1	UNITED STATES DISTRICT COURT
2	SOUTHERN DISTRICT OF FLORIDA
3	WEST PALM BEACH DIVISION CASE NO. 20-md-02924-ROSENBERG
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5	IN RE: ZANTAC (RANITIDINE) . PRODUCTS LIABILITY . West Palm Beach, FL
6	LITIGATION September 13, 2021
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9	DISCOVERY CONFERENCE (through Zoom)
10	BEFORE THE HONORABLE BRUCE REINHART
11	UNITED STATES MAGISTRATE JUDGE
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1 THE COURT: Good afternoon, everyone. This is Case 2 Number 20-02924, In re: Zantac (Ranitidine) Product Liability 3 Multi District Litigation. We are here today for a discovery 4 conference. Let me begin by recognize -- well, we have lots of people, so I am not going to go by person. You can each 5 6 introduce yourselves as we go to your specific topics. 7 Really there are three broad topics I want to cover today in this order: First, the PTO 32 request relating to the 8 9 production of inventory and reserved products. Secondly, the issues that have arisen in the PTO 32 request relating to the 10 corporate representative deposition of GSK; and then third, 11 12 kind of an omnibus status update, anything else that anybody 13 needs me to know. 14 So, turning to the first issue, which is the 15 production of the reserved product, let me recognize counsel for the Plaintiffs first. 16 17 MS. JUNG: Good afternoon, your Honor, Je Yon Jung on behalf of the Plaintiffs. 18 19 MS. FINKEN: Good afternoon, your Honor, Tracy Finken 20 on behalf of the Plaintiffs. 21 THE COURT: Good afternoon. On behalf of Sanofi. No one on behalf of Sanofi. 22 23 MS. FINKEN: Your Honor, I believe Mr. Nigh is going 24 to enter an appearance. 25 THE COURT: Yes, go ahead, Mr. Nigh. I didn't mean to

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cut you off. Feel free.

2 MR. NIGH: I am sorry. Good afternoon, your Honor,
3 Daniel Nigh for the Plaintiffs.

THE COURT: All right. Now on behalf of Sanofi. *MR. BEROUKHIM:* Good afternoon, your Honor, Alex
Beroukhim of Arnold & Porter on behalf of Sanofi.

7 THE COURT: Good afternoon. On behalf of BI.
8 MR. SENTENAC: Good afternoon, your Honor, Mark
9 Sentenac on behalf of BI.

THE COURT: Good afternoon. On behalf of GSK.

MR. SACHSE: Good afternoon, your Honor, Will Sachse
 on behalf of GSK.

13 THE COURT: Thank you all. I have read the 14 submissions, and if I understand the state of the world, here 15 is where we are, as to at least Sanofi and BI, there was a negotiated resolution of the request for production of 16 17 products, and at least from the Plaintiffs' perspective, there 18 was an agreement to produce by September 10th. It sounds to me 19 like from Sanofi's and BI's perspective, it was a softer 20 deadline in their view.

GSK is in a different bucket because we had a hearing and I had an order as to that. We will address GSK separately. I will hear from all parties, but what I am primarily

24 interested in knowing is this, whether on August 26th Sanofi 25 and BI agreed to a hard deadline of September 10th or a soft deadline of September 10th, what has changed since then, what do you know today that you didn't know then, and why didn't you know it then when you made whatever commitments you made to the Plaintiffs. That is sort of the issue I want to address.

5 Let me also address the issue I am not going to 6 address, which is the request to modify the scheduling order. 7 I don't have that authority. I understand the Plaintiffs are 8 asking for a hundred days and a change in the schedule for 9 expert witness disclosures. You are talking to the wrong 10 person. I do not have the authority to give that to you, so we 11 will put that issue to the side.

12 So, let me turn first to Mr. Beroukhim on behalf of 13 Sanofi. Can you bring me up to date on where you are in terms 14 of your production, and if you are not going to make it by 15 September 10th, what has changed since August 25th or 26th?

16 MR. BEROUKHIM: Thank you, your Honor. So, we have 17 gotten out -- Plaintiffs have made kind of three buckets of 18 requests from us. They have asked for some API, and we have 19 already shipped to them all the API that they requested.

They have asked from us bulk product that was manufactured and had not yet been packaged, and we are at the site collecting them today and we are planning to ship that product by Wednesday.

The reason for the slight delay there, your Honor, is we were waiting to receive these tamper-proof bottles that we

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could put the materials in, and what happens is, once you put 1 them in and you seal it, when it is opened by someone, they can 2 tell that it has been sealed when it was being shipped, so it 3 is just a way of maintaining the integrity of the product for 4 5 shipping, and it took us a little bit longer to get those 6 bottles than we thought. I think we got them on -- I think it 7 was on September 8th, we finally received those bottles, and it took us a little bit longer to get those than we thought it 8 9 would take.

10 The third bucket is recalled product. That is not 11 being maintained by us, it is being maintained by a recall 12 vendor who has over 3,000 pallets of recalled product, and the 13 difficulty in -- we have hit a snag in identifying the exact 14 products from the pallets the Plaintiffs have selected.

15 Plaintiffs have selected 150 plus different types of products from that vendor and there is over 3,000 pallets, and 16 17 we not only have to find the pallets, but we have to try to 18 match what is in the pallets to Plaintiffs' selection, and the 19 latest I heard this morning is, one of the problems we are 20 hitting is, because of staffing due to the pandemic it is just 21 taking longer than it was originally anticipated, and we are 22 working as diligently as we can.

I have had several exchanges with the vendor, the client and I have had several exchanges about this. We are working as fast as we can to get this product to Plaintiffs.

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By Wednesday, the Plaintiffs will have all -- excuse me, by Thursday -- right now the Plaintiffs have all the API. By Thursday, Plaintiffs will have 41 samples of 500 tablets each that they can begin testing, and our hope is that we will be able -- our expectation is that we will be able to get the recalled product to them by next week.

7 THE COURT: When you say by next week, next week is a
8 long week, is it Monday the 20th or is it Friday the -9 whatever day that is, 24th?

MR. BEROUKHIM: Based on my last exchange with the client, I believe it is possible it will be earlier in the week. It is just a matter of really how long it is going to take to try to identify the specific products the Plaintiffs are asking for within the pallets. We are doing our best, we are putting as many people as we can on it, we are doing our best.

17 It is possible that it will be early in the week, I 18 just don't have any more certainty that I can represent to the 19 Court in good faith.

THE COURT: I appreciate that. Thank you.

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Let me turn to -- I don't know if it is Mr. Nigh,

Ms. Jung, or Ms. Finken, I don't know who is going to speak for the Plaintiffs on this.

24Does your expert -- help me understand. Does your25expert need all of this to begin doing whatever your expert

1 needs to do or can your expert at least get started with what 2 they have now and then kind of ramp up as they get additional 3 product?

MS. JUNG: Thank you, your Honor. I think, your 4 5 Honor, you can understand that testing and what our experts 6 need to do with this is an iterative process. You also 7 understand that they have had two years to do what we are trying to do as expeditiously as possible to comply with the 8 9 Court's scheduling order, and while -- they will start as soon as everything comes in, and as soon as it comes in the door 10 11 they are trying to start.

But to have these kind of hopes and a prayer as to when we can expect the rest is what is causing us difficulty because if we don't have a date certain by when we will receive all of the product it is very difficult for our experts to prioritize and to do the testing and to do the various amounts of testing that are required.

Again, we are doing in three months what they have had two years to do, so we will start with whatever we have as soon as possible, no question, but not knowing and having these potential hopes of when we will receive the rest of the product is the problem we are having, your Honor.

23 THE COURT: I hear you, and I hear you loud and clear.
24 I understand you need it yesterday, so I got it. From your
25 perspective, you need it yesterday.

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1 I am trying to understand -- I mean there is a big 2 difference between saying we are dead in the water and we can't do anything until we get all of it, and saying we can't do 3 4 everything we want to do until we get all of it, but we can at 5 least get started now. That is what I am trying to understand 6 because that helps me understand the bigger picture. 7 Which is it, Ms. Jung? Can you at least get started now -- not waiving your position that you need it all right 8 9 away, but I am just trying to understand. Can you get started with what you have or do you need it all to get started? 10 MS. JUNG: Of course we will start with what we have, 11 12 but a lot of our testing and the critical testing may require 13 as much time as possible. So it is --14 THE COURT: I understand. 15 MR. NIGH: Your Honor, if I --16 THE COURT: Hold on. For the record, Mr. Nigh. Go 17 ahead. 18 MR. NIGH: It is kind of backwards in terms of what we 19 would need to prioritize for Sanofi and how it came in. API is 20 what the experts would test last. Bulk product, no container 21 would be in the middle, and what they would want to be testing 22 first and takes the longest is the returned product in the 23 container, and that is what we are going to get last. 24 THE COURT: Okay. Thank you. That is helpful for me 25 to understand.

Okay. Anything further from the Plaintiffs, at least as to Sanofi? I want to think about this for a second, I want to hear from the other two Defendants. I understand how -- I understand where you are left given the current situation. Anything further, either Ms. Jung or Mr. Nigh?

6 MS. JUNG: One thing, your Honor, is that after the 7 PTO hearing on the 26th, when we thought we had an agreement 8 with Sanofi in particular, the next day we were informed that 9 there were actually different products, different understandings of inventory than we were provided, so we were 10 back to a different kind of, oh, we made a mistake, here is a 11 12 new list that we need to go from, please make a request from 13 that.

So, that has kind of been the examples of how we have been dealing with this, and so again we were stuck on August 27th with yet a new spreadsheet. So, one of those, which is the product that Mr. Nigh indicated, is delayed and we received different information regarding a spreadsheet that we had been operating under for weeks. So, I just wanted to add that as another layer of what is happening.

THE COURT: I understand and, look, in some respects, how we got where we are today is -- for what is before me today doesn't really matter. What I am trying to figure out is, I want to order this produced to you as fast as it is feasible to do so, and whether we got here from good, bad, negligence,

incompetence, or simply best efforts, that at some level 1 2 doesn't matter to me. I am just trying to figure out want do 3 you need, how fast can I get it for you, and what is feasible. 4 That is helpful though. 5 Okay, let me go back to Mr. Beroukhim. Anything 6 further from Sanofi? 7 MR. BEROUKHIM: Your Honor, I am going to continue to work as diligently as possible to get this. There has not been 8 9 a day where I haven't been on the phone and sending emails to 10 people trying to make this happen. We are working as fast as we can. We have already gotten out a production. We are using 11 12 our best efforts and acting in good faith. We are trying our 13 best to get them exactly what they want. 14 THE COURT: I understand. Okay. 15 If I understand it correctly, all of Sanofi's product 16 is domestic, so we don't have an international shipping issue 17 with Sanofi? 18 MR. BEROUKHIM: Yes, sir. Yes, your Honor. 19 THE COURT: All right. Lucky you. Let me put Sanofi to the side for a second, and let me 20 21 turn to BI, who I understand is at the other end of the 22 universe in that, at least from your discovery statement, you 23 are fighting at least two different Governments and lots of 24 regulations and all sorts of other logistical problems. 25 So, how much of this did you know on August 26th, and

MR. SENTENAC: We were very clear from the beginning, 2 your Honor -- this is Mark Sentenac on behalf of BI. 3 We knew from the beginning that we were facing complicated transport 4 5 and primarily import issues after speaking with our logistics 6 people. Those have certainly crystallized in the last 14 days 7 That is the primary issue that has crystallized for for us. us, but we have been clear with them that those were issues. 8

how much of it have you learned in the last 14 days?

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9 In fact, when we confirmed the agreement before August 26th, we specifically identified that, and I think the 10 exhibit, the Plaintiffs' papers demonstrate that, too, that we 11 12 are continuing to deal with the nature of the beast, that this 13 product is in Mexico, and really from our perspective, Judge, 14 what is crystallized is that the issue for us is responsibility 15 for the import process. We have worked with our client's Mexican affiliate to offer to handle the export processes from 16 17 Mexico.

What remains is really responsibility for the import processes and, you know, our understanding is that, you know, there are regulations that fall within the purview of both FDA and Customs, and not having any responsibility after the product is imported, that responsibility will lie with Plaintiffs.

24 Being in the position -- there are financial and 25 significant penalties associated with not doing that process

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right, making statements, and the client doesn't feel like it can be in the position of making representations about what the product is to be done with and what controls are in place with respect to that product because Plaintiffs haven't identified that for us, so it's really responsibility.

Plaintiffs will be responsible for this product after it is imported and they need to take responsibility for the import and Customs process, and frankly, our understanding is that the process for doing so is pretty straightforward.

This is what -- when we last spoke we told them we need to know from them who -- you know, they have now said Saturday evening that they don't believe they need a Customs broker, which is fine. We still need to know who is going to file the Customs paperwork and be the responsible importer of record. That is really the issue that has crystallized for us, your Honor.

17 *THE COURT:* Were these issues raised in the conferrals18 before August 26th?

19 MR. SENTENAC: Certainly. We flagged that we are 20 still working through import processes, and that these issues 21 could delay the timeline for this, and that they are very 22 complex.

23 THE COURT: Well, I am -- let me ask you, on or about 24 August 26th, you committed, at least at some level, that you 25 thought you could get things done by September 10th. You must

1 2 have -- you must have at that point at least thought that you could get through these Customs issues relatively quickly.

MR. SENTENAC: Provided that we worked these issues 3 4 out, was our perspective. This was always the biggest issue 5 from our perspective, and we felt like at the time that we 6 could complete the shipment at the time provided that we got 7 logistics issues worked out, and I have email statements to the 8 effect that we can submit after the fact if it would be 9 helpful, but those were -- that issue was made very clear from our perspective to the other side. 10

THE COURT: At what level of detail, though? 11 It is 12 one thing to say we will get it to you by the 10th, but we are 13 going to have to work through some shipping issues, and it's 14 another thing to say we can get it to you around the 10th, but 15 you are going to have to come up with your own freight 16 forwarder, you're going to have to fill out the Customs forms, 17 we are going to do this. There is a level of specificity 18 involved.

At what level of specificity were the conversations? *MR. SENTENAC:* That is the point that crystallized for us, your Honor, that after speaking with Customs, more folks internally, that's really the issue that crystallized for us. We explained that that was the issue, that we saw that as the way that this would be in everyone's interest to get it as quickly as possible, I think during our conferrals last week,

1 it could be before that. That is what we have been working on 2 in the last ten days before we were told that we were going to 3 have another PTO 32 hearing.

4 *THE COURT:* But again, were these conversations had 5 before August 26th?

6 MR. SENTENAC: Not this specific question -- I am 7 sorry, not --

THE COURT: Had you --

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MR. SENTENAC: I am sorry.

10 THE COURT: Had you talked -- for example, had you 11 talked to your shipping people in Mexico before August 26th, 12 and understood the detailed steps that you were going to need 13 to take to get this product into the United States?

MR. SENTENAC: Yes, we had spoken with our logistics people prior to August 26th, and at the time we had an estimate that this could be done within two weeks. That was the information we were working off of.

18 THE COURT: Okay. So, what has changed? That is what 19 I am trying to understand. If these people looked at this, and 20 you talked about it with the Plaintiffs, and on August 26th you 21 thought it could be done in two weeks, what changed?

22 MR. SENTENAC: It is the import process from the U.S. 23 Customs perspective that crystallized for us, that -- the 24 responsibility issue and who needs to have responsibility as 25 the importer of record is the specific issue that crystallized over the last now two weeks. It was -- whenever we disclosed it and talked about it with Plaintiffs, it was seven days that we had identified that information working with these -- once we had resolved the issue on the identity of the product and the terms in which it would be produced, that was an issue that crystallized then.

7 THE COURT: Let me turn to the Plaintiffs. I feel
8 like Howard Baker at the Watergate hearings. What did you know
9 and when did you know it?

MS. JUNG: Your Honor, thank you. I think what is important to remember here is that the Defendants, including BI, have had the Plaintiffs' shipping instructions for weeks, if not months now, and that shipping instruction includes Federal Express, had Plaintiffs' account number, and to have it all shipped by FedEx. We are not talking about freight, we are not talking about large cargo shipments.

17 As the affidavit that the Plaintiffs submitted with its briefing, it indicates that we spoke to a logistics Customs 18 19 expert after they raised this last week as the complex issue 20 that caused all of these delays, and we were told that this is 21 a standard routine process of international shipping with FedEx 22 and their courier release process given that the value of this 23 product is less than \$800 because it is not for commercial 24 sale.

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I think the important piece of this is that our

clients are individuals with cancer. Their clients are 1 2 manufacturers who routinely engage in this process. So, for 3 them to say there are all kinds of complex issues that they 4 didn't recognize or realize would cause these delays I think is 5 a bit disingenuous because when we talked about it, we are 6 asking, particularly from BI, a very small amount of product 7 that will fit in a very small box, and with FedEx, that commercial value that we would claim for Custom purposes only, 8 9 commercial sale value that is under the requirement for escalating to a higher tier of complexity. 10

So, in short, FedEx has indicated to us -- or our 11 12 expert has indicated, who has 40 years of experience with FedEx 13 and other shipping logistics, that there is nothing there, that 14 this is a fairly routine process that FedEx handles all the 15 time with international shipping, and as long as we are clear on what the invoice is for, what the manifest includes, the 16 17 value, that it is not for commercial sale, that there should be 18 no problems. However, if there are any problems, they are 19 ready to engage to help with that process.

Again, I will note that GSK has volunteered their folks who are dealing with this Customs process on a routine basis that they will be handling it, but for BI to raise that there is this complexity that we are being told is not really an issue is of concern.

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THE COURT: Has your expert talked to their expert?

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MS. JUNG: No. We learned of this last week from them 1 2 that we needed to get the Customs broker and there were all 3 these complexities, so we were reaching out and talking to 4 folks, and this all happened over the weekend, your Honor. 5 MR. NIGH: Your Honor --6 THE COURT: Okay. Hold on. Ms. Roddy (phon), who is 7 the affiant on your exhibit, she has not had the opportunity to speak to BI's shipping people; is that correct? 8 9 By the way, is it Ms. Jung or Ms. Jung? How do you 10 pronounce your last name? 11 MS. JUNG: Thank you, Judge, it's Ms. Jung. 12 THE COURT: Okay. Thank you. Ms. Jung, has your expert had the opportunity yet to speak to their people? 13 The answer to that is no? 14 15 MS. JUNG: That is correct, your Honor, she has not. 16 THE COURT: Okay. Mr. Nigh, did you want to add 17 something? I'm sorry, I cut you off. 18 MR. NIGH: Yes, I was just going to add a couple of 19 extra points to your question, which is first off, in terms of 20 the shipping instructions, Plaintiffs have provided shipping 21 instructions months and months ago. Ultimately, Defendants even sent us a protocol that included those ship instructions 22 23 multiple months ago and we agreed on a protocol that included 24 those shipping instructions. 25 So, this issue of product and how it was to be shipped

both with BI and Sanofi, this was information that was shipped months and months ago, and then we heard about this for the first time just recently.

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THE COURT: Let me turn back to Mr. Sentenac.

5 My other question, Mr. Sentenac, is, is the product 6 ready to go? If someone can arrange shipping tomorrow, can the 7 product be picked up and shipped tomorrow?

8 MR. SENTENAC: We have not taken and created the 9 samples until the logistics issues were worked out because we weren't sure of the timing. Creating the samples and having 10 them sit there for an unknown time until -- we had an unclear 11 12 picture from Plaintiffs on who was going to be responsible for 13 the import process we weren't comfortable with, so we wanted to 14 keep them in the controlled environment in which they were 15 located.

Our estimate -- right now, the best estimate we have from the client is that once we have these issues worked out, we can have it ready to go in about a week, maybe ten days, and we are still -- that is our estimate, but we have not moved them to create the samples.

This is batches of product that they have then requested smaller amounts of, and then they have specific instructions by which they want it bagged and packaged and then ultimately shipped, which we understand, and we can move quickly on that, but we didn't want to do so until the product

was -- until the logistic issues were cleared up. 1 2 THE COURT: Why? That makes no sense to me. Whv 3 would you waste a week and not prepare the samples to go? 4 MR. SENTENAC: Well, we are preparing -- we are 5 prepared to move quickly once these issues -- we didn't want 6 the samples to sit out of their controlled environment until 7 the issue --8 THE COURT: Why do they have to leave their controlled 9 environment? Can't you put the samples in a separate container next to the old samples in the same controlled environment? 10 MR. SENTENAC: I don't know the answer to that 11 12 specific --13 THE COURT: Why do you not know the answer to that? 14 Hasn't your client looked into this question? Isn't your 15 client committed to actually complying with their discovery obligations in this case? 16 17 MR. SENTENAC: Absolutely. We have been working 18 extremely hard to try to resolve these issues on the logistics 19 We are in communications with the manufacturing folks at end. 20 Promeco who can move quickly to get this product ready to go, 21 but we don't know how long it was going to take to hear from Plaintiffs on what the ultimate agreement would be with respect 22 23 to U.S. Customs responsibility. 24 What is your response to their expert who THE COURT: 25 says, just put it in a FedEx package and ship it?

1	MR. SENTENAC: Well, we have discussed this with
2	Plaintiffs, too. We could make the product available if it
3	is as easy as they are making it out to be, we could discuss
4	with making the product available in Mexico and they can
5	pick it up if it is as easy to get it across out of the
6	export and into the import process, but we have tried to work
7	with them to find a mutually agreeable solution that will be in
8	everyone's interest to get this product to them as quickly as
9	possible, including working with our logistics folks to help
10	with those solutions, and we have identified the easiest way
11	my understanding is that it is a matter of telling us who will
12	be responsible and submitting the paperwork, and it can be
13	handled very efficiently from there.
14	THE COURT: Okay, okay, I understand.
15	Ms. Jung, anything further?
16	MS. JUNG: Nothing further, your Honor.
17	THE COURT: Okay. As to Sanofi and BI, I am going to
18	order the product be in the hands of the Plaintiffs a week from
19	today. I want all of it in the hands of the Plaintiffs a week
20	from today at five o'clock Eastern time.
21	MR. BEROUKHIM: Your Honor, we will do our best to
22	comply. Monday receipt is difficult because they don't want
23	the product shipped on Friday, and that would be Saturday
24	delivery. Can we have Tuesday so it could leave on
25	THE COURT: You can have Friday or you can have

1 Monday. Which one do you want?

2 MR. BEROUKHIM: Okay. Okay. We will try to figure it 3 out. We will do our best, that is all I can say.

4 THE COURT: It is a defense to contempt that you 5 couldn't do it. You may have to prove that at some point, but 6 that is a defense. But you will produce it and BI will produce 7 it by next Monday at five o'clock.

8 Let me turn to GSK. Where are we, Mr. Sachse?
 9 MR. SACHSE: Good afternoon again, your Honor, Will
 10 Sachse for GSK.

So, I think we are, obviously, a little bit 11 12 differently situated in a few respects. First of all, 13 following the hearing that we had, we, of course, are going to 14 comply with the Court's order, and so I had a conversation with 15 Mr. Nigh early the following week, and we agreed -- certainly I wouldn't say -- we did not agree on hard deadlines, but I 16 17 agreed that we were going to make best efforts to get this in 18 their hands as quickly as possible on a rolling basis because 19 there are some challenges unique to each jurisdiction.

We are shipping from, I think, 11 different countries, and one of the issues that I discussed with Mr. Nigh and said we were still trying to figure out with our logistics people was, are we better off centralizing everything in one location and then shipping it, or are we better off kind of doing it piecemeal?

I think where we landed, after talking to our
 logistics people later that week, was we are just going to send
 it from individual sites.

So, we have been in the process of collecting the 4 materials, packing them, but in the meantime, some of our sites 5 6 had some specific questions and concerns about the shipping 7 instructions. For example, in Singapore, where I think it is 245 samples of API were getting shipped from, they can't use 8 9 FedEx, so we were going to use UPS. There was some back and forth with the Plaintiffs last week -- or two weeks ago about 10 11 that.

12 There were some other sites, such as Ecuador, where we 13 learned that we were not going to be able to export expired 14 product. Apparently that's the law in Ecuador. We just 15 weren't going to be able to get -- it's only a handful, maybe 16 five samples, something like that.

17 After a lot of investigation and sort of conversations internally with logistics people from around the world, we 18 19 decided last week that the easiest and best way to do this, and 20 fastest, would be if GSK voluntarily just agreed, we will take 21 care of all of the logistics concerns that we have heard about 22 today, we will arrange for, I think it is -- there is an FDA 23 guideline statement that needs to accompany the product, there 24 are specific numbers and specific coding that has to be done. 25 Our people who are sort of familiar with all of that

just agreed, let's just do it ourselves, and from a tracking perspective, it would be better if we used a preferred porter so that we can track it and track everything kind of through one system as opposed to a more piecemeal tracking.

5 So, we did make that offer to the Plaintiffs last week 6 and told them that we were willing to voluntarily, at GSK's 7 expense, do that and they accepted that offer, but they want the product yesterday, as we saw in their submission, which is 8 9 something that I -- I will tell you, Judge, that I have spoken to the -- there are sort of two people who are coordinating 10 this, or three, I guess, one who is the finished product person 11 12 collecting the stuff from around the world who believes, best 13 efforts, we should be able to get product by -- finished 14 product for the ten jurisdictions to the Plaintiffs by end of 15 this week, early next week.

And then the Jurong API, which is the bigger ask, 16 17 there is 245 samples, we actually had a little -- as your Honor 18 remembers, we were supposed to go and talk about maybe there 19 was a way to kind of narrow the request that the Plaintiffs 20 were asking for. Plaintiffs, to their credit, they did come 21 back with a modestly narrowed, I would call it, request. It still is a lot of samples, it is 245 samples, but it is fewer 22 23 grams of each.

24 So, our colleagues in Jurong have been collecting 25 those samples, have been making the labels so that everything

is clear in terms of which batch relates to which of the 245
 samples.

I did ask last week for kind of what is your estimate 3 of how quickly this can go. The two things I heard were, we 4 5 won't have an accurate estimate, one that we can kind of take 6 to the bank, until probably tomorrow or Wednesday; and second, 7 apparently for Jurong there was a concern about shipping in a way that ends up -- the product ends up arriving on a weekend, 8 9 they thought that that was not going to be feasible with the 10 porters that they use because they won't just leave the 11 product.

So, these are all issues around the edges that we are happy to talk to the Plaintiffs about, but by and large, I think we have a plan in place. I apologize, it is still a little fuzzy in terms of a date certain, but we are doing the best we can, and we hope that we are going to have the stuff in the Plaintiffs' hands, completely in the Plaintiffs' hands, in the next, I would say, one to two weeks.

19 THE COURT: Okay. Mr. Nigh already told me he doesn't 20 need the API first, he wants the other stuff first anyway. So, 21 maybe that gives us an ordering here.

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MR. SACHSE: I was glad to hear that.

23 THE COURT: Before I address that let me go back to 24 one thing. What I am going to do in terms of the deadline for 25 the other two is, actually I am going to make it noon West

1 Coast -- I understand the expert is in California. Is that correct, Ms. Jung? 2 3 MS. JUNG: Yes, your Honor. THE COURT: Okay. So, I will allow the product to be 4 5 delivered by noon West Coast time on Tuesday. That I hope will 6 alleviate Mr. Beroukhim's concern that if the product 7 shipped -- he can ship the product Monday and that is really 8 3:00 o'clock East Coast time, and still gives the expert to at 9 least get the boxes by noon and start working on them on Tuesday. I hope that balances everybody's concerns. 10 MR. SHORTNACY: Your Honor, Michael Shortnacy for BI. 11 12 If I could be heard on this issue very briefly. 13 THE COURT: Yes. 14 MR. SHORTNACY: I take your Honor's direction to, 15 obviously, the order and also to take steps to prepare the 16 product, to get it ready and in the hands of Plaintiffs. 17 I just wanted to note, unlike Sanofi, we are exporting and importing into the country, there are intermediate steps 18 19 that are really beyond BI's control, which includes Customs and 20 Border Protection and FDA. I wanted to clarify that for your 21 Honor. 22 I don't want anybody to have to do a contempt hearing, obviously, but I wanted to sensitize your Honor to that. 23 We 24 certainly will take all necessary steps that we can, but those 25 things are out of our hands, and if we do drop it into FedEx,

chances are it really will get held up. I think that defeats 1 2 what Plaintiffs ultimately want as well here, which I think we 3 share, which is to get this product to them as soon as 4 possible. 5 THE COURT: I hear you. My order stands, next 6 Tuesday, noon, West Coast time. 7 Let me turn to the Plaintiffs as to the GSK issue. Ms. Jung, it sounds like Mr. Sachse said he can get you 8 9 everything except the API probably by the Tuesday deadline I 10 just set. 11 Am I hearing you correctly, Mr. Sachse? 12 MR. SACHSE: I think that is right, Tuesday at noon 13 Pacific. 14 THE COURT: Ms. Jung, I will hear you on that, but 15 that sounds to me like that is okay with GSK. What about the API issue, though? And Ms. Jung, I will hear from you. 16 17 MS. JUNG: Again, I think having a date certain is what we seek from you and we thank you, your Honor, for giving 18 19 The difficulty, as you can see, and I won't belabor it to us. 20 the point anymore, is just the leaps of faith and the fuzziness 21 of the deadlines is what is causing us a lot of angst because 22 we have to get the product, and we don't want to be in the same 23 position next week coming to your Honor and going through the 24 hoops of a PTO 32 saying, your Honor, we still don't have it, 25 and there are new excuses as to why we don't, many of them

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perhaps legitimate.

I think for us, a date certain that we can all live byI think is really important.

THE COURT: Okay. I hear you.

MR. SACHSE: Can I just briefly respond to that?
THE COURT: Yes.

7 MR. SACHSE: One thing that just occurred to me, listening to the back and forth with everybody else, is that I 8 9 appreciate the need for a date certain. It does seem to me that maybe the date certain should be tied to when the -- if we 10 have put the product into the stream -- not the stream of 11 12 commerce, but the shipping stream, I quess, to get it to the 13 Plaintiffs' experts by noon Pacific on Tuesday, then, if there 14 is some kind of Customs thing that is out of our control, to 15 your point, Judge, we would be able to explain that, but I want to make sure that we are thinking about exactly what the order 16 17 looks like.

Is it receipt in the hands of the Plaintiffs' experts by noon, or is it that we have put it into the shipping to make it get there in the ordinary course as of Tuesday at noon?

21 THE COURT: My vision is that it will arrive --22 obviously, if you put it in the normal stream of shipment with 23 a reasonable expectation that it is going to arrive, and the 24 Plaintiffs are aware of what you are doing and they have signed 25 off, essentially, on what you are shipping, I am hard pressed to believe that, consistent with Rule 11, they would come
 running to court and ask me to hold you in contempt because
 somebody beyond their control held it up at the border.

4 MR. SACHSE: Well, stranger things have happened. I
5 hope you are right, Judge.

6 THE COURT: I hear you. Here is what I am going to do 7 as far as GSK -- not that they are rewarded for having actually 8 fought the issue, but since they didn't actually know until I 9 ordered them on whatever day that was that they had to do this, 10 and I declined to give them a date certain, what I am going to 11 do is this:

I am going to order the production of the non API, that is the easiest way for me to remember it, products by noon West Coast time next Tuesday, and the remainder or the balance of the production from the Jurong facility by five o'clock Friday of next week West Coast time.

So, I will give you until the end of next week, Mr.Sachse.

MR. SACHSE: Thank you, your Honor.

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20 THE COURT: All right. Not waiving any objections 21 anyone may have to my rulings, have I at least ruled on all the 22 issues the parties wanted to present with regard to the 23 product? I'll start with Ms. Jung.

24 MS. JUNG: I believe so, your Honor, but I will allow
25 Ms. Finken or Mr. Nigh to weigh in if I am incorrect, but I

believe so. If I may ask one thing, your Honor.

THE COURT: Sure.

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3 MS. JUNG: If you can issue an order reflecting your 4 order for today in paper so that we can have those just in case 5 we have any issues, and I just want a caveat. I understand 6 what Mr. Sachse is saying, but I want to make it clear for the 7 record that all of the stream of courier process is going to start with them and to make sure that they provide whatever 8 9 information is necessary in order for that process to run smoothly, instead of saying, well, we put it in FedEx and we --10 there are problems later that are outside of our control. 11

I hope that we will all work in good faith for them to provide the necessary information on the manifest or the invoice and the FDA documents that we have been discussing.

15 THE COURT: Look, I would expect -- I don't think I 16 have to get to the granular level of ordering the parties to 17 exchange documents, but I would assume you all will talk to 18 each other. Just like when I ship things to my children, I 19 send them the tracking number, and they will send you the 20 tracking number and all the materials you will need. I am 21 assuming that as a matter of course, but I will do a written 22 order so that everybody has that.

MR. SACHSE: Thank you, your Honor.

24 *THE COURT:* Mr. Sachse, on behalf of GSK, not waiving 25 any objections you may have to my orders, have I addressed the

1 issues that we believe were raised today? 2 MR. SACHSE: Yes, your Honor, you have. I guess I 3 could invite Ms. Jung, if she wanted to do a whirlwind tour of 4 our eleven facilities and pick up the stuff individually, more 5 power to her, but we will abide by the order and we will keep 6 working as quickly as possible to get the finished product and 7 the API in the hands of the Plaintiffs. 8 THE COURT: I appreciate that. Mr. Sentenac, again, 9 not waiving any objections you may have to my orders, anything I haven't addressed or any clarifications that you need? 10 MR. SENTENAC: Nothing further from me, your Honor. 11 12 THE COURT: Thank you very much. Mr. Beroukhim, 13 anything for Sanofi that is either unclear or that I haven't addressed? 14 15 MR. BEROUKHIM: No, your Honor. Thank you very much. THE COURT: Thank you all very much. I will excuse 16 17 the counsel who are dealing with this issue. I will move now 18 to the issues relating to the corporate representative 19 deposition of GSK. 20 Who is going to handle that for the Plaintiffs, 21 please? 22 MS. FINKEN: Tracy Finken on behalf of Plaintiffs. 23 THE COURT: Good afternoon. 24 MS. LUHANA: Good afternoon, your Honor, Roopal Luhana 25 on behalf of Plaintiffs.

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THE COURT: Good afternoon. And on behalf of GSK. 1 2 MR. SACHSE: Good afternoon, your Honor, Will Sachse 3 on behalf of GSK. I wasn't their introduction piece of this. 4 THE COURT: Okay. Mr. Cotton, good afternoon. 5 MR. COTTON: Good afternoon. I was. Chris Cotton for 6 GSK. 7 THE COURT: I was having flashbacks reading this transcript today, but let me retrace the steps that bring us 8 9 here. This all started, Plaintiffs served request for 10 production, I believe it is request for production number 29 11 12 relating to human clinical trials and animal trials. 13 Ms. Finken, were those included as well? 14 MS. FINKEN: Yes, it was for human clinical trials as 15 well as all nonclinical and pre-clinical testing as well, to include animal trials. 16 17 THE COURT: That's right. That was the distinction we were making, human clinical trials and then pre-clinical. 18 19 There was a request made. There was a partial objection and 20 then there was production by GSK, and we have had a number of 21 hearings about the PIER system, the people in London with the 22 white gloves who handle the archives at GSK, and lots and lots of testimony about that. 23 24 What I have said repeatedly, and I think we have finally reached this point, is that there will never come a 25

point when GSK will say they have produced everything because they are not capable of credibly saying that they have recovered 40 years' worth of materials and have produced every single shred of paper, but there would come a point when GSK would say we have done enough, we have done everything we are required to do by the rules, and I guess today is that day.

7 In the meantime, the Plaintiffs said, well, if they 8 are ever going to get to that point we want some transparency, 9 we want to know what are they giving us, what are they holding 10 back, what have they looked for, and we have had a lot of 11 conferral and a lot of good cooperation between the parties, 12 for which I thank you, but, as with many things, we have 13 arrived at the margin and we have some disputes about that.

In furtherance of trying to give the Plaintiffs the transparency that I felt they needed to make a decision whether they were going to challenge GSK's assertion that they had done enough, I authorized a 30(b)(6) deposition on the ESI issue -it wasn't limited to ESI, but on the status of these studies and things of that nature.

I guess there were two representatives designated by GSK, Mr. Fell, F-E-L-L, and Ms. Mitchell, and as I understand it, the Plaintiffs are now asking me to do three things.

One is to compel GSK to produce an adequately prepared 30(b)(6) witness, because their contention is that there were a number of topics where they asked the 30(b)(6) witness a

question and the answer was, "I don't know." Plaintiffs' argument is that, under Rule 30(b)(6), the witness is required to know and to educate themselves and be able to answer those questions. That is one assertion, that they were not adequately prepared to respond to the questions.

6 Another has to do with that Plaintiffs want me to 7 overrule some privilege objections that were asserted -- it 8 wasn't clear in the record, but I assume, Mr. Cotton, those 9 were work product objections. My recollection from reading the transcript was the line of questioning was primarily, what 10 searches did you do, what efforts did you take, and I think the 11 12 assertion was privilege, but I am assuming that is a work 13 product assertion.

MR. COTTON: Yes, I think in most instances work product, but there may have been attorney/client privileges and whether they were direct communications with counsel.

17 *THE COURT:* Okay. I will go back over that in a18 second.

So, let me -- I guess the other thing is that GSK asserted that certain questions -- they instructed the witness not to answer certain questions, or at least objected to certain questions as beyond the scope of the properly noticed topics in the deposition.

As I read through the transcripts and read your memo, those were the three big buckets that I thought I was supposed

to be studying up for, so that is what I studied up for. Let
 me address one of the buckets quickly and dispose of that.

To the extent the question was asked and there was no 3 4 substantive objection, so a form objection doesn't count, no 5 substantive objection, and the witness' answer was, "I don't 6 know," I will order GSK to provide an answer to that question. 7 It can be a written answer by declaration, but they have to answer the question. Okay. They didn't object in real time, 8 9 you've got to answer the question. If the witness couldn't answer the question, you've got to answer the question now. 10

11 That is how I am going to deal with that large bucket 12 of what occurred at the deposition, which leaves me then with 13 the other two buckets which were, to me, more worthy of further 14 analysis. One had to do with the privileges, one had to do 15 with the scope.

16 Let me address the privilege issue. I appreciate, 17 Ms. Finken and Ms. Luhana, that you were working off of my 18 words from the last hearing, so I don't fault you for that. 19 Sometimes I say things I probably shouldn't say without 20 thinking them through all the way, but in reading through the 21 transcript at least I didn't see that many privilege 22 objections. I think there were maybe four or five in each 23 total of the two depositions.

I think to the extent that the question was, what searches did you do, and those searches were guided by things

that the lawyers told the witness to do -- not this witness, 1 2 but instructed the client to do, why shouldn't those be privileged? Ms. Finken or Ms. Luhana, I don't know who wants 3 4 to address that question, but why isn't that a valid privilege If you tell your client, go search for this, why 5 assertion? 6 isn't that the lawyer's thoughts and opinion work product? 7 MS. FINKEN: Well, your Honor, first of all, let me draw your attention to an example of one of the privilege 8

9 objections that Mr. Cotton asserted. For example,
10 Ms. Mitchell, who was the witness who testified about the
11 MedTrack spreadsheet, of which your Honor probably never wants
12 to hear about again --

13THE COURT: Can you point me to a page at least?14MS. FINKEN: Sure, of course, yes. It would be page1567 and 68, the end of 67, beginning of 68.

THE COURT: Okay, I am with you.

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17 MS. FINKEN: Sure thing. So, Ms. Mitchell had testified that she was the individual who pulled the MedTrack 18 19 spreadsheet from the database and had provided that spreadsheet 20 I had asked her if she applied any type of filters of studies. 21 when she was pulling that information from the database. Mr. 22 Cotton said, objection. He claimed privilege for that 23 particular question, and I said -- he said, if that was at the 24 direction of counsel, then I instruct her not to answer the question. And I said, I didn't ask if she was doing anything 25

at the instruction of counsel, I just wanted to know if filters
 had been applied when she pulled the information from the
 database. He refused to allow her to answer that question.

That is an example of one of the privilege objections that was made by Mr. Cotton during the course of that deposition.

7 THE COURT: But my question is this: Whether -- first 8 of all, you asked two questions. One was, when did you do the 9 search. I don't think that is privileged. When you did the 10 search is not privileged, but what filters did you apply, if in 11 fact she got those filters from counsel, whether you know that 12 or not, why isn't that privileged?

MS. FINKEN: Your Honor, if that is, in fact, the case and it was at the instruction of counsel, I guess it would be considered a privileged communication, but it would also indicate that counsel was instructing GSK not to provide information about relevant clinical trials that were requested in the request for production and that pertained to Zantac.

So, it would go towards the fact that they are hiding the ball in terms of their clinical trial production and they are limiting our ability to see clinical trials that actually had been conducted on behalf of their client for purposes of Zantac and its safety and efficacy.

I would hope that would not be the case, but it would be a simple yes or no answer on whether or not filters had been

1 applied. I certainly didn't ask what filters had been applied, 2 or what she had been told. It was a simple question on whether 3 or not any filters had been applied when she pulled the data.

4 THE COURT: Let me turn to Mr. Cotton. Did you 5 understand the question to be that limited? I understand you 6 are sitting there in real time and it is easy for us to read 7 the transcript months later, so I don't fault you if you heard a different question, or maybe Ms. Finken asked a different 8 9 question than you thought she was asking.

To the extent the question is simply were filters 10 applied, that is a binary yes or no question, do you have an 11 12 objection to answering that question?

13 MR. COTTON: I wouldn't have an objection to answering 14 that question, as to whether they were applied. But I do think 15 that the next question, the answer should resolve the issue 16 here.

17 If we turn to the very bottom of that page, Ms. Finken So, when you did the data export from the LSC database 18 asked: 19 as it relates to Zantac or Ranitidine, did you pull the 20 entirety of the data that is housed there relating to those projects? The answer was yes. So, I do feel like we should be 21 22 able to move on at least from that question and answer. 23

THE COURT: Okay, I understand.

24 MS. FINKEN: Your Honor -- I'm sorry, I didn't mean to 25 interrupt.

THE COURT: Go ahead.

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2 MS. FINKEN: On page 67, and it's specifically lines 3 16 to 19, my question was: When you did the search as the 4 expert from the LSC database, did you use any type of filters 5 for the information that you exported?

6 That is the question that she was instructed not to 7 answer at the direction of Mr. Cotton. It's a simple question, 8 a yes or no question on whether or not any filters had been 9 applied, not about what directions she received or didn't 10 receive, what filters she had actually applied or didn't apply. 11 It was a yes or no question. So, that is an example of the 12 type of privilege objection that was being asserted.

13 THE COURT: I went through this, I used the search 14 function for the word "privilege", I think there were four 15 privilege objections in the 200 pages of deposition. We can go through each one of them, but I think they were all akin to 16 17 this. I think there was a whole line of questions about what 18 searches did you do, what searches did you do, and that is 19 pages 54 -- was it 54? There were a number of questions about 20 that, and it seemed to me it is the same thing.

21 MS. FINKEN: Yes. Your Honor, I am looking at another 22 one on page 160 where I said: Sitting here today, can you tell 23 me where GSK looked for these particular studies? I was 24 referring to the MedTrack spreadsheet he asserted a privilege 25 objection there and instructed her not to answer.

Then I asked specific questions on whether or not she searched different areas for the studies, which the answer was she did not or she didn't know. So, they are not limited to just that one.

I agree with you that there are very few privilege objections that were asserted during the deposition. The majority of the objections were to scope, and if you read through the transcript, your Honor, it becomes very apparent as Mr. Cotton objects to the scope of the deposition, the witness was coached to say, I am not prepared to discuss that, I am sorry, I am not prepared to discuss that.

And that was continuous throughout the entirety of the deposition to the point where there were several times where I pressed and said, I understand that Mr. Cotton is coaching you to say that, but I would like to know, if you know the answer to my question, I would like a response, and she did at times then expound and give me some answers to those questions.

But it was clear that she was being improperly coached throughout the course of the deposition that things were beyond the scope, and then her automatic response would be, I am sorry, I am not prepared to discuss that. I wasn't prepared to discuss that.

23 THE COURT: Would you prefer that he followed my
24 approved procedure and simply instructed her not to answer
25 because it was beyond the scope? You would have ended up in

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the same place.

MS. FINKEN: I think, your Honor, that the witness had the information at her disposal. At times she was in the middle of answering the question when the objection would be asserted, and then she would backtrack and say that she didn't know or wasn't prepared to answer those questions.

Some of these were very simple, they were questions like, how long was MedTrack in use at GSK? She could not tell me how long MedTrack had been in use tracking clinical studies. She could not tell me where any of the clinical study documents were housed before or after MedTrack, and really her limitation was anything before 2001, she was unable to answer those questions.

14 Your Honor, I am sure that Mr. Cotton and Mr. Sachse 15 would agree that the bulk of the clinical trial studies that were done by GSK were done before 2001, because that is when 16 17 the product was being developed in its entirety. She was 18 unprepared to answer any questions about the clinical study 19 documents, how they were housed, where they were kept, what the 20 policies were prior to that 2001 timeframe, which would rule 21 out the large majority of studies and information pertaining to 22 those.

23 We have also since requested, because Ms. Mitchell did 24 cite to a retention policy for the PIER database during the 25 course of her deposition, and we have asked for those SOPs that

would pertain to that, because my understanding is that with the PIER database, if items were destroyed in accordance with a retention policy -- and this is not from Ms. Mitchell's testimony, this is just from some other documents that were found in the database -- it would be noted within the field of the PIER spreadsheet.

7 We requested those retention policies, we have yet to 8 receive them, those SOPs that would pertain to it, things of 9 that nature. If those items were actually destroyed and there 10 was a retention policy in place would help us put to bed a lot 11 of these questions, but we have not received much cooperation 12 in trying to get to the bottom of these answers from her.

13 THE COURT: I understand, but my recollection from the 14 transcript is, you did ask those questions, and her answer was, 15 "I don't know." I don't recall that Mr. Cotton interposed a scope objection to those questions. If you can point me to the 16 17 page, we can double check that, but to the extent my 18 recollection is correct, I have already ordered them to answer 19 those questions for you, so you are going to get that 20 information.

MS. FINKEN: Fantastic. Thank you, your Honor.

THE COURT: Again, the distinction I am making, I want to be clear -- and look, sometimes in these, especially a 30(b)(6) deposition like this, there is a lot to cover, there is a lot to prep for, and the witness sometimes just doesn't

have the answer. It just happens that way.
I was satisfied both Ms. Fell and Mr. Mitchell -Ms. Mitchell were clear about making a distinction between I am
not prepared to answer that, I don't know it, versus I am not
going to answer that because I have been told not to answer
that, or something similar to that.

7 To the extent it is the former, and I will say it 8 again, to the extent there was no objection, so you asked the 9 question, Mr. Cotton did not object, and the witness says, I 10 don't know, I have now ordered them to answer that. So maybe 11 you all want to go back and look.

12 The number of scope objections then is pretty limited 13 and I think you are going to end up getting pretty much 14 everything you want, Ms. Finken. If you want, I can go through 15 and I can rule on the scope objections, or if you all want to 16 go back and revisit those, maybe it solves part of your 17 problem.

MS. FINKEN: Your Honor, respectfully, I think it would probably make sense for us to go back and look at it now given your ruling, and that may solve the problem for us so that we get the answers that we need. I am not sure off the top of my head today which objections were just to form versus scope as we sit here, but that ruling certainly will be helpful in getting us the information that --

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THE COURT: I knew I was going to raise the issue, so

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1 I actually have a list, I have it for you.

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MS. FINKEN: I appreciate that. Thank you.

3 THE COURT: Let me also do this. I am going to 4 sustain the privilege objections that were asserted and to the 5 extent perhaps -- as I read the questions -- and again, in real 6 time maybe we are at the margin here, but as I read the 7 question -- any question that had to do with what searches did 8 GSK do, what searches did GSK affirmatively choose not to do, 9 if that thought process was informed by counsel and counsel's input, I believe that is privileged. Any objection that goes 10 to that, whether it was a scope objection or a privilege 11 12 objection, I would sustain.

Some of the other ones, when I read some of her answers it wasn't clear to me if she was saying I don't know that, I have never known that, or I used to know that, I don't remember that, or I wasn't there when that happened.

17 I think a lot of it had to do with historical -- I 18 know there was a whole line of questioning, Ms. Luhana was 19 asking one of the two witnesses about the Legacy chromatograph 20 databases, and at some point if they say, look, everything 21 basically got migrated forward such that what we have today is what we have always had, at the margin, I am not sure how 22 23 proportional it is to go back and explore the whole history of 24 those systems, but it is your case. I don't want to 25 micromanage that aspect of your case.

MR. SACHSE: Your Honor, if I may be heard on that point. Will Sachse again. THE COURT: Yes. MR. SACHSE: I think that is exactly right, and obviously we are happy to have the conversation with Ms. Finken and Ms. Luhana about all those I don't knows, but I do think we should also not lose sight of the mission here.

8 The mission that we set out in June was sort of 9 two-fold; one was understanding the batch records, the data systems that relate to batch records, and since that time we 10 have produced countless, dozens and dozens of exemplar batch 11 12 records. Maybe -- I agree Mr. Fell didn't know all of the in's 13 and out's of every Legacy database, or Legacy system. I also 14 think a lot of questions focused on how a user would use it, 15 which is not a data storage question, that is more of a substantive question. We will be happy to go back and work on 16 17 the extent to which they really need the answers to all those 18 questions.

And then turning to the studies, I also wanted -- this started, as we all know, with the notorious MedTrack sheet, and I do think that when you take the testimony that Ms. Mitchell gave about MedTrack and marching through all of the fields, all of the various information collected there confirms what we have been saying for months in both sworn responses and here in these hearings, that this MedTrack is not a database, it's not a collection of studies. It doesn't even tell you where any
 studies, if they are studies, would exist.

And when you take the testimony and you compare it to the MedTrack sheet and compare it to what we have already produced, which is hundreds of entries from this MedTrack, by my math, I think we are now down to about 17 entries that may be studies potentially, and we are happy to kind of walk through that with Ms. Finken and Ms. Luhana.

9 Of those 17, most of them I think actually relate to 10 the Tritec product, which I don't think any Plaintiff took, it 11 is a combination product, but we will work through those 12 issues. I think we are really coming to the end here on the 13 studies.

14 THE COURT: I hope so. Before I forget, let me also 15 address -- I do want to make a specific ruling on this 16 question, which is on page 167. I will read it to you so you 17 don't have to pull it up.

Ms. Finken asks Ms. Mitchell: Are you aware of any GSK policy or SOP that indicates that clinical trial data should be maintained for the life cycle of the product? Mr. Cotton objects for beyond the scope, and her answer is, "I don't know."

I will order GSK to answer that question. I think that is information that the Plaintiffs are entitled to know and I am hoping will guide Ms. Finken and Ms. Luhana, because

1 if the truth of the matter is we have a policy that we keep all 2 Zantac stuff for as long as we ever sell Zantac, that is very 3 different from, I think she has testified we destroy it after 4 30 years.

Okay. Either you have such a policy or you don't, and I think the Plaintiffs should know the answer to that question.

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If you look, Ms. Finken, if you go back, that is right after you have asked a whole line of questions about the retention policy and the destruction policy, to which there is no substantive objection. She doesn't know the answer to some of the questions, but there is no substantive objection to the question. So, that will be my ruling as to that one specific guestion.

14 Is there anything left, then, that the Plaintiffs need 15 me to deal with as it relates to these issues right now?

16 MS. FINKEN: Your Honor, Tracy Finken on behalf of 17 Plaintiffs.

If you could -- I don't believe that you provided a date on which we should have these answers, and we are scheduled to take a 30(b)(6) deposition of their clinical trial witness, I believe it is last week of September. To the extent we can get this information in advance of that deposition, that would be very helpful, your Honor.

24 THE COURT: The last week of September has five days
25 in it. Do you know what the date of the deposition is?

1 Mr. Watts is trying to speak up. Mr. Watts, what is 2 the date? 3 MR. WATTS: September 29. 4 THE COURT: Okay. I will take that under -- we will 5 set a date before you go. 6 Mr. Sachse, Mr. Cotton, did you want to be heard? 7 MR. SACHSE: Yes. Let me respond to that quickly. First of all, obviously we will have a followup conversation 8 9 with Ms. Luhana and Ms. Finken and now Mr. Watts to figure out exactly what really matters, timing of all of that. 10 I think that all of the Fell questions are not really 11 12 related to the depositions that are happening in the U.K. at 13 the end of this month, so maybe we can do this in a staged 14 manner so that they get the answers to the clinical trial 15 questions in advance of those depositions, which I think is fair, and then we can kind of work on the batch testing 16 17 questions or batch system questions sort of after we finish the 18 Ms. Mitchell questions. That is what I would recommend. 19 THE COURT: Ms. Finken, does that make sense to you? 20 MS. FINKEN: Your Honor, I believe we are scheduled to 21 take another deposition that week as well of a gentleman by the 22 name of Giuseppe I deposition, who the chromatogram issue may 23 have some bearing on that deposition. So, I would appreciate 24 if we could get all the information in a timely manner. 25 THE COURT: I'm sorry, one more time, Mr. Watts, the

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deposition is on the 29th?

2 MR. WATTS: The 30(b)(6) is on the 29th, Mr. Giuseppe 3 is on the 28th.

4 THE COURT: Okay. Here is what I would like to do. I 5 want to make sure the Plaintiffs have the answers to the 6 questions that they need for those two depos.

7 I am guessing, as Mr. Sachse kind of points out, maybe you don't need the answer to every single question by those 8 9 dates, so I would ask you to work together to stage that out and sequence it properly. My expectation is that by a week 10 11 from this Friday, which would be the 24th, that the Plaintiffs 12 will have whatever questions in these two depositions that I 13 have ordered better answers to will be answered in writing such 14 that they can prepare any witness for the deposition.

15 That will ruin Mr. Watts' associate's weekend and let 16 him be prepared for the depositions the following week.

MR. COTTON: Your Honor.

THE COURT: Yes, Mr. Cotton.

19 MR. COTTON: I am not sure how many questions we are 20 talking about, but we certainly will take your guidance and go 21 from there.

Just a couple of observations. I know there are at least some instances, and I don't know if it is many, but some instances where it wasn't entirely clear the relevance of the question. For example, I think Ms. Finken asked about some

systems that we didn't have reason to believe (inaudible) at least nothing related to clinical trials. I know there was a guestion to --

THE COURT REPORTER: I am having a problem.

5 MR. COTTON: Sorry. I will just repeat, Judge, I am 6 not sure what all you heard.

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In short, there are some questions, and I don't know that it is very many, but there are some where I think it is worth a conversation about where we are going with them. So, I would just ask for some latitude for a conversation around some of those questions.

So, for example, I know there was a system that came up in Ms. Mitchell's deposition for which we have no reason to think Zantac information was included with it. I know there was a question of Mr. Fell about the instruments used for chromatography, which is really not what Mr. Fell was there to address.

I am not saying that each and every one of these questions is going to be problematic. My request would be just a recognition that there is room for discussion, perhaps with guidance from the special master if necessary, to resolve any disputes, the understanding being that it will be resolved well before next Friday.

24 THE COURT: Again, to the extent the objection was to 25 the scope, that this was not -- chromatography instruments were

simply not a proper topic and you raised that objection, I have not ruled on that. I think Ms. Finken said she wants to go back and look at what is left being objected to given my rulings.

5 So, look, I will let the parties work through that, 6 and if you need to see me again before a week from Friday, you 7 can see me again before a week from Friday, and I will rule on 8 anything you need me to rule on.

9 There is some limit on the amount of questions Mr. 10 Watts is going to ask at this deposition. He may choose not to 11 spend a lot of time asking questions about chromatography 12 instruments and he will be up front about that, and he is not 13 going to waste your time and you are not going to waste his 14 time.

I trust the parties to work through it themselves and with the special master, but if you need me to get back involved to rule on discrete issues like that before the depositions I will make myself available.

19 MS. LUHANA: Judge, can I raise one thing about Mr.
20 Fell's deposition?

THE COURT: Yes.

22 MS. LUHANA: As to those objections where Mr. Cotton 23 objected to things being outside the scope --

24 THE COURT: Yes.

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MS. LUHANA: -- unfortunately what happened with Mr.

1 Fell's deposition is, there were notes produced the night 2 before the deposition, similar to Ms. Mitchell, and Mr. Fell, 3 who was designated to testify about Lift and Empower, setting 4 aside the predecessor systems, he said he could not provide any further testimony but for what was in his notes. 5 6 He was essentially an IT administrator that just 7 installed software and he created user I.D.'s and formatted 8 reports, but he couldn't talk about where data was stored. He 9 couldn't speak about how searches were conducted. He couldn't 10 speak about the interplay between the systems. I could cite to the specific language if you would 11 12 like. If you take a look at 22, 36, he says --13 THE COURT: Hold on. Page what? 14 MS. LUHANA: 22, line 3.

THE COURT: Hold on. 22.

MS. LUHANA: Line 3.

THE COURT: Okay.

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18 MS. LUHANA: He says: I can only talk to Empower 3, 19 but only to the information I prepared in my notes. That is 20 all he could answer questions about.

Previously, when we appeared before your Honor on June 30th, you had advised that they could not sit there and just read the interrogatory responses. That is not the point of the deposition. It was supposed to be a baseline initially to ask questions.

Similarly, if you take a look at page 124, line 15 to 1 2 20, I ask him: What about any other information aside from 3 what is in your notes about Lift? He says, no, I don't have 4 any further knowledge on Lift other than what is in my notes. 5 So, repeatedly throughout the deposition there 6 continued to be objections as to scope when they were clearly 7 within the scope of the deposition, as to data and --8 THE COURT: There is no scope objection there. 9 MS. LUHANA: No, no, it is to form there, but my point 10 is there was numerous times -- the first point I am raising is that Mr. Fell was only able to testify as to what was in his 11 12 notes and that is it. 13 In addition to that, when I asked questions about data 14 that was stored in the systems, when I asked about the 15 interplay of these systems, when I asked about how searches could be conducted, Mr. Cotton repeatedly objected to being 16 17 outside the scope. Even looking at GSK's objections, they 18 didn't object to those areas of inquiry. 19 THE COURT: First of all, Ms. Luhana, all I read were 20 the things that you highlighted in yellow for me. That was, to 21 my mind, the only things that were at issue here. 22 In looking at that, the only scope objections I saw in Mr. Fell's testimony were on pages 50 and 51, 56 to 65, that is 23 24 it. You say he kept repeatedly making scope objections. At 25 least in what you pointed me to in this deposition that is not

1 true. He made a bunch of scope objections as to your questions 2 about the predecessor chromatogram systems. That is at pages 3 56 to 65, and there was an objection on page 50 to the 4 Statistica (phon) and I think some predecessor systems like 5 that. Beyond that, if there were multiple objections based on 6 scope, you all certainly didn't point me to them.

MS. LUHANA: It was a combination of objections. Some responses were, I don't know, objections to form, and then there were others that were objections to scope.

10 So, what I am raising is, they didn't prepare a 11 deponent who was appropriate and should have been testifying 12 about these topics, because he knew nothing about Lift and 13 Empower outside of what was provided in the notes 14 unfortunately.

15 THE COURT: What do you want me to do about that 16 today? I gave you an opportunity to have a hearing. You set a 17 hearing, you noticed for me, and I instructed the special 18 master to tell you to highlight for me the questions and 19 answers that you want me to rule on. That is what I read, that 20 is what I am ruling on. Okay.

The remedy you have asked me for is, compel GSK to produce an adequately prepared 30(b)(6) witness. I have ordered them to answer the questions that you pointed out to me were objectionable to which they did not assert a scope objection. I am reserving as to their scope objections, and

I've ruled on their privilege objections. So, as I have said to the parties for a year and a half, what is it you are asking me to do? It is nice that you don't think he was prepared. I am sorry to hear that. What do you want me to do about it today as I sit here? MS. LUHANA: We were requesting that adequately prepared deponents be produced for these depositions. THE COURT: As to which topics and which questions am I supposed to order them to adequately prepare somebody? The adequate preparation I am ordering is to answer the questions that you asked to which they did not give a satisfactory answer. Now, if there are other questions to which you don't think you got a satisfactory answer, you didn't point me to those, or to the extent you didn't ask questions and therefore didn't get adequate answers, you didn't ask the questions. I

MS. LUHANA: Judge, I understand and I appreciate your guidance and your ruling. In terms of what was happening in the deposition, some of the questions we were asking were baseline questions, and then we couldn't get to the other questions that we wanted to ask because these folks were not knowledgeable.

can't rule on things that don't happen.

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We will meet and confer with GSK per your ruling and

1 come before the Court if there are any other issues. 2 THE COURT: Thank you. 3 The Plaintiffs have also raised the issue that they 4 wanted sanctions, including, but not limited to, a negative 5 inference. 6 I guess the first question is, what other sanctions? 7 Because including, but not limited to doesn't really limit it. 8 MS. FINKEN: Your Honor, I think we were referring to 9 the costs associated with the deposition that we took and 10 prepared for that we were unable to actually get adequate answers to the questions that were posed that were well within 11 12 the scope of the notice. 13 THE COURT: Okay. I will allow you to file a written 14 motion for sanctions and I will let GSK respond in writing 15 within the time set by the local rules as to that. 16 MS. FINKEN: And -- sorry, your Honor. 17 THE COURT: No, go ahead. 18 MS. FINKEN: I was just going to clarify, in terms of 19 the negative inference, that is something that we wanted to put 20 on your Honor's radar. I don't know that it is something that 21 is ripe at this point in time, as we still have depositions to 22 take with the 30(b)(6) clinical trial witness, and some 23 questions now that have arisen based upon this hearing. 24 Mr. Sachse just represented that there were only 17 25 studies that have not been produced. That is news to me, so I

1 would request an updated MedTrack spreadsheet with the Bates 2 numbers of the studies and where they were produced in the 3 record, because the last time I checked it was 380 or so that 4 had not been produced, and we were not limited to 17. 5 So that would be just another request, your Honor, and 6 then --7 THE COURT: I am done micromanaging that list. If GSK says they produced what they have produced and they are not 8 9 producing no more, and the Plaintiffs don't like that answer, 10 you can file the appropriate motion and seek the appropriate relief. I am not going to not micromanage yours and Mr. 11 12 Sachse's list anymore. 13 MS. FINKEN: Okay. Thank you, your Honor. 14 Then the last issue I would just raise is if we would 15 have an order to compel production of the SOPs that relate to the document retention policies for the clinical trials that 16 17 were referenced in the transcript, please. 18 THE COURT: I think I did order that, because I 19 ordered them to answer the questions. Yes, to the extent the 20 questions related to the production of SOPs, Mr. Sachse, Mr. 21 Cotton, what is your position on that? 22 MR. SACHSE: Your Honor, I think maybe we should take 23 this step wise. I agree that you have ordered us to answer the 24 question about the GSK policies and the SOPs, and we will do 25 that. Then maybe sort of the next step is, if there is a

1 request for the actual underlying documents, we can see if we 2 can reach some sort of agreement on that; and if not, we can 3 brief that for the Court as well.

4 And the reason I am just sort of thinking it makes 5 sense to do this in a step wise fashion is that we are talking 6 about 40 years, and we are talking about -- I don't think it is 7 really easy to paint with a broad brush and say we want the 8 "GSK policies and the SOPs relating to retention." It is a 9 thorny, much more complicated issue, and so I think it is going to take some time for the parties to work through. We will get 10 the narrative responses sworn on those issues, and then we can 11 12 kind of follow up and obviously identify, to the extent we can, 13 the source of that and then we can follow up on what makes 14 sense in terms of documents.

15 THE COURT: For the time being, I will stand by my 16 prior order, which is, answer the questions that were asked. 17 To the extent there is a request for the production of the 18 documents and there is an objection, we will deal with that 19 separately.

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MR. SACHSE: Okay.

21 THE COURT: All right. Anything further on the 22 30(b)(6) deposition issue from the Plaintiffs? 23 MS. LUHANA: Nothing from me, your Honor, thank you. 24 MS. FINKEN: No, your Honor, thank you. 25 THE COURT: From GSK?

MR. SACHSE: Nothing, your Honor, thank you.

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THE COURT: Thank you all very much. We will put this issue to the side. Let me turn to the last issue on my agenda, which was the original reason I had set the hearing for today, which was to check in with you all and get all the good news of all the wonderful things you have been doing and why there are no other issues for me to deal with in this case.

8 Ms. Finken, what else is there out there that you are 9 waiting for or that I have ordered you to get that you haven't 10 gotten yet that you need me to get involved at this point?

MS. FINKEN: Well, your Honor, there are a couple of outstanding issues that are kind of brewing on the peripheral that we did not prep for today's hearing, but may be on your agenda coming up.

15 One of them -- and Mr. Watts, I am glad that he is on 16 this call because he may want to weigh in on this. We had been 17 discussing a deposition of a former GSK employee who is 18 overseas. We had an agreement that the deposition would move 19 forward on October 5th with Mr. Sachse, and we were advised a 20 couple of weeks ago that we now needed to go through the Hague in order to notice up that deposition, which, of course, we are 21 22 going to do, but that process takes approximately four months.

23 We had asked Mr. Sachse if he would be willing, for 24 the purposes of that witness, to take that deposition after the 25 December 20th discovery deadline because we don't anticipate

being able to get the Hague production before December 20th. He has refused to honor that request, so that is something that we probably are going to need your Honor's assistance with in the future.

5 THE COURT: Okay. When it is ripe, if it becomes 6 ripe, you all can bring it to my attention. I am not going to 7 get involved at this point.

8 Mr. Sachse, if you have anything you feel compelled to 9 say, I will be happy to hear you, but I am not going to get 10 involved at this point.

MR. SACHSE: Let's see how this whole process plays
out. Maybe they can get the Hague paperwork done in advance.

The only thing I do want to raise is, I did have a conversation -- or an email conversation with Ms. Finken over the weekend about this, and as I understand Swiss law, and I am not a Swiss law expert, nor do I ever want to be because it is complicated, I believe that the witness would still retain the right to object, and essentially not show up for the deposition under Swiss law.

We are not putting our thumb on the scale at all on this one. I told Ms. Finken if -- and the witness, I think, as of now is sort of agnostic about it, but if the Plaintiffs, maybe to short circuit this whole thing, if they want us to get a firm yes or no, thumbs up, thumbs down, we can go and do that.

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1 THE COURT: If I understand what Ms. Finken is saying, 2 this is not a current employee, this is a former employee. 3 MR. SACHSE: Retired. 4 THE COURT: I see. Because they are not a current 5 employee, you are taking the position they are not within your 6 control and you can't voluntarily produce them, they have to be 7 served through other means? 8 MR. SACHSE: Actually the Swiss law is that -- there 9 are actually two issues. Let me back up. Maybe we should talk about it. 10 11 The two issues were, we will be in Europe, in the 12 U.K., I quess not in Europe anymore, in the U.K. in a couple of 13 weeks for these other depositions that we have been talking 14 about. At the time, to try to be efficient, we were talking 15 about trying to do this witness, the Swiss witness, remotely. 16 At that time I said, well, look, I don't know whether 17 we can even do a remote deposition in Switzerland, I don't know 18 what the laws are about what a witness -- how you go about 19 doing a deposition in Switzerland, but go ahead and notice it, 20 and we can deal with that later. 21 What I learned subsequently is, good news, we can do 22 remote depositions now under Swiss law; bad news, you do have 23 to comply with the Haque, and it is not a waiveable thing. 24 It's not like we can lean on this guy, or the witness could 25 say, oh, sure, come over to my house and do my deposition. The

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Swiss interest in sovereignty still requires us to go through
 this formal process, so that is kind of where we find ourselves
 on this one.

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THE COURT: Mr. Watts, yes.

5 MR. WATTS: Just a little bit more background, and 6 again, I do want to commend Mr. Sachse. We have gotten a lot 7 of stuff done, so this is a glass is half full moment.

8 What happened is, there is a document that is a 9 nitrosation document that went to some of the highest members of Glaxo, and originally I asked for the deposition of a 10 gentleman named Paul Girolami, who is now Sir Paul Girolami. 11 Τ 12 received an email that said I shouldn't depose him because he 13 is a Sir, and I sent back a smart aleck email about the right 14 to every man's evidence, but he is 95 years old. Then we kind 15 of drift back to another recipient of the same email, which was Richard McKissick (phon), and then we stumbled into this Swiss 16 17 law.

Just to be clear, the only reason we are bringing it up, we are not asking for a ruling or anything like that, but yes, Mr. Sachse, I would like to know whether the gentleman will agree to be deposed because then my reversion is to depose the 95 year old man in England where I can get him subpoenaed.

I have already met with Mr. Sachse on another gentleman in California who is 87, agreed to limit it to a half a day. If we have to do that with Girolami, that is fine. I

have a document I need to get into evidence, and we will get back to the Court, but we wanted to tell you that issue is out there, and then there is another issue that is really across all of the Defendants, and that is, I take depositions, and then within so many days there is confidentiality designations.

6 I can tell you from my view, let's just put it 7 politely, these designations have been over used, if you will. 8 So, there will come a time, and frankly, I just don't have time 9 to do it until we get most of these depositions done, but we are going to come before the Court, and I am warning you, it is 10 not occasional, it is pervasive in a way that I don't think 11 12 complies with Federal law or Florida Sunshine law. It is 13 across all four of the brands.

So, I just mark that as something that is still out there, just so you could say, hey, I asked you what was up, and this is up.

17 THE COURT: I appreciate that. This would not be the 18 first and only case where I have had to deal with that issue. 19 Usually it hits right about the time summary judgment pleadings 20 are due or class cert or something else where you need to use 21 the document. Then we have to figure out how to deal with 22 them. We'll cross that bridge when we get there.

23 *MR. WATTS:* Mr. Sachse has me pretty busy taking the 24 rest of these depos through the end of October, but I am 25 guessing sometime in early November.

1 THE COURT: When you are ready for me, I am here. 2 MR. SACHSE: Mr. Watts, you assume that I am going to 3 be handling the confidentiality issues. 4 MR. WATTS: Well, I can assure you that Mr. Sachse is not the one filing these because he would not do it with a 5 6 straight face, but we will get there. 7 THE COURT: Anything else that the Plaintiffs wanted to put on the table today? I am glad to hear you are not 8 9 sitting here telling me, no, there is all this stuff we haven't gotten, and you need to punish them for it, so that's good. 10 MR. WATTS: Judge, one other thing. I had sent out 11 12 notices of depositions for 30(b)(6) with respect to knowledge 13 of NDMA, and we achieved a stipulation with Pfizer. I believe 14 we have agreements with Sanofi, BI, and now Mr. Sachse at GSK 15 to do short half-day notice of 30(b)(6)s tagged along with witnesses we have already taken. They are not going to count 16 17 on the limit, but I agreed to keep it to half an hour -- half a 18 day, rather, and we will get all of those done, but that is now 19 resolved as far as I am concerned. 20 THE COURT: Very good. Great. 21 MR. SACHSE: I am glad Mr. Watts just raised the 22 knowledge of NDMA deposition because maybe, Mr. Watts, that is 23 a way that you can get into that nitrosation document, you 24 don't even have to bother this poor retired doctor in 25 Switzerland.

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1 MR. WATTS: Maybe so. Okay, we will talk about it. 2 THE COURT: I would expect, knowing all the lawyers in this case, that if it is really a matter of just laying an 3 4 evidentiary foundation for some documents, that the parties --5 I don't know that I have ever seen a case lost on the inability 6 to authenticate a document. Mr. Watts and his team will figure 7 out a way to get it into evidence. The jury may not give it the weight that Mr. Watts wants them to give it, but he will 8 9 get it in. The parties tend to work those things out. 10 All right. Thank you very much. Mr. Sachse, anything 11 else from GSK? 12 MR. SACHSE: Nothing for today, your Honor. 13 THE COURT: Thank you. Mr. Shortnacy, I have you on 14 my agenda, so I don't know whether, on behalf of BI, you had 15 anything you wanted to report, ask, raise, anything like that. MR. SHORTNACY: Nothing, your Honor. Thank you for 16 17 checking in. 18 THE COURT: Mr. Beroukhim, because you made the 19 mistake of appearing earlier for Sanofi, let me call on you. 20 Anything from Sanofi that you wanted to raise? 21 MR. BEROUKHIM: No, your Honor. 22 THE COURT: Thank you. Pfizer has strategically 23 managed to not even show up here on the screen, but let me ask. 24 Speak now or forever hold your peace. If there is anyone on 25 behalf of Pfizer who wanted to raise an issue, please introduce

1	yourself and speak now.
2	MS. SHOWALTER: Your Honor, this is Annie Showalter
3	with Williams & Connolly for Pfizer, and I have no issues to
4	raise.
5	THE COURT: Thank you very much, Ms. Showalter.
6	All right, everybody, thank you all for your time. Is
7	there any issue that anybody wanted to raise today that I have
8	not ruled on, not waiving any objections anybody may have to a
9	ruling I may have made?
10	All right. Hearing none, I will thank the parties and
11	excuse you. Thank you very much.
12	MS. FINKEN: Thank you, your Honor.
13	(Thereupon, the hearing was concluded.)
14	* * *
14 15	* * * I certify that the foregoing is a correct transcript
15	I certify that the foregoing is a correct transcript
15 16	I certify that the foregoing is a correct transcript
15 16 17	I certify that the foregoing is a correct transcript from the record of proceedings in the above matter.
15 16 17 18	I certify that the foregoing is a correct transcript from the record of proceedings in the above matter. Date: September 14, 2021
15 16 17 18 19	I certify that the foregoing is a correct transcript from the record of proceedings in the above matter. Date: September 14, 2021 <u>/s/ Pauline A. Stipes, Official Federal Reporter</u>
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