b> [6] 13/6 19/13 21/20 21/21 21/24 22/5 <b>confer</b> [1] 4/14 <b>CONFERENCE</b> [1] 1/8 <b>confers</b> [1] 4/7 <b>confidence</b> [1] 36/16 <b>confirm</b> [2] 3/14 14/23 <b>confusing</b> [1] 19/14 <b>confusion</b> [4] 16/5 16/8 30/14 30/15 <b>considering</b> [2] 33/6 33/23 <b>consistent</b> [1] 20/6 <b>consumption</b> [1] 6/9 <b>contains</b> [1] 4/18 <b>contamination</b> [1] 5/2 <b>contracted</b> [1] 5/13 <b>control</b> [3] 21/20 22/15 23/2 <b>controlled</b> [2] 13/6 22/5 <b>controversy</b> [2] 33/7 33/15 <b>conundrum</b> [1] 12/20 <b>conversation</b> [4] 27/11 30/25 31/4 36/21 <b>conversations</b> [1] 22/12 <b>cookies</b> [1] 32/16 <b>core</b> [1] 8/8 <b>correct</b> [10] 3/4 3/6 3/8 3/10 5/15 7/17 7/18 8/13 8/13 37/10 <b>corrected</b> [1] 30/1 <b>could</b> [8] 2/14 16/13 20/6 21/11 22/18 26/3 27/12 35/2 <b>counsel</b> [3] 2/5 2/14 6/24 <b>country</b> [1] 31/13 <b>couple</b> [1] 21/3 <b>course</b> [5] 12/3 19/4 22/12 29/2 30/17 <b>court</b> [6] 1/1 1/23 3/3 5/5 7/9 37/15 <b>cross</b> [1] 27/25 <b>cross-examination</b> [1] 27/25 <b>crystallization</b> [4] 5/20 6/19 25/4 25/18 <b>curve</b> [2] 18/11 19/10 <b>customers</b> [1] 28/7 <b>cut</b> [2] 12/23 12/23	<b>deal</b> [2] 12/23 30/12 <b>dealing</b> [1] 19/8 <b>December</b> [2] 8/23 11/17 <b>December 2014</b> [1] 8/23 <b>December of</b> [1] 11/17 <b>Dechert</b> [1] 1/14 <b>decide</b> [1] 24/14 <b>DEFENDANTS</b> [3] 1/13 2/24 3/3 <b>Defense</b> [1] 27/25 <b>defer</b> [1] 36/1 <b>deference</b> [1] 32/11 <b>definition</b> [2] 23/13 23/14 <b>degradation</b> [11] 5/3 6/15 10/21 10/22 14/24 18/12 18/13 18/18 18/21 34/5 34/7 <b>degrade</b> [5] 5/24 10/20 10/20 11/9 24/8 <b>degraded</b> [1] 23/22 <b>degrades</b> [2] 15/22 31/25 <b>degree</b> [2] 24/1 24/3 <b>demonstrating</b> [1] 6/15 <b>depending</b> [1] 8/7 <b>depositions</b> [1] 12/14 <b>detail</b> [2] 4/9 4/12 <b>did</b> [10] 3/22 3/25 5/7 14/8 14/19 15/4 15/4 15/15 21/1 29/22 <b>difference</b> [1] 32/17 <b>differences</b> [1] 6/15 <b>different</b> [15] 6/10 10/4 11/2 11/24 14/15 14/20 15/2 19/12 23/13 23/19 28/9 29/14 30/13 32/23 34/10 <b>disagree</b> [1] 10/23 <b>discovery</b> [10] 1/8 2/4 3/2 14/1 19/2 31/23 31/24 32/18 33/9 33/21 <b>discrete</b> [1] 9/1 <b>discussion</b> [1] 35/1 <b>dispute</b> [3] 3/20 6/2 8/13 <b>disputed</b> [1] 3/12 <b>distributed</b> [1] 4/19 <b>distribution</b> [2] 13/12 16/20 <b>DISTRICT</b> [2] 1/1 1/1 <b>DIVISION</b> [1] 1/2 <b>do</b> [41] <b>documents</b> [1] 27/6 <b>does</b> [12] 6/9 10/20 17/12 17/13 17/15 23/12 25/17 26/18 29/3 31/19 32/13 32/25 <b>doesn't</b> [4] 15/7 15/25 18/25 24/8 <b>doing</b> [3] 14/20 18/15 31/23 <b>don't</b> [24] 4/1 12/22 15/11 17/7 18/7 18/14 18/20 20/12 20/13 21/19 21/20 22/23 23/5 25/2 26/12 27/2 27/8 27/14 28/10 30/4 33/18 34/23 35/12 36/4 <b>done</b> [6] 7/25 10/16 19/12 22/20 23/15 26/1 <b>doubt</b> [1] 15/10 <b>dovetail</b> [1] 20/11 <b>down</b> [2] 11/16 14/4 <b>Dr</b> [28] 4/22 4/23 5/14 5/14 5/18 6/16 6/19 6/22 8/15 8/19 9/5 10/12 10/13 12/15 20/15 20/22 20/23 21/2 21/5	26/10 26/11 26/14 28/5 31/9 31/13 34/1 34/2 34/3 <b>draw</b> [3] 18/11 18/22 21/25 <b>DRL</b> [14] 4/23 5/14 6/3 6/5 7/5 7/7 7/10 7/11 7/15 7/17 24/20 26/18 26/19 34/5 <b>DRL API</b> [1] 6/3 <b>dug</b> [1] 13/18
<b>D</b> <b>daily</b> [1] 11/20 <b>dance</b> [1] 8/1 <b>DANIEL</b> [2] 1/10 2/7 <b>date</b> [3] 13/9 32/16 37/13 <b>Daubert</b> [3] 19/1 32/21 36/9 <b>day</b> [4] 17/14 17/25 32/20 32/23 <b>days</b> [2] 19/17 32/15		<b>E</b> <b>each</b> [2] 29/9 29/17 <b>earlier</b> [3] 3/23 16/19 18/6 <b>easy</b> [3] 20/4 21/12 22/11 <b>EFFERdose</b> [3] 10/4 21/4 31/9 <b>efforts</b> [1] 36/18 <b>electron</b> [1] 11/3 <b>element</b> [1] 22/6 <b>elephant</b> [1] 9/23 <b>else</b> [3] 19/11 23/9 29/1 <b>elsewhere</b> [1] 30/11 <b>EMA</b> [2] 12/4 34/6 <b>end</b> [3] 8/18 11/17 32/20 <b>enough</b> [4] 24/17 30/11 30/19 34/6 <b>entitled</b> [3] 14/1 30/18 34/8 <b>equal</b> [1] 16/19 <b>equate</b> [1] 6/9 <b>ESQ</b> [4] 1/10 1/13 1/17 1/20 <b>essence</b> [3] 8/23 10/5 35/21 <b>essentially</b> [4] 10/1 13/21 24/5 28/25 <b>estimating</b> [1] 29/11 <b>etc</b> [1] 9/13 <b>Europeans</b> [1] 12/4 <b>even</b> [5] 23/15 23/25 27/13 29/12 32/5 <b>event</b> [1] 17/1 <b>ever</b> [1] 16/2 <b>every</b> [1] 29/9 <b>everybody</b> [1] 37/5 <b>everyone</b> [1] 27/20 <b>everyone's</b> [1] 23/2 <b>everything</b> [1] 29/19 <b>evidence</b> [3] 7/1 12/17 16/1 <b>exact</b> [1] 29/12 <b>exactly</b> [6] 11/5 13/20 15/6 15/20 22/15 25/15 <b>examination</b> [1] 27/25 <b>examining</b> [1] 6/21 <b>excipients</b> [2] 28/9 28/10 <b>excuse</b> [2] 3/17 37/3 <b>exempts</b> [1] 6/25 <b>expect</b> [1] 15/20 <b>expense</b> [1] 33/10 <b>experts</b> [11] 6/8 6/11 6/21 7/20 13/22 13/24 27/22 32/7 32/8 32/22 34/16 <b>expiration</b> [5] 32/14 32/16 32/18 32/18 32/25 <b>expired</b> [65] <b>expired API</b> [1] 13/16 <b>expired Jurong</b> [1] 15/15 <b>expiry</b> [6] 11/18 13/10 15/18 18/20 18/20 18/22 <b>explain</b> [1] 4/2 <b>explanation</b> [2] 12/1 13/20 <b>exponentially</b> [1] 30/14 <b>exposed</b> [1] 15/1



<b>E</b> <b>extensive</b> [5] 9/3 9/4 10/9 12/2 12/3 <b>extremely</b> [3] 6/11 6/23 36/25	<b>fully</b> [1] 34/24 <b>further</b> [4] 3/24 5/18 12/19 35/1	<b>having</b> [1] 6/10 <b>he</b> [3] 8/13 21/23 29/8 <b>head</b> [1] 24/2 <b>hear</b> [3] 3/25 34/2 34/21 <b>heard</b> [7] 14/2 15/8 22/13 23/3 23/12 24/14 26/10 <b>hearing</b> [3] 2/4 2/24 37/8 <b>heart</b> [2] 6/23 24/7 <b>Heat</b> [1] 10/21 <b>heavily</b> [2] 16/18 33/14 <b>help</b> [1] 31/19 <b>helpful</b> [1] 31/16 <b>helps</b> [1] 15/11 <b>here</b> [28] 2/3 4/14 4/16 8/9 8/25 9/8 9/24 12/22 12/22 13/15 14/16 14/20 15/5 15/9 16/17 17/2 19/6 19/8 28/3 28/10 30/10 30/11 30/22 31/17 32/11 34/17 35/15 36/12 <b>here is</b> [1] 30/22 <b>high</b> [2] 16/5 17/3 <b>higher</b> [1] 15/19 <b>him</b> [1] 20/1 <b>himself</b> [1] 30/1 <b>his</b> [8] 13/21 17/12 20/1 20/1 22/13 28/24 32/21 32/22 <b>history</b> [2] 8/11 8/12 <b>hold</b> [1] 13/5 <b>hometown</b> [1] 30/8 <b>HON</b> [1] 1/24 <b>Honor</b> [18] 2/7 2/11 2/16 2/20 3/5 3/13 3/15 3/19 4/4 4/15 7/13 7/22 12/5 19/21 20/3 35/21 35/24 36/14 <b>HONORABLE</b> [1] 1/8 <b>hopefully</b> [2] 31/22 35/23 <b>hoping</b> [1] 36/5 <b>host</b> [1] 22/4 <b>how</b> [15] 5/21 15/1 18/21 22/15 23/5 23/20 23/21 25/4 26/18 29/3 29/19 30/25 35/3 35/7 35/8 <b>however</b> [1] 27/4 <b>human</b> [1] 6/9 <b>humidity</b> [1] 10/22 <b>hundreds</b> [7] 10/3 10/10 10/17 10/17 24/4 25/7 25/7 <b>hurdle</b> [2] 33/24 36/6
<b>F</b> <b>faced</b> [1] 19/15 <b>facility</b> [1] 8/14 <b>facing</b> [1] 13/15 <b>fact</b> [8] 15/17 16/3 23/14 24/12 25/13 26/5 31/19 32/25 <b>factor</b> [1] 33/14 <b>factors</b> [2] 5/21 33/23 <b>factual</b> [2] 31/8 36/4 <b>factually</b> [1] 28/20 <b>favor</b> [1] 33/14 <b>FDA</b> [2] 12/4 34/6 <b>Federal</b> [1] 37/14 <b>Feel</b> [1] 4/2 <b>few</b> [6] 2/2 8/17 8/20 10/9 14/12 22/10 <b>Figueroa</b> [1] 1/21 <b>figure</b> [5] 10/5 10/6 11/23 14/24 16/21 <b>fill</b> [1] 18/13 <b>find</b> [2] 13/15 33/2 <b>finding</b> [1] 6/2 <b>findings</b> [1] 11/1 <b>fine</b> [3] 3/21 17/9 32/16 <b>finish</b> [1] 20/1 <b>finished</b> [19] 4/19 5/1 7/7 7/10 7/16 8/16 9/7 9/12 9/19 9/19 10/3 10/12 10/14 17/21 18/1 26/17 28/6 28/13 34/12 <b>finishing</b> [1] 18/17 <b>firm</b> [1] 2/8 <b>first</b> [14] 5/6 6/6 8/1 8/10 9/5 9/16 14/21 15/13 18/22 23/11 26/11 30/1 31/5 31/18 <b>five</b> [9] 11/18 11/18 13/10 17/25 18/23 19/17 23/15 23/23 27/22 <b>five-year</b> [2] 11/18 13/10 <b>FL</b> [3] 1/5 1/12 1/24 <b>flavor</b> [1] 9/18 <b>flavors</b> [2] 9/2 21/14 <b>FLORIDA</b> [1] 1/1 <b>footnote</b> [1] 28/24 <b>foregoing</b> [1] 37/10 <b>forget</b> [2] 12/15 12/24 <b>form</b> [1] 10/20 <b>formation</b> [2] 10/7 15/23 <b>forms</b> [1] 5/21 <b>formulate</b> [1] 17/21 <b>formulation</b> [1] 34/5 <b>formulations</b> [3] 10/4 21/9 31/14 <b>forth</b> [3] 4/13 13/17 27/11 <b>forthcoming</b> [1] 4/8 <b>fortunately</b> [1] 27/7 <b>found</b> [3] 11/3 23/22 33/5 <b>fraction</b> [1] 25/11 <b>framed</b> [1] 34/24 <b>free</b> [2] 4/2 6/25 <b>front</b> [3] 14/6 25/12 35/13 <b>Ft</b> [1] 1/24	<b>G</b> <b>GA</b> [1] 1/18 <b>gargantuan</b> [1] 4/11 <b>gave</b> [2] 7/18 29/7 <b>general</b> [9] 31/22 31/24 31/25 32/3 32/5 32/11 32/13 33/11 33/22 <b>generally</b> [1] 26/22 <b>get</b> [25] 15/7 16/6 17/3 18/10 19/14 20/6 20/17 20/18 25/16 26/15 26/24 27/2 27/16 29/19 30/18 33/19 33/23 35/8 35/9 35/9 35/10 36/6 36/17 36/19 36/19 <b>gets</b> [1] 12/2 <b>getting</b> [2] 8/19 13/7 <b>give</b> [6] 19/25 20/2 28/25 30/13 32/7 32/11 <b>given</b> [3] 4/9 34/15 34/16 <b>giving</b> [1] 35/10 <b>global</b> [1] 29/18 <b>go</b> [10] 12/19 18/25 20/8 21/1 22/11 28/19 30/6 32/13 36/22 37/4 <b>goal</b> [1] 25/16 <b>goes</b> [5] 6/22 24/7 31/22 34/4 34/18 <b>going</b> [46] <b>gone</b> [1] 27/22 <b>good</b> [10] 2/9 2/11 2/13 2/16 2/18 2/20 2/23 11/7 17/14 34/6 <b>got</b> [2] 8/15 12/16 <b>gotten</b> [2] 13/22 32/2 <b>gram</b> [2] 13/5 13/8 <b>grams</b> [11] 7/5 9/5 29/13 30/2 31/1 31/1 31/2 35/2 35/2 35/2 36/21 <b>great</b> [2] 3/16 18/3 <b>GSK</b> [58] <b>GSK tested</b> [1] 6/14 <b>GSK's</b> [9] 5/18 5/23 8/16 10/11 11/16 15/10 15/11 21/20 25/23 <b>guess</b> [4] 3/22 8/5 19/7 31/12	<b>I</b> <b>I think</b> [1] 18/24 <b>I'll</b> [3] 2/5 4/6 21/16 <b>I'm</b> [3] 5/4 27/10 33/3 <b>I've</b> [1] 21/17 <b>Illinois</b> [1] 30/8 <b>impacts</b> [1] 27/19 <b>importance</b> [4] 33/6 33/9 33/21 34/15 <b>important</b> [11] 8/12 11/12 22/17 26/6 26/17 26/25 26/25 27/4 28/1 33/12 33/13 <b>Inc</b> [1] 2/22 <b>included</b> [1] 11/6 <b>including</b> [1] 24/15 <b>inconsistency</b> [1] 28/21 <b>inefficient</b> [1] 16/8 <b>information</b> [6] 20/17 20/18

<b>I</b> <b>information...</b> [4] 33/8 33/18 35/5 36/1 <b>Ingelheim</b> [2] 2/19 2/21 <b>ingredient</b> [8] 4/21 4/23 4/25 5/1 23/21 23/23 24/17 24/21 <b>injection</b> [1] 31/8 <b>injections</b> [3] 9/13 10/4 21/5 <b>input</b> [1] 15/2 <b>inquiry</b> [1] 29/23 <b>instance</b> [2] 17/22 17/24 <b>instead</b> [1] 20/8 <b>intended</b> [2] 3/2 26/16 <b>interim</b> [1] 18/21 <b>internal</b> [1] 27/6 <b>interrupting</b> [1] 5/5 <b>inures</b> [1] 33/19 <b>involved</b> [1] 12/16 <b>irrelevant</b> [2] 16/9 16/23 <b>is</b> [282] <b>isn't</b> [2] 13/25 16/20 <b>issue</b> [16] 19/6 23/8 27/5 28/1 28/10 28/12 28/13 28/19 30/22 31/19 32/14 33/12 33/13 33/22 34/16 35/7 <b>issues</b> [12] 3/2 3/12 4/15 5/2 5/3 6/19 6/25 33/7 33/9 35/18 36/12 36/14 <b>it</b> [147] <b>it's</b> [9] 5/11 8/5 9/9 13/4 14/10 14/14 17/3 17/14 34/4 <b>items</b> [2] 9/1 29/9 <b>its</b> [15] 4/18 4/25 6/7 6/14 8/14 8/18 11/14 11/14 11/19 15/15 16/2 16/12 20/24 28/15 33/10 <b>itself</b> [3] 5/7 5/13 26/19	29/10 30/2 <b>kind</b> [20] 8/6 8/10 8/11 9/2 9/16 9/18 9/25 11/4 12/2 12/9 16/14 18/5 18/11 19/6 20/10 21/13 22/9 30/14 32/17 36/17 <b>King</b> [6] 1/17 6/1 6/4 6/13 12/7 25/20 <b>know</b> [25] 4/3 4/10 12/5 14/1 17/7 17/23 18/7 18/14 18/20 21/19 21/20 22/2 22/6 22/15 22/16 23/5 25/1 25/2 26/11 26/12 28/10 28/12 34/24 35/12 37/2 <b>known</b> [1] 4/21 <b>knows</b> [1] 6/12	16/17 16/17 18/13 19/3 20/16 20/16 20/20 20/25 25/13 25/17 25/17 25/18 26/20 27/7 27/9 27/10 29/6 30/22 34/7 <b>looked</b> [5] 5/24 6/17 10/16 11/2 25/6 <b>looking</b> [3] 24/6 24/13 29/11 <b>loose</b> [1] 27/2 <b>Los</b> [1] 1/21 <b>lot</b> [8] 3/25 4/1 4/9 4/11 9/8 15/12 27/7 29/2 <b>lots</b> [1] 24/14 <b>low</b> [3] 10/20 11/19 32/24 <b>lumpy</b> [1] 11/10
<b>J</b> <b>J-E-R-O-N-G</b> [1] 5/8 <b>J-U-R-O-N-G</b> [3] 5/9 5/11 5/12 <b>JUDGE</b> [5] 1/9 9/16 18/3 29/24 37/6 <b>Jurong</b> [36] 4/21 4/22 5/7 5/8 5/23 6/3 6/7 6/7 6/16 6/19 7/4 7/10 7/15 8/14 8/19 9/4 10/15 11/12 11/19 12/21 12/21 13/3 15/15 15/15 16/14 17/5 23/16 24/20 25/10 26/4 26/5 26/6 26/9 28/22 34/1 34/6 <b>Jurong's</b> [1] 6/21 <b>just</b> [28] 9/22 10/10 11/22 13/7 14/6 14/14 15/3 16/3 16/8 17/3 19/10 19/17 21/10 21/16 23/5 23/13 25/25 26/25 28/8 28/19 29/24 29/24 30/13 30/24 31/7 32/16 36/4 36/7	<b>L</b> <b>Lab</b> [1] 5/14 <b>land</b> [1] 11/25 <b>large</b> [1] 26/8 <b>last</b> [3] 20/2 21/12 23/1 <b>late</b> [1] 2/2 <b>later</b> [6] 5/13 8/20 15/16 19/6 19/15 36/9 <b>law</b> [1] 2/8 <b>lawsuit</b> [1] 31/20 <b>learn</b> [1] 18/18 <b>least</b> [8] 3/7 5/24 23/4 24/19 27/9 34/7 35/18 36/12 <b>led</b> [1] 11/13 <b>left</b> [6] 12/25 21/20 22/15 23/2 29/1 30/3 <b>less</b> [3] 9/4 28/23 31/1 <b>lesser</b> [1] 36/22 <b>let</b> [13] 2/5 7/25 8/10 9/22 17/23 20/1 20/13 22/24 28/19 31/20 35/14 37/3 37/3 <b>let's</b> [3] 13/1 18/9 20/1 <b>level</b> [2] 14/25 32/7 <b>levels</b> [4] 10/21 11/19 15/19 18/10 <b>Levin</b> [2] 1/11 2/8 <b>LIABILITY</b> [2] 1/5 2/3 <b>lick</b> [1] 15/12 <b>like</b> [21] 3/18 3/24 10/6 11/4 14/11 15/2 16/19 16/20 16/21 18/14 19/17 21/3 22/11 22/25 23/1 23/7 23/10 25/18 26/23 26/24 36/8 <b>likelihood</b> [1] 16/5 <b>likely</b> [1] 4/11 <b>limit</b> [1] 11/21 <b>lines</b> [1] 25/15 <b>lingo</b> [1] 9/25 <b>list</b> [1] 26/20 <b>litigation</b> [14] 1/5 6/23 11/21 13/4 13/4 14/21 16/11 17/18 19/18 21/10 31/15 33/7 33/13 34/16 <b>little</b> [10] 8/4 8/5 8/8 9/22 10/24 11/22 13/5 14/3 18/6 20/20 <b>LLP</b> [3] 1/14 1/17 1/20 <b>load</b> [1] 25/12 <b>long</b> [2] 24/9 28/8 <b>longer</b> [3] 8/18 17/20 17/21 <b>look</b> [22] 11/5 13/12 15/19	<b>M</b> <b>made</b> [22] 4/18 5/13 7/2 8/14 8/18 10/12 10/15 11/7 11/12 16/2 16/12 16/24 20/14 20/24 20/25 21/2 21/18 26/10 28/15 31/13 34/25 35/18 <b>MAGISTRATE</b> [1] 1/9 <b>maintain</b> [2] 6/8 6/21 <b>maintained</b> [2] 22/16 22/16 <b>major</b> [1] 28/10 <b>majority</b> [1] 26/8 <b>make</b> [12] 2/15 3/24 19/4 19/5 19/15 24/16 29/24 30/19 30/20 31/7 34/17 36/18 <b>makes</b> [1] 4/25 <b>making</b> [4] 5/25 9/13 19/20 23/2 <b>manufacture</b> [1] 13/9 <b>manufactured</b> [7] 4/22 4/23 5/7 7/17 21/2 25/15 27/13 <b>manufacturing</b> [1] 8/24 <b>many</b> [5] 21/3 22/12 25/19 27/5 35/3 <b>MARK</b> [2] 1/17 2/20 <b>market</b> [5] 18/2 21/3 21/5 26/16 28/9 <b>massive</b> [1] 30/15 <b>master</b> [2] 2/25 36/6 <b>material</b> [2] 17/16 28/24 <b>matter</b> [3] 21/24 32/12 37/11 <b>matters</b> [1] 18/19 <b>may</b> [8] 7/20 8/21 29/13 32/2 32/20 35/8 35/17 36/11 <b>maybe</b> [13] 5/9 10/23 18/7 18/8 18/10 18/14 20/19 20/20 26/25 28/9 30/5 30/24 36/22 <b>md</b> [1] 1/3 <b>me</b> [25] 2/5 4/2 5/17 7/25 8/10 9/22 10/24 11/8 17/23 19/22 20/13 22/10 23/3 28/19 28/21 31/20 31/21 32/4 32/8 32/25 33/12 34/24 35/4 35/13 37/3 <b>mean</b> [4] 17/12 17/15 23/12 24/20 <b>meaning</b> [2] 31/19 31/24 <b>means</b> [3] 13/10 17/19 19/22 <b>measure</b> [1] 27/16 <b>meet</b> [2] 4/6 4/13 <b>mentioned</b> [8] 10/11 11/16 12/14 13/17 16/17 20/7 25/2 26/3 <b>methodology</b> [1] 34/7
<b>K</b> <b>keep</b> [1] 8/12 <b>kept</b> [1] 13/6 <b>key</b> [1] 28/2 <b>kilograms</b> [5] 7/4 7/4 7/5		

<b>M</b> <b>Michael</b> [1] 5/19 <b>microscope</b> [1] 6/18 <b>microscopes</b> [1] 11/3 <b>might</b> [2] 5/9 9/24 <b>milk</b> [1] 32/15 <b>mind</b> [1] 8/12 <b>minutes</b> [1] 2/2 <b>missing</b> [1] 29/3 <b>molecule</b> [1] 17/13 <b>moment</b> [1] 22/21 <b>months</b> [5] 10/9 12/3 13/18 14/12 22/13 <b>moot</b> [1] 3/3 <b>more</b> [8] 15/23 22/17 24/7 24/8 26/24 29/2 33/15 35/5 <b>morphology</b> [6] 10/25 11/4 11/10 11/11 11/13 12/1 <b>most</b> [4] 10/15 13/12 33/12 33/13 <b>motion</b> [1] 32/21 <b>move</b> [2] 17/8 33/1 <b>moved</b> [1] 31/12 <b>Mr</b> [48] <b>much</b> [18] 3/19 5/21 7/14 11/9 15/1 17/9 18/21 22/14 22/17 23/20 23/22 27/8 30/25 31/16 34/15 34/22 35/8 36/24 <b>muddy</b> [1] 17/4 <b>multiple</b> [1] 25/1 <b>my</b> [12] 2/24 3/5 4/5 5/5 17/11 19/20 20/11 24/2 30/8 32/16 34/25 36/12	21/6 21/10 21/25 22/11 31/11 31/11 33/19 34/17 36/7 <b>no-go</b> [1] 22/11 <b>noodling</b> [1] 18/5 <b>not</b> [45] <b>notes</b> [1] 22/21 <b>nothing</b> [2] 15/2 21/10 <b>noticed</b> [1] 2/24 <b>notion</b> [1] 13/18 <b>now</b> [17] 3/3 6/8 12/18 13/4 15/16 15/19 18/11 18/12 19/15 20/19 23/13 30/7 30/13 31/24 35/1 35/10 36/15 <b>number</b> [2] 2/2 29/12 <b>numbers</b> [1] 17/3 <b>numerous</b> [2] 4/6 6/12 <b>nutshell</b> [1] 16/14	<b>ourselves</b> [2] 13/15 30/19 <b>out</b> [16] 5/13 7/4 7/20 8/23 10/5 10/6 11/20 11/23 14/24 16/21 18/1 25/11 26/24 27/22 31/17 36/17 <b>outcome</b> [1] 30/10 <b>outweighs</b> [1] 33/10 <b>over</b> [13] 8/17 10/20 12/3 15/22 22/12 23/22 24/9 25/17 28/7 33/23 35/21 36/6 36/19 <b>overarching</b> [2] 21/16 21/18 <b>overrule</b> [4] 33/25 34/11 34/12 34/19 <b>own</b> [5] 8/14 8/18 11/14 11/19 12/19
<b>N</b> <b>nanograms</b> [2] 27/18 27/23 <b>narrowed</b> [1] 4/17 <b>narrowing</b> [1] 4/15 <b>NDMA</b> [10] 5/21 10/7 10/21 14/24 15/1 15/23 16/11 27/24 32/1 32/1 <b>need</b> [17] 4/2 7/19 7/21 17/10 26/6 28/13 30/4 30/17 30/19 30/20 31/1 34/22 35/2 35/4 36/1 36/1 36/2 <b>needed</b> [5] 7/20 23/16 23/18 23/20 35/6 <b>needle</b> [1] 33/1 <b>needs</b> [1] 19/18 <b>negotiate</b> [1] 30/6 <b>never</b> [4] 22/15 23/8 31/8 34/3 <b>new</b> [1] 10/24 <b>next</b> [5] 8/17 26/10 35/15 35/15 35/22 <b>NIGH</b> [28] 1/10 2/7 2/9 3/7 3/14 3/22 5/4 8/13 9/1 10/11 10/19 12/13 13/17 13/20 14/3 15/8 17/11 21/23 22/13 22/24 28/18 29/5 30/1 30/12 32/8 32/17 35/1 36/16 <b>Nigh's</b> [1] 8/11 <b>nine</b> [1] 24/15 <b>no</b> [27] 1/3 6/10 8/18 16/1 16/1 16/3 16/23 17/5 17/20 17/21 17/22 17/24 19/23 20/19 20/23 21/4 21/5 21/6	<b>O</b> <b>o'clock</b> [1] 2/1 <b>objection</b> [5] 8/1 33/3 33/25 34/11 34/12 <b>objections</b> [3] 34/19 35/17 36/11 <b>obviously</b> [4] 19/3 23/9 26/14 30/4 <b>October</b> [1] 11/15 <b>odds</b> [1] 16/7 <b>off</b> [1] 26/11 <b>Official</b> [2] 1/23 37/14 <b>often</b> [1] 5/1 <b>okay</b> [7] 5/12 18/9 19/19 20/3 28/18 29/21 31/6 <b>old</b> [2] 23/15 27/22 <b>older</b> [1] 13/7 <b>oldest</b> [1] 13/14 <b>once</b> [2] 8/13 21/20 <b>one</b> [29] 5/6 5/12 8/6 8/9 9/2 9/17 11/1 14/8 14/17 14/19 15/4 15/12 16/16 20/5 21/13 21/14 22/2 22/10 24/15 25/18 28/19 29/9 29/17 30/3 33/16 33/18 34/18 36/3 36/7 <b>one-third</b> [2] 29/17 30/3 <b>only</b> [12] 4/18 8/19 9/9 9/13 9/14 14/17 15/4 19/11 21/18 22/9 25/7 29/15 <b>open</b> [1] 27/25 <b>opposed</b> [1] 36/3 <b>opposing</b> [1] 6/24 <b>option</b> [2] 8/6 8/6 <b>options</b> [1] 8/5 <b>oranges</b> [2] 15/14 16/7 <b>Orchev</b> [1] 8/22 <b>order</b> [3] 22/25 30/23 33/2 <b>originally</b> [2] 2/23 13/3 <b>other</b> [21] 5/21 6/19 8/20 8/22 10/11 11/24 18/4 20/5 21/14 22/4 22/8 22/24 25/19 25/24 28/19 30/5 31/12 33/19 33/23 34/20 35/7 <b>other issues</b> [1] 6/19 <b>others</b> [3] 6/22 10/13 25/22 <b>our</b> [21] 6/8 6/11 6/21 6/25 7/1 7/2 7/8 7/20 8/21 11/6 12/7 12/23 12/24 13/22 16/4 19/11 22/15 25/16 29/9 30/9 31/2	<b>P</b> <b>PA</b> [1] 1/15 <b>packaged</b> [1] 27/4 <b>packaging</b> [3] 26/25 27/4 27/8 <b>page</b> [1] 7/23 <b>PALM</b> [3] 1/2 1/5 1/24 <b>Papantonio</b> [2] 1/11 2/8 <b>papers</b> [4] 4/5 8/21 14/7 16/4 <b>paraphrasing</b> [1] 29/1 <b>part</b> [1] 10/15 <b>particular</b> [4] 14/25 22/25 23/7 33/21 <b>parties</b> [4] 2/17 3/2 3/23 37/3 <b>parties'</b> [2] 33/8 33/17 <b>pass</b> [1] 33/16 <b>past</b> [4] 15/18 18/20 18/20 32/15 <b>Pauline</b> [2] 1/23 37/14 <b>Peachtree</b> [1] 1/18 <b>peer</b> [1] 12/6 <b>Pensacola</b> [1] 1/12 <b>people</b> [3] 2/14 26/8 31/3 <b>per</b> [3] 13/2 30/2 30/3 <b>percent</b> [7] 13/13 23/23 24/16 28/23 29/3 29/15 29/19 <b>percentage</b> [3] 7/6 25/14 29/15 <b>perhaps</b> [3] 27/10 34/25 36/6 <b>period</b> [6] 11/18 13/14 16/19 20/16 24/9 28/8 <b>perspective</b> [1] 12/20 <b>pertinent</b> [1] 16/10 <b>Pharmaceuticals</b> [1] 2/21 <b>Philadelphia</b> [2] 1/15 30/8 <b>picked</b> [6] 25/6 25/7 25/11 25/11 25/12 25/14 <b>picks</b> [1] 25/13 <b>picture</b> [1] 11/7 <b>piece</b> [1] 16/15 <b>Pierce</b> [1] 1/24 <b>Pierce/West</b> [1] 1/24 <b>pills</b> [2] 27/2 27/3 <b>Plaintiff</b> [7] 2/6 16/13 16/23 20/12 20/14 31/11 31/12 <b>PLAINTIFFS</b> [22] 1/10 2/8 3/1 3/9 6/2 6/2 12/11 12/11 12/18 13/8 13/13 14/14 14/15 15/6 15/18 20/18 30/18 32/2

<p><b>P</b></p> <p><b>PLAINTIFFS...</b> [4] 33/14 33/18 33/19 34/18</p> <p><b>Plaintiffs'</b> [1] 33/20</p> <p><b>play</b> [2] 12/9 22/7</p> <p><b>players</b> [2] 30/5 30/7</p> <p><b>pleasure</b> [1] 4/13</p> <p><b>point</b> [10] 14/17 19/6 20/10 23/1 23/11 26/13 31/5 31/7 34/18 35/10</p> <p><b>points</b> [3] 20/1 20/4 21/17</p> <p><b>Porter</b> [2] 1/20 2/17</p> <p><b>position</b> [2] 19/11 34/23</p> <p><b>possible</b> [2] 17/3 36/18</p> <p><b>possibly</b> [2] 6/22 19/1</p> <p><b>potential</b> [1] 12/1</p> <p><b>potentially</b> [2] 17/17 30/6</p> <p><b>precise</b> [1] 25/20</p> <p><b>premature</b> [1] 20/20</p> <p><b>prescription</b> [1] 26/9</p> <p><b>present</b> [2] 25/24 36/13</p> <p><b>presentation</b> [1] 20/1</p> <p><b>presented</b> [2] 29/8 36/25</p> <p><b>presenting</b> [1] 4/15</p> <p><b>presumably</b> [3] 15/18 15/23 35/9</p> <p><b>presumptively</b> [1] 23/4</p> <p><b>pretty</b> [5] 13/18 21/12 22/11 26/2 32/24</p> <p><b>prevail</b> [1] 32/21</p> <p><b>probably</b> [2] 29/12 30/4</p> <p><b>probative</b> [10] 6/10 6/23 16/3 24/22 24/24 26/3 27/15 31/14 32/9 34/10</p> <p><b>problem</b> [3] 15/13 21/17 21/19</p> <p><b>problematic</b> [1] 18/16</p> <p><b>problems</b> [1] 15/12</p> <p><b>proceedings</b> [1] 37/11</p> <p><b>process</b> [1] 11/13</p> <p><b>produce</b> [4] 6/6 7/10 30/24 30/24</p> <p><b>produced</b> [1] 26/21</p> <p><b>product</b> [85]</p> <p><b>production</b> [1] 33/2</p> <p><b>products</b> [13] 1/5 4/19 5/1 6/17 7/21 8/16 9/15 21/11 25/18 28/16 34/3 34/3 34/8</p> <p><b>products'</b> [1] 6/18</p> <p><b>promptly</b> [1] 36/20</p> <p><b>prong</b> [1] 9/17</p> <p><b>proportional</b> [5] 7/3 7/8 8/2 33/2 33/6</p> <p><b>proportionality</b> [6] 9/18 9/20 20/21 33/3 33/4 33/24</p> <p><b>proportionate</b> [1] 19/17</p> <p><b>prove</b> [1] 31/19</p> <p><b>provide</b> [1] 36/3</p> <p><b>provides</b> [1] 17/16</p> <p><b>providing</b> [2] 33/25 34/12</p> <p><b>provision</b> [1] 17/6</p> <p><b>PTO</b> [2] 2/3 2/24</p> <p><b>publication</b> [3] 6/13 12/6 12/13</p> <p><b>published</b> [3] 5/25 11/5 27/5</p> <p><b>purpose</b> [2] 17/13 19/11</p> <p><b>purposes</b> [6] 8/12 17/17 23/5</p>	<p>23/17 24/4 32/19</p> <p><b>put</b> [5] 11/2 18/1 18/1 20/13 35/13</p> <p><b>Q</b></p> <p><b>question</b> [14] 9/16 10/24 13/16 15/3 16/10 17/11 18/3 18/4 24/23 26/10 31/18 32/4 34/15 35/23</p> <p><b>questions</b> [6] 17/7 19/20 22/19 22/24 34/20 34/21</p> <p><b>quick</b> [1] 17/8</p> <p><b>quickly</b> [2] 35/11 36/17</p> <p><b>R</b></p> <p><b>Rafferty</b> [1] 1/11</p> <p><b>raise</b> [1] 35/19</p> <p><b>ranging</b> [1] 13/9</p> <p><b>RANITIDINE</b> [10] 1/4 2/3 8/19 8/24 10/8 10/20 11/17 15/21 17/25 31/25</p> <p><b>rate</b> [7] 6/15 10/21 10/22 11/9 18/12 18/13 18/18</p> <p><b>rates</b> [2] 34/5 34/7</p> <p><b>rather</b> [2] 6/11 22/14</p> <p><b>RCA</b> [1] 9/25</p> <p><b>re</b> [2] 1/4 2/2</p> <p><b>reach</b> [1] 35/23</p> <p><b>reached</b> [1] 3/1</p> <p><b>react</b> [1] 26/19</p> <p><b>read</b> [3] 3/22 3/25 4/5</p> <p><b>reading</b> [1] 30/22</p> <p><b>real</b> [2] 16/5 20/4</p> <p><b>really</b> [20] 9/13 9/20 9/21 13/25 14/3 14/16 15/9 17/2 18/4 18/8 20/10 20/11 20/21 21/9 30/25 31/3 34/22 34/23 35/2 35/5</p> <p><b>reason</b> [3] 14/20 25/6 35/25</p> <p><b>reasons</b> [8] 6/12 7/9 17/5 22/4 22/4 22/8 34/11 34/13</p> <p><b>reasons we</b> [1] 7/9</p> <p><b>received</b> [2] 4/11 37/1</p> <p><b>recently</b> [1] 14/14</p> <p><b>recess</b> [1] 37/5</p> <p><b>reconcile</b> [1] 29/4</p> <p><b>record</b> [3] 19/4 31/8 37/11</p> <p><b>Reddy</b> [5] 5/14 5/14 34/1 34/2 34/3</p> <p><b>Reddy's</b> [25] 4/22 4/23 6/16 6/20 6/22 8/15 8/20 9/5 10/12 10/13 20/4 20/5 20/6 20/13 20/15 20/22 20/23 21/2 21/5 26/11 26/12 26/14 28/5 31/9 31/13</p> <p><b>reference</b> [1] 8/21</p> <p><b>regard</b> [1] 36/7</p> <p><b>regarding</b> [1] 4/7</p> <p><b>regardless</b> [1] 26/15</p> <p><b>registry</b> [2] 20/19 31/11</p> <p><b>regulators</b> [2] 10/2 12/12</p> <p><b>regulatory</b> [7] 8/15 13/3 14/21 17/20 23/12 24/23 32/18</p> <p><b>REINHART</b> [1] 1/8</p> <p><b>relative</b> [2] 33/8 33/17</p> <p><b>relatively</b> [1] 35/10</p> <p><b>relevance</b> [14] 8/9 9/9 9/13</p>	<p>9/18 9/21 13/16 14/2 19/9 20/22 20/23 31/18 31/21 32/24 33/1</p> <p><b>relevancy</b> [1] 26/13</p> <p><b>relevant</b> [15] 6/11 8/2 13/19 13/21 13/22 19/18 28/16 31/18 32/4 32/6 32/6 32/12 33/5 33/5 33/17</p> <p><b>reliable</b> [7] 18/23 22/1 22/17 23/4 23/17 24/10 24/18</p> <p><b>remarks</b> [1] 17/12</p> <p><b>remind</b> [1] 6/24</p> <p><b>Reporter</b> [3] 1/23 37/14 37/15</p> <p><b>reporter's</b> [1] 5/5</p> <p><b>reports</b> [1] 10/7</p> <p><b>representative</b> [2] 25/5 25/16</p> <p><b>request</b> [8] 9/3 9/4 10/2 14/22 16/18 17/1 19/16 29/13</p> <p><b>requested</b> [6] 4/17 7/3 7/5 7/6 7/11 27/11</p> <p><b>requesting</b> [2] 13/13 29/14</p> <p><b>requests</b> [5] 7/2 7/8 9/8 9/9 20/25</p> <p><b>requirement</b> [2] 13/4 13/5</p> <p><b>reserve</b> [1] 19/5</p> <p><b>reserved</b> [1] 36/9</p> <p><b>resolve</b> [5] 34/23 35/4 35/11 35/14 35/15</p> <p><b>resolved</b> [1] 34/10</p> <p><b>resolving</b> [2] 33/9 33/22</p> <p><b>resources</b> [1] 33/8</p> <p><b>respond</b> [4] 19/21 19/25 22/25 29/22</p> <p><b>response</b> [3] 14/21 19/22 19/24</p> <p><b>rest</b> [2] 17/8 20/11</p> <p><b>results</b> [4] 11/23 12/13 16/6 24/18</p> <p><b>retain</b> [1] 30/19</p> <p><b>retained</b> [1] 13/3</p> <p><b>return</b> [1] 27/16</p> <p><b>returned</b> [18] 9/11 9/12 9/12 9/19 21/13 21/14 21/14 21/17 21/19 21/21 22/1 22/7 22/9 26/20 27/12 27/14 27/14 34/14</p> <p><b>reviewed</b> [1] 12/6</p> <p><b>right</b> [8] 3/16 5/10 6/3 19/15 31/17 31/23 31/23 35/25</p> <p><b>ROBIN</b> [1] 1/24</p> <p><b>rolling</b> [1] 36/20</p> <p><b>room</b> [1] 9/23</p> <p><b>root</b> [11] 9/22 10/1 10/7 11/1 12/9 12/16 14/23 23/14 23/25 24/12 25/4</p> <p><b>ROSENBERG</b> [2] 1/3 1/24</p> <p><b>row</b> [7] 29/7 29/7 29/7 29/8 29/8 29/8 29/8</p> <p><b>rule</b> [5] 19/7 31/4 34/23 35/12 36/4</p> <p><b>ruled</b> [2] 36/12 36/15</p> <p><b>ruling</b> [1] 34/25</p> <p><b>rulings</b> [2] 35/17 36/12</p>
---	--	--

<p><b>S</b></p> <p><b>said</b> [6] 15/21 16/4 25/1 25/10 33/11 36/8</p> <p><b>sake</b> [2] 5/5 5/6</p> <p><b>sale</b> [1] 26/16</p> <p><b>sales</b> [1] 20/17</p> <p><b>same</b> [8] 6/13 12/23 27/3 27/13 28/14 29/25 30/12 34/11</p> <p><b>sample</b> [1] 25/16</p> <p><b>samples</b> [18] 7/15 7/15 7/16 7/19 9/3 10/3 10/10 10/17 11/2 11/20 13/8 14/11 14/11 14/13 19/16 21/6 22/10 25/5</p> <p><b>Sanofi</b> [5] 2/14 2/14 2/17 2/25 3/11</p> <p><b>Saraca</b> [4] 6/16 8/22 10/12 10/13</p> <p><b>say</b> [26] 4/6 12/20 12/22 12/23 13/22 14/11 15/19 17/15 18/9 18/11 19/4 19/7 21/23 24/7 24/8 24/19 26/5 26/22 27/22 27/23 29/16 30/4 30/12 32/22 34/16 35/20</p> <p><b>saying</b> [4] 24/1 24/19 28/22 28/24</p> <p><b>says</b> [3] 10/6 23/25 24/2</p> <p><b>scales</b> [1] 16/17</p> <p><b>science</b> [1] 4/1</p> <p><b>scientific</b> [4] 5/25 6/13 15/2 23/14</p> <p><b>scope</b> [1] 4/17</p> <p><b>sealed</b> [1] 13/6</p> <p><b>search</b> [1] 14/22</p> <p><b>searching</b> [1] 13/20</p> <p><b>Searle</b> [2] 5/19 12/14</p> <p><b>second</b> [4] 9/7 14/22 20/10 31/7</p> <p><b>secondary</b> [1] 34/21</p> <p><b>see</b> [21] 5/2 7/23 11/6 15/20 15/23 16/18 18/12 20/12 20/22 20/23 23/16 23/18 23/19 23/20 25/3 25/4 25/14 26/18 27/19 27/20 36/22</p> <p><b>see whether</b> [1] 20/12</p> <p><b>seeing</b> [3] 4/5 11/24 28/14</p> <p><b>seeming</b> [1] 29/2</p> <p><b>seems</b> [6] 11/9 20/6 22/10 23/3 31/21 32/4</p> <p><b>seen</b> [1] 8/21</p> <p><b>sees</b> [1] 11/19</p> <p><b>selling</b> [1] 4/20</p> <p><b>sent</b> [1] 3/23</p> <p><b>SENTENAC</b> [4] 1/17 2/21 3/4 3/17</p> <p><b>September</b> [1] 11/15</p> <p><b>serially</b> [1] 30/6</p> <p><b>several</b> [3] 25/20 26/3 27/12</p> <p><b>shape</b> [1] 10/25</p> <p><b>share</b> [1] 36/15</p> <p><b>shenanigans</b> [1] 19/7</p> <p><b>shifts</b> [1] 8/8</p> <p><b>shipped</b> [5] 7/12 23/8 28/2 28/4 28/7</p> <p><b>shop</b> [2] 30/10 30/12</p> <p><b>short</b> [1] 4/1</p> <p><b>should</b> [4] 6/6 14/11 17/5</p>	<p>26/14</p> <p><b>show</b> [2] 24/13 24/16</p> <p><b>shows</b> [4] 15/8 17/2 24/12 25/9</p> <p><b>shut</b> [1] 11/16</p> <p><b>sided</b> [1] 33/18</p> <p><b>Signature</b> [1] 37/15</p> <p><b>significant</b> [3] 9/20 9/20 22/3</p> <p><b>silly</b> [1] 27/24</p> <p><b>similar</b> [3] 28/3 28/6 28/15</p> <p><b>similarly</b> [1] 9/11</p> <p><b>since</b> [2] 16/23 21/9</p> <p><b>Singapore</b> [1] 8/14</p> <p><b>single</b> [2] 20/12 20/14</p> <p><b>sitting</b> [2] 13/7 22/5</p> <p><b>situation</b> [1] 14/15</p> <p><b>six</b> [5] 15/17 15/22 16/23 18/20 36/2</p> <p><b>slip</b> [1] 9/24</p> <p><b>slower</b> [1] 11/9</p> <p><b>small</b> [4] 7/6 10/14 13/2 25/11</p> <p><b>SMS</b> [2] 8/22 10/12</p> <p><b>so</b> [81]</p> <p><b>sobeit</b> [1] 32/22</p> <p><b>sold</b> [2] 31/8 34/3</p> <p><b>some</b> [17] 8/3 14/2 15/8 15/17 17/23 18/4 18/11 22/6 25/3 27/10 31/12 32/6 32/11 35/9 35/10 36/17 36/22</p> <p><b>somebody</b> [2] 14/25 17/22</p> <p><b>something</b> [9] 10/23 13/24 14/10 23/25 24/2 24/16 27/1 31/1 36/3</p> <p><b>Sometimes</b> [1] 9/24</p> <p><b>soon</b> [1] 35/7</p> <p><b>sorry</b> [4] 2/1 5/4 12/6 33/3</p> <p><b>sort</b> [7] 10/5 13/7 13/19 15/5 17/19 18/12 30/22</p> <p><b>sorts</b> [1] 24/22</p> <p><b>sounds</b> [1] 11/4</p> <p><b>source</b> [1] 20/8</p> <p><b>sources</b> [1] 20/5</p> <p><b>South</b> [2] 1/11 1/21</p> <p><b>SOUTHERN</b> [1] 1/1</p> <p><b>space</b> [1] 22/4</p> <p><b>Spalding</b> [1] 1/17</p> <p><b>speaking</b> [2] 14/2 26/22</p> <p><b>special</b> [3] 2/25 22/9 36/5</p> <p><b>specific</b> [2] 7/18 26/15</p> <p><b>specifically</b> [3] 7/11 23/1 31/24</p> <p><b>specifications</b> [1] 17/21</p> <p><b>speculate</b> [1] 18/13</p> <p><b>speculating</b> [1] 19/10</p> <p><b>spelled</b> [1] 5/8</p> <p><b>spelling</b> [1] 5/9</p> <p><b>spreadsheet</b> [3] 25/9 27/9 27/10</p> <p><b>spreadsheets</b> [1] 29/6</p> <p><b>stability</b> [1] 5/3</p> <p><b>stacked</b> [4] 23/20 24/8 24/21 25/5</p> <p><b>stake</b> [1] 33/13</p> <p><b>standard</b> [5] 14/1 32/23 32/24 32/24 33/4</p> <p><b>standpoint</b> [2] 24/5 24/23</p>	<p><b>start</b> [6] 2/5 8/10 8/15 13/1 31/20 35/10</p> <p><b>starting</b> [4] 2/1 18/16 18/19 34/7</p> <p><b>state</b> [1] 12/9</p> <p><b>STATES</b> [4] 1/1 1/9 23/9 31/10</p> <p><b>stick</b> [1] 17/23</p> <p><b>still</b> [6] 3/20 6/25 23/16 23/19 23/21 23/24</p> <p><b>Stipes</b> [2] 1/23 37/14</p> <p><b>stock</b> [1] 22/15</p> <p><b>storage</b> [3] 21/20 21/21 21/24</p> <p><b>straight</b> [1] 9/9</p> <p><b>Street</b> [4] 1/11 1/15 1/18 1/21</p> <p><b>structure</b> [1] 10/24</p> <p><b>struggling</b> [2] 20/11 20/22</p> <p><b>stuff</b> [5] 12/24 13/14 13/23 21/7 23/2</p> <p><b>submission</b> [3] 7/24 12/4 12/5</p> <p><b>submissions</b> [4] 3/23 11/6 12/8 12/12</p> <p><b>submit</b> [4] 16/4 16/9 16/22 19/18</p> <p><b>success</b> [1] 20/19</p> <p><b>such</b> [2] 24/3 25/12</p> <p><b>suddenly</b> [1] 17/14</p> <p><b>sufficient</b> [2] 31/2 33/23</p> <p><b>suggest</b> [2] 29/2 36/20</p> <p><b>Suite</b> [1] 1/18</p> <p><b>summarize</b> [1] 3/24</p> <p><b>suppliers</b> [2] 8/21 10/11</p> <p><b>suppose</b> [1] 35/7</p> <p><b>sure</b> [9] 14/7 19/4 29/25 30/12 30/19 30/20 31/7 36/16 36/21</p> <p><b>suspension</b> [3] 10/5 21/6 31/9</p> <p><b>syrup</b> [4] 9/13 10/4 21/6 31/8</p> <p><b>T</b></p> <p><b>tablets</b> [9] 9/12 10/4 21/1 21/2 21/4 21/18 26/11 27/13 35/3</p> <p><b>take</b> [3] 17/9 18/9 22/21</p> <p><b>taken</b> [4] 16/13 16/24 17/24 37/3</p> <p><b>taking</b> [3] 20/7 21/11 32/3</p> <p><b>talk</b> [3] 5/6 9/22 14/13</p> <p><b>talking</b> [11] 8/7 8/25 11/21 12/18 13/1 14/23 15/16 15/17 18/19 29/25 30/14</p> <p><b>task</b> [2] 4/11 22/17</p> <p><b>taste</b> [1] 32/16</p> <p><b>tell</b> [5] 6/11 7/20 21/9 22/2 32/8</p> <p><b>telling</b> [2] 18/8 31/3</p> <p><b>temperature</b> [2] 22/7 22/16</p> <p><b>ten</b> [3] 29/14 36/2 36/21</p> <p><b>tend</b> [2] 31/19 32/16</p> <p><b>Tennessee</b> [1] 30/7</p> <p><b>term</b> [1] 11/11</p> <p><b>terminology</b> [1] 5/16</p> <p><b>terms</b> [9] 4/10 5/2 26/13</p>
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<p><b>T</b></p> <p><b>terms...</b> [6] 26/20 26/23 27/17 28/2 34/14 34/21</p> <p><b>test</b> [19] 6/3 6/5 10/2 11/20 14/5 14/8 14/19 15/6 15/15 15/25 21/25 23/16 24/9 24/10 24/14 27/1 27/19 30/18 30/20</p> <p><b>tested</b> [7] 6/4 6/14 10/18 11/14 14/4 14/9 15/15</p> <p><b>testing</b> [33] 6/9 7/1 10/9 10/16 11/25 12/3 12/13 12/19 13/16 14/12 14/22 15/10 15/11 15/14 15/16 15/17 16/3 16/6 16/9 17/6 18/5 19/9 19/12 22/1 23/17 24/4 24/18 24/24 26/4 26/24 30/15 31/14 32/9</p> <p><b>tests</b> [6] 6/22 7/20 11/19 25/20 26/3 30/16</p> <p><b>Texas</b> [1] 30/7</p> <p><b>than</b> [6] 11/10 14/20 28/23 29/3 31/1 33/16</p> <p><b>Thank</b> [18] 3/16 3/19 4/4 5/16 7/13 7/14 7/22 7/23 19/20 20/3 22/22 22/23 28/18 31/16 36/24 37/5 37/6 37/7</p> <p><b>that</b> [325]</p> <p><b>that's</b> [4] 3/5 3/6 5/8 32/23</p> <p><b>the fact</b> [1] 32/25</p> <p><b>their</b> [15] 4/7 4/11 4/20 6/5 6/16 6/18 12/19 16/9 21/24 23/25 24/12 25/24 27/7 28/8 32/10</p> <p><b>them</b> [17] 3/25 4/14 11/2 15/7 15/12 25/12 25/13 25/14 25/17 27/3 29/7 29/8 30/13 32/10 35/10 36/17 36/20</p> <p><b>theme</b> [1] 21/24</p> <p><b>then</b> [14] 5/13 7/16 8/20 9/4 9/11 15/7 18/3 20/2 21/12 22/15 27/19 28/6 32/11 36/21</p> <p><b>theory</b> [3] 31/21 31/25 32/3</p> <p><b>there</b> [57]</p> <p><b>there's</b> [1] 3/25</p> <p><b>therefore</b> [1] 32/2</p> <p><b>thereof</b> [1] 8/3</p> <p><b>Thereupon</b> [1] 37/8</p> <p><b>these</b> [14] 6/17 6/22 7/9 7/12 9/12 10/7 10/9 11/2 13/5 13/11 16/6 25/18 29/9 29/13</p> <p><b>they</b> [105]</p> <p><b>thing</b> [7] 16/16 22/2 25/19 26/17 27/3 27/22 29/25</p> <p><b>things</b> [6] 6/11 23/3 25/3 25/19 25/25 27/20</p> <p><b>think</b> [59]</p> <p><b>thinking</b> [1] 25/23</p> <p><b>third</b> [3] 9/11 29/17 30/3</p> <p><b>this</b> [88]</p> <p><b>those</b> [20] 3/3 8/22 9/14 11/23 17/4 18/22 19/5 19/15 21/1 21/9 21/11 25/11 25/15 25/20 27/13 28/16 29/14 29/15 31/13 34/13</p> <p><b>though</b> [2] 23/15 34/20</p> <p><b>thought</b> [2] 11/7 29/5</p>	<p><b>thousands</b> [2] 29/11 29/14</p> <p><b>three</b> [6] 2/24 7/23 8/5 9/1 32/15 36/3</p> <p><b>threshold</b> [1] 15/13</p> <p><b>through</b> [5] 1/8 8/6 14/7 18/10 32/8</p> <p><b>throw</b> [2] 35/3 35/13</p> <p><b>tied</b> [1] 35/8</p> <p><b>tightly</b> [1] 25/5</p> <p><b>time</b> [10] 10/20 15/22 17/9 18/19 20/16 23/22 24/9 25/17 28/8 34/10</p> <p><b>timeframe</b> [1] 27/13</p> <p><b>timeline</b> [1] 15/23</p> <p><b>times</b> [2] 5/1 25/1</p> <p><b>timing</b> [3] 35/7 35/12 35/20</p> <p><b>tin</b> [1] 10/6</p> <p><b>tipping</b> [1] 34/18</p> <p><b>today</b> [13] 3/23 4/14 14/3 15/8 17/14 30/10 32/7 32/24 34/24 35/12 35/19 36/10 36/12</p> <p><b>together</b> [1] 21/16</p> <p><b>tomorrow</b> [1] 17/14</p> <p><b>too</b> [3] 14/5 25/23 30/21</p> <p><b>took</b> [5] 12/14 15/1 20/13 20/14 31/13</p> <p><b>tool</b> [1] 17/17</p> <p><b>top</b> [2] 5/18 24/2</p> <p><b>total</b> [1] 29/16</p> <p><b>touched</b> [2] 17/12 18/6</p> <p><b>trace</b> [1] 18/10</p> <p><b>transcript</b> [1] 37/10</p> <p><b>transition</b> [1] 8/17</p> <p><b>treat</b> [1] 21/16</p> <p><b>trend</b> [2] 16/21 16/22</p> <p><b>trial</b> [1] 34/10</p> <p><b>true</b> [1] 24/19</p> <p><b>trust</b> [2] 13/23 13/25</p> <p><b>try</b> [5] 4/4 18/11 19/12 30/10 35/14</p> <p><b>trying</b> [10] 10/5 10/6 14/24 16/21 17/3 17/4 20/17 20/18 25/24 35/22</p> <p><b>turn</b> [2] 7/25 22/24</p> <p><b>two</b> [14] 3/3 6/10 7/3 8/6 9/2 15/16 15/22 16/22 18/20 18/22 20/4 21/14 34/20 36/5</p> <p><b>type</b> [3] 5/19 20/21 22/17</p> <p><b>U</b></p> <p><b>U.S</b> [14] 4/19 4/20 20/24 21/1 21/3 21/5 21/18 26/16 28/2 28/4 28/7 28/16 31/15 34/3</p> <p><b>ultimately</b> [2] 12/5 16/9</p> <p><b>under</b> [3] 6/17 11/3 19/12</p> <p><b>undermine</b> [1] 19/12</p> <p><b>understand</b> [7] 2/13 3/12 3/20 15/11 19/9 19/19 29/21</p> <p><b>understanding</b> [3] 2/25 3/5 29/9</p> <p><b>undertook</b> [1] 10/2</p> <p><b>unduly</b> [1] 8/3</p> <p><b>unexpired</b> [10] 10/17 12/21 12/21 12/23 16/12 16/12 18/14 20/6 20/8 21/14</p> <p><b>Unfortunately</b> [1] 12/24</p>	<p><b>UNITED</b> [4] 1/1 1/9 23/9 31/9</p> <p><b>universe</b> [1] 29/19</p> <p><b>unless</b> [2] 22/19 31/12</p> <p><b>unreliable</b> [2] 32/22 32/22</p> <p><b>unsold</b> [1] 27/8</p> <p><b>up</b> [7] 11/17 12/2 18/10 25/15 27/25 33/16 35/8</p> <p><b>upon</b> [1] 6/25</p> <p><b>Urquhart</b> [2] 5/19 12/15</p> <p><b>us</b> [15] 4/9 6/11 7/10 7/12 7/20 13/23 13/25 17/2 18/8 26/21 29/7 29/9 30/24 31/3 31/4</p> <p><b>use</b> [6] 23/4 23/17 26/11 32/14 32/15 34/17</p> <p><b>used</b> [8] 4/20 5/20 7/7 17/21 26/7 26/14 28/7 28/9</p> <p><b>useful</b> [1] 24/4</p> <p><b>using</b> [10] 5/23 7/11 7/17 8/15 20/15 21/5 26/8 26/9 28/5 31/9</p> <p><b>utilizing</b> [1] 6/5</p> <p><b>utmost</b> [1] 26/6</p> <p><b>V</b></p> <p><b>vacation</b> [1] 37/2</p> <p><b>value</b> [7] 6/10 16/3 18/4 24/22 24/24 31/14 34/10</p> <p><b>versus</b> [2] 23/21 36/22</p> <p><b>very</b> [19] 3/19 7/14 9/3 10/14 10/14 10/14 11/19 11/19 14/6 17/19 17/19 19/12 28/15 31/16 31/16 32/20 36/24 36/24 36/25</p> <p><b>vials</b> [2] 13/5 29/18</p> <p><b>W</b></p> <p><b>waiving</b> [3] 35/17 36/7 36/11</p> <p><b>walk</b> [1] 8/6</p> <p><b>wall</b> [1] 30/23</p> <p><b>want</b> [23] 7/15 7/15 7/16 12/19 12/19 13/23 13/24 14/5 14/6 15/3 15/6 15/10 16/16 17/7 19/16 19/21 23/11 25/23 25/25 27/2 27/21 29/22 35/3</p> <p><b>wanted</b> [2] 35/19 36/13</p> <p><b>warehouse</b> [1] 22/5</p> <p><b>was</b> [57]</p> <p><b>waters</b> [1] 17/4</p> <p><b>way</b> [16] 4/19 4/25 16/2 16/12 18/10 19/16 20/13 20/24 21/25 25/12 25/23 27/9 28/15 29/8 33/19 35/5</p> <p><b>we</b> [172]</p> <p><b>we'd</b> [2] 12/22 12/23</p> <p><b>we've</b> [2] 13/19 13/22</p> <p><b>week</b> [4] 35/15 35/16 35/22 36/4</p> <p><b>weeks</b> [1] 36/3</p> <p><b>weighs</b> [1] 33/14</p> <p><b>weight</b> [2] 19/1 34/4</p> <p><b>weighted</b> [1] 16/18</p> <p><b>well</b> [17] 3/14 6/12 8/5 11/23 14/2 14/16 14/17 15/5 19/7 24/17 28/20 30/12 31/21 32/20 36/24 36/25 36/25</p> <p><b>went</b> [3] 21/2 21/4 21/18</p> <p><b>were</b> [12] 6/4 8/5 8/22 14/10</p>
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<p><b>W</b></p> <p><b>were...</b> [8] 15/1 21/1 21/4 21/5 23/17 26/8 30/23 34/3</p> <p><b>WEST</b> [3] 1/2 1/5 1/24</p> <p><b>what</b> [76]</p> <p><b>whatever</b> [4] 3/1 22/25 23/9 30/9</p> <p><b>when</b> [24] 5/6 9/17 11/13 11/23 13/11 14/13 15/14 15/14 16/1 16/17 18/14 18/19 20/20 20/25 22/3 24/13 25/14 25/17 26/20 27/7 27/10 27/16 29/13 35/11</p> <p><b>where</b> [11] 5/2 9/17 10/19 10/23 17/22 17/24 20/5 20/8 23/5 31/17 36/22</p> <p><b>whether</b> [11] 17/16 17/25 19/9 20/12 23/18 23/19 26/15 33/4 33/6 33/10 34/9</p> <p><b>which</b> [16] 3/21 4/21 4/22 8/12 9/23 11/4 11/10 12/7 16/11 17/2 23/13 25/24 31/22 32/9 35/8 36/4</p> <p><b>While</b> [1] 4/20</p> <p><b>who</b> [4] 20/14 21/11 26/8 31/13</p> <p><b>whole</b> [2] 20/1 22/4</p> <p><b>wholly</b> [1] 16/9</p> <p><b>why</b> [9] 11/24 13/20 14/19 17/15 18/25 27/11 28/16 36/2 36/2</p> <p><b>will</b> [38]</p> <p><b>will degrade</b> [1] 5/24</p> <p><b>wish</b> [1] 12/20</p> <p><b>within</b> [2] 14/12 17/20</p> <p><b>won't</b> [1] 29/1</p> <p><b>word</b> [1] 20/2</p> <p><b>work</b> [4] 13/23 13/25 35/22 36/16</p> <p><b>working</b> [1] 36/5</p> <p><b>world</b> [1] 36/19</p> <p><b>worldwide</b> [1] 4/9</p> <p><b>would</b> [35] 3/24 12/22 13/11 14/9 15/20 16/21 16/23 17/22 17/23 17/24 18/13 18/21 19/5 20/24 22/14 22/25 23/1 23/7 23/9 24/1 24/4 24/9 26/5 26/11 26/23 26/24 27/24 27/24 28/3 28/6 28/16 30/12 30/24 35/20 36/1</p> <p><b>wrapped</b> [1] 12/2</p> <p><b>writing</b> [1] 30/23</p> <p><b>wrong</b> [2] 5/9 27/10</p>	<p><b>your</b> [26] 2/7 2/11 2/16 2/20 3/5 3/13 3/15 3/19 4/4 4/15 7/13 7/22 7/24 8/1 9/16 12/5 19/21 20/3 22/21 27/24 34/2 34/9 35/21 35/24 36/14 36/15</p> <p><b>yourself</b> [1] 4/2</p> <p><b>Z</b></p> <p><b>ZANTAC</b> [12] 1/4 2/3 4/18 4/20 5/20 5/22 8/19 20/14 21/2 26/10 31/13 32/3</p> <p><b>zero</b> [2] 18/23 31/15</p> <p><b>zeros</b> [1] 33/15</p> <p><b>Zoom</b> [2] 1/8 30/5</p>	
<p><b>Y</b></p> <p><b>year</b> [4] 11/18 11/18 13/10 17/25</p> <p><b>years</b> [20] 8/17 15/16 15/18 15/22 15/22 16/22 16/23 18/1 18/20 18/20 18/22 18/23 21/3 23/15 23/23 24/4 24/10 24/10 24/15 27/22</p> <p><b>yes</b> [10] 3/9 3/13 3/15 5/8 5/11 14/8 22/22 29/20 29/24 36/14</p> <p><b>you</b> [118]</p> <p><b>you'd</b> [1] 3/18</p>		