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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
    WEST PALM BEACH DIVISION
CASE NO. 20-md-02924-ROSENBERG
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IN RE: ZANTAC (RANITIDINE)
PRODUCTS LIABILITY . West Palm Beach, FL
LITIGATION.
. September 13, 2021
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DISCOVERY CONFERENCE (through Zoom)
BEFORE THE HONORABLE BRUCE REINHART UNITED STATES MAGISTRATE JUDGE

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THE COURT: Good afternoon, everyone. This is Case Number 20-02924, In re: Zantac (Ranitidine) Product Liability Multi District Litigation. We are here today for a discovery conference. Let me begin by recognize -- well, we have lots of people, so I am not going to go by person. You can each introduce yourselves as we go to your specific topics.

Really there are three broad topics I want to cover today in this order: First, the PTO 32 request relating to the production of inventory and reserved products. Secondly, the issues that have arisen in the PTO 32 request relating to the corporate representative deposition of GSK; and then third, kind of an omnibus status update, anything else that anybody needs me to know.

So, turning to the first issue, which is the production of the reserved product, let me recognize counsel for the Plaintiffs first.

MS. JUNG: Good afternoon, your Honor, Je Yon Jung on behalf of the Plaintiffs.

MS. FINKEN: Good afternoon, your Honor, Tracy Finken on behalf of the Plaintiffs.

THE COURT: Good afternoon. On behalf of Sanofi. No one on behalf of Sanofi.

MS. FINKEN: Your Honor, I believe Mr. Nigh is going to enter an appearance.

THE COURT: Yes, go ahead, Mr. Nigh. I didn't mean to
cut you off. Feel free.
MR. NIGH: I am sorry. Good afternoon, your Honor, 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.
THE COURT: Good afternoon. On behalf of BI.
MR. SENTENAC: Good afternoon, your Honor, Mark 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.

THE COURT: Thank you all. I have read the submissions, and if $I$ understand the state of the world, here is where we are, as to at least Sanofi and BI, there was a negotiated resolution of the request for production of products, and at least from the Plaintiffs' perspective, there was an agreement to produce by September 10th. It sounds to me like from Sanofi's and BI's perspective, it was a softer 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 interested in knowing is this, whether on August 26 th Sanofi and BI agreed to a hard deadline of September 10th or a soft
deadline of September 10 th, 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.

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

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

MR. BEROUKHIM: Thank you, your Honor. So, we have gotten out -- Plaintiffs have made kind of three buckets of requests from us. They have asked for some API, and we have 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
could put the materials in, and what happens is, once you put them in and you seal it, when it is opened by someone, they can tell that it has been sealed when it was being shipped, so it is just a way of maintaining the integrity of the product for shipping, and it took us a little bit longer to get those bottles than we thought. I think we got them on -- I think it was on September 8th, we finally received those bottles, and it took us a little bit longer to get those than we thought it would take.

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

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

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.

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

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.

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

THE COURT: I appreciate that. Thank you.
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.

Does your expert -- help me understand. Does your expert need all of this to begin doing whatever your expert
needs to do or can your expert at least get started with what they have now and then kind of ramp up as they get additional product?

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

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

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I am trying to understand -- I mean there is a big 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 everything we want to do until we get all of it, but we can at least get started now. That is what I am trying to understand because that helps me understand the bigger picture.

Which is it, Ms. Jung? Can you at least get started now -- not waiving your position that you need it all right 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?

MS. JUNG: Of course we will start with what we have, but a lot of our testing and the critical testing may require as much time as possible. So it is --

THE COURT: I understand.
MR. NIGH: Your Honor, if I --
THE COURT: Hold on. For the record, Mr. Nigh. Go ahead.

MR. NIGH: It is kind of backwards in terms of what we would need to prioritize for Sanofi and how it came in. API is what the experts would test last. Bulk product, no container would be in the middle, and what they would want to be testing first and takes the longest is the returned product in the container, and that is what we are going to get last.

THE COURT: Okay. Thank you. That is helpful for me 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?

MS. JUNG: One thing, your Honor, is that after the PTO hearing on the 26th, when we thought we had an agreement with Sanofi in particular, the next day we were informed that there were actually different products, different understandings of inventory than we were provided, so we were back to a different kind of, oh, we made a mistake, here is a new list that we need to go from, please make a request from 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 doesn't matter to me. I am just trying to figure out want do you need, how fast can $I$ get it for you, and what is feasible. That is helpful though.

Okay, let me go back to Mr. Beroukhim. Anything further from Sanofi?

MR. BEROUKHIM: Your Honor, I am going to continue to work as diligently as possible to get this. There has not been a day where $I$ haven't been on the phone and sending emails to people trying to make this happen. We are working as fast as we can. We have already gotten out a production. We are using our best efforts and acting in good faith. We are trying our best to get them exactly what they want.

THE COURT: I understand. Okay.
If $I$ understand it correctly, all of Sanofi's product is domestic, so we don't have an international shipping issue with Sanofi?

MR. BEROUKHIM: Yes, sir. Yes, your Honor.

THE COURT: All right. Lucky you.
Let me put Sanofi to the side for a second, and let me turn to BI, who $I$ understand is at the other end of the universe in that, at least from your discovery statement, you are fighting at least two different Governments and lots of regulations and all sorts of other logistical problems.

So, how much of this did you know on August 26 th, and
how much of it have you learned in the last 14 days?
MR. SENTENAC: We were very clear from the beginning, your Honor -- this is Mark Sentenac on behalf of BI. We knew from the beginning that we were facing complicated transport and primarily import issues after speaking with our logistics people. Those have certainly crystallized in the last 14 days for us. That is the primary issue that has crystallized for us, but we have been clear with them that those were issues.

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

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

THE COURT: Were these issues raised in the conferrals before August 26th?

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

THE COURT: Well, I am -- let me ask you, on or about August 26th, you committed, at least at some level, that you thought you could get things done by September 10 th. You must
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 out, was our perspective. This was always the biggest issue from our perspective, and we felt like at the time that we could complete the shipment at the time provided that we got logistics issues worked out, and I have email statements to the effect that we can submit after the fact if it would be helpful, but those were -- that issue was made very clear from our perspective to the other side.

THE COURT: At what level of detail, though? It is one thing to say we will get it to you by the 10 th, but we are going to have to work through some shipping issues, and it's another thing to say we can get it to you around the 10th, but you are going to have to come up with your own freight forwarder, you're going to have to fill out the Customs forms, we are going to do this. There is a level of specificity 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,
it could be before that. That is what we have been working on in the last ten days before we were told that we were going to have another PTO 32 hearing.

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

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

THE COURT: Had you --
MR. SENTENAC: I am sorry.
THE COURT: Had you talked -- for example, had you talked to your shipping people in Mexico before August 26th, and understood the detailed steps that you were going to need to take to get this product into the United States?

MR. SENTENAC: Yes, we had spoken with our logistics people prior to August 26 th, 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.

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

MR. SENTENAC: It is the import process from the U.S. Customs perspective that crystallized for us, that -- the responsibility issue and who needs to have responsibility as 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.

THE COURT: Let me turn to the Plaintiffs. I feel like Howard Baker at the Watergate hearings. What did you know 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.

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

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

So, in short, FedEx has indicated to us -- or our expert has indicated, who has 40 years of experience with FedEx and other shipping logistics, that there is nothing there, that this is a fairly routine process that FedEx handles all the time with international shipping, and as long as we are clear on what the invoice is for, what the manifest includes, the value, that it is not for commercial sale, that there should be no problems. However, if there are any problems, they are 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 $B I$ to raise that there is this complexity that we are being told is not really an issue is of concern.

THE COURT: Has your expert talked to their expert?

MS. JUNG: No. We learned of this last week from them that we needed to get the Customs broker and there were all these complexities, so we were reaching out and talking to folks, and this all happened over the weekend, your Honor.

MR. NIGH: Your Honor --
THE COURT: Okay. Hold on. Ms. Roddy (phon), who is the affiant on your exhibit, she has not had the opportunity to speak to BI's shipping people; is that correct?

By the way, is it Ms. Jung or Ms. Jung? How do you pronounce your last name?

MS. JUNG: Thank you, Judge, it's Ms. Jung.
THE COURT: Okay. Thank you. Ms. Jung, has your expert had the opportunity yet to speak to their people? The answer to that is no?

MS. JUNG: That is correct, your Honor, she has not. THE COURT: Okay. Mr. Nigh, did you want to add something? I'm sorry, I cut you off.

MR. NIGH: Yes, $I$ was just going to add a couple of extra points to your question, which is first off, in terms of the shipping instructions, Plaintiffs have provided shipping instructions months and months ago. Ultimately, Defendants even sent us a protocol that included those ship instructions multiple months ago and we agreed on a protocol that included those shipping instructions.

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.

THE COURT: Let me turn back to Mr. Sentenac.
My other question, Mr. Sentenac, is, is the product ready to go? If someone can arrange shipping tomorrow, can the product be picked up and shipped tomorrow?

MR. SENTENAC: We have not taken and created the samples until the logistics issues were worked out because we weren't sure of the timing. Creating the samples and having them sit there for an unknown time until -- we had an unclear picture from Plaintiffs on who was going to be responsible for the import process we weren't comfortable with, so we wanted to keep them in the controlled environment in which they were 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.
THE COURT: Why? That makes no sense to me. Why would you waste a week and not prepare the samples to go?

MR. SENTENAC: Well, we are preparing -- we are prepared to move quickly once these issues -- we didn't want the samples to sit out of their controlled environment until the issue --

THE COURT: Why do they have to leave their controlled environment? Can't you put the samples in a separate container next to the old samples in the same controlled environment?

MR. SENTENAC: I don't know the answer to that specific --

THE COURT: Why do you not know the answer to that? Hasn't your client looked into this question? Isn't your client committed to actually complying with their discovery obligations in this case?

MR. SENTENAC: Absolutely. We have been working extremely hard to try to resolve these issues on the logistics end. We are in communications with the manufacturing folks at Promeco who can move quickly to get this product ready to go, 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 to U.S. Customs responsibility.

THE COURT: What is your response to their expert who says, just put it in a FedEx package and ship it?

MR. SENTENAC: Well, we have discussed this with Plaintiffs, too. We could make the product available -- if it is as easy as they are making it out to be, we could discuss with -- making the product available in Mexico and they can pick it up if it is as easy to get it across -- out of the export and into the import process, but we have tried to work with them to find a mutually agreeable solution that will be in everyone's interest to get this product to them as quickly as possible, including working with our logistics folks to help with those solutions, and we have identified the easiest way -my understanding is that it is a matter of telling us who will be responsible and submitting the paperwork, and it can be handled very efficiently from there.

THE COURT: Okay, okay, I understand.
Ms. Jung, anything further?
MS. JUNG: Nothing further, your Honor.
THE COURT: Okay. As to Sanofi and BI, I am going to order the product be in the hands of the Plaintiffs a week from today. I want all of it in the hands of the Plaintiffs a week from today at five o'clock Eastern time.

MR. BEROUKHIM: Your Honor, we will do our best to comply. Monday receipt is difficult because they don't want the product shipped on Friday, and that would be Saturday delivery. Can we have Tuesday so it could leave on --

THE COURT: You can have Friday or you can have

Monday. Which one do you want?
MR. BEROUKHIM: Okay. Okay. We will try to figure it out. We will do our best, that is all I can say.

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

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

So, I think we are, obviously, a little bit differently situated in a few respects. First of all, following the hearing that we had, we, of course, are going to comply with the Court's order, and so I had a conversation with Mr. Nigh early the following week, and we agreed -- certainly I wouldn't say -- we did not agree on hard deadlines, but I agreed that we were going to make best efforts to get this in their hands as quickly as possible on a rolling basis because 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 materials, packing them, but in the meantime, some of our sites had some specific questions and concerns about the shipping instructions. For example, in Singapore, where I think it is 245 samples of API were getting shipped from, they can't use FedEx, so we were going to use UPS. There was some back and forth with the Plaintiffs last week -- or two weeks ago about that.

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

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

Our people who are sort of familiar with all of that

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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.

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

And then the Jurong API, which is the bigger ask, there is 245 samples, we actually had a little -- as your Honor remembers, we were supposed to go and talk about maybe there was a way to kind of narrow the request that the Plaintiffs were asking for. Plaintiffs, to their credit, they did come 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 grams of each.

So, our colleagues in Jurong have been collecting 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 of how quickly this can go. The two things I heard were, we won't have an accurate estimate, one that we can kind of take to the bank, until probably tomorrow or Wednesday; and second, apparently for Jurong there was a concern about shipping in a way that ends up -- the product ends up arriving on a weekend, they thought that that was not going to be feasible with the porters that they use because they won't just leave the 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.

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

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

Coast -- I understand the expert is in California. Is that correct, Ms. Jung?

MS. JUNG: Yes, your Honor.
THE COURT: Okay. So, I will allow the product to be delivered by noon West Coast time on Tuesday. That I hope will alleviate Mr. Beroukhim's concern that if the product shipped -- he can ship the product Monday and that is really 3:00 o'clock East Coast time, and still gives the expert to at least get the boxes by noon and start working on them on Tuesday. I hope that balances everybody's concerns.

MR. SHORTNACY: Your Honor, Michael Shortnacy for BI. If $I$ could be heard on this issue very briefly. THE COURT: Yes. MR. SHORTNACY: I take your Honor's direction to, obviously, the order and also to take steps to prepare the product, to get it ready and in the hands of Plaintiffs.

I just wanted to note, unlike Sanofi, we are exporting and importing into the country, there are intermediate steps that are really beyond BI's control, which includes Customs and Border Protection and FDA. I wanted to clarify that for your Honor.

I don't want anybody to have to do a contempt hearing, obviously, but I wanted to sensitize your Honor to that. We certainly will take all necessary steps that we can, but those 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 what Plaintiffs ultimately want as well here, which I think we share, which is to get this product to them as soon as possible.

THE COURT: I hear you. My order stands, next Tuesday, noon, West Coast time.

Let me turn to the Plaintiffs as to the GSK issue. Ms. Jung, it sounds like Mr. Sachse said he can get you everything except the API probably by the Tuesday deadline I just set.

Am I hearing you correctly, Mr. Sachse?
MR. SACHSE: I think that is right, Tuesday at noon Pacific.

THE COURT: Ms. Jung, I will hear you on that, but that sounds to me like that is okay with GSK. What about the API issue, though? And Ms. Jung, I will hear from you.

MS. JUNG: Again, I think having a date certain is what we seek from you and we thank you, your Honor, for giving it to us. The difficulty, as you can see, and I won't belabor the point anymore, is just the leaps of faith and the fuzziness of the deadlines is what is causing us a lot of angst because we have to get the product, and we don't want to be in the same position next week coming to your Honor and going through the hoops of a PTO 32 saying, your Honor, we still don't have it, and there are new excuses as to why we don't, many of them
perhaps legitimate.
I think for us, a date certain that we can all live by I think is really important.

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

MR. SACHSE: One thing that just occurred to me, listening to the back and forth with everybody else, is that $I$ 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 have put the product into the stream -- not the stream of commerce, but the shipping stream, I guess, to get it to the Plaintiffs' experts by noon Pacific on Tuesday, then, if there is some kind of Customs thing that is out of our control, to 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 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?

THE COURT: My vision is that it will arrive -obviously, if you put it in the normal stream of shipment with a reasonable expectation that it is going to arrive, and the Plaintiffs are aware of what you are doing and they have signed 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.

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

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

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

MS. JUNG: I believe so, your Honor, but I will allow 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.

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

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.

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

MR. SACHSE: Thank you, your Honor.
THE COURT: Mr. Sachse, on behalf of GSK, not waiving any objections you may have to my orders, have I addressed the
issues that we believe were raised today?
MR. SACHSE: Yes, your Honor, you have. I guess I could invite Ms. Jung, if she wanted to do a whirlwind tour of our eleven facilities and pick up the stuff individually, more power to her, but we will abide by the order and we will keep working as quickly as possible to get the finished product and the API in the hands of the Plaintiffs.

THE COURT: I appreciate that. Mr. Sentenac, again, not waiving any objections you may have to my orders, anything I haven't addressed or any clarifications that you need?

MR. SENTENAC: Nothing further from me, your Honor.
THE COURT: Thank you very much. Mr. Beroukhim, anything for Sanofi that is either unclear or that $I$ haven't addressed?

MR. BEROUKHIM: No, your Honor. Thank you very much.
THE COURT: Thank you all very much. I will excuse the counsel who are dealing with this issue. I will move now to the issues relating to the corporate representative deposition of GSK.

Who is going to handle that for the Plaintiffs, please?

MS. FINKEN: Tracy Finken on behalf of Plaintiffs.
THE COURT: Good afternoon.

MS. LUHANA: Good afternoon, your Honor, Roopal Luhana on behalf of Plaintiffs.

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THE COURT: Good afternoon. And on behalf of GSK.
MR. SACHSE: Good afternoon, your Honor, Will Sachse on behalf of GSK. I wasn't their introduction piece of this.

THE COURT: Okay. Mr. Cotton, good afternoon. MR. COTTON: Good afternoon. I was. Chris Cotton for GSK.

THE COURT: I was having flashbacks reading this transcript today, but let me retrace the steps that bring us here.

This all started, Plaintiffs served request for production, I believe it is request for production number 29 relating to human clinical trials and animal trials. Ms. Finken, were those included as well?

MS. FINKEN: Yes, it was for human clinical trials as well as all nonclinical and pre-clinical testing as well, to include animal trials.

THE COURT: That's right. That was the distinction we were making, human clinical trials and then pre-clinical. There was a request made. There was a partial objection and then there was production by GSK, and we have had a number of hearings about the PIER system, the people in London with the white gloves who handle the archives at GSK, and lots and lots of testimony about that.

What I have said repeatedly, and I think we have finally reached this point, is that there will never come a
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. In the meantime, the Plaintiffs said, well, if they are ever going to get to that point we want some transparency, we want to know what are they giving us, what are they holding back, what have they looked for, and we have had a lot of conferral and a lot of good cooperation between the parties, for which I thank you, but, as with many things, we have 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 $30(\mathrm{~b})(6)$ 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 $30(\mathrm{~b})(6)$ witness $a$
question and the answer was, "I don't know." Plaintiffs' argument is that, under Rule $30(\mathrm{~b})(6)$, 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.

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

THE COURT: Okay. I will go back over that in a 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 substantive objection, so a form objection doesn't count, no substantive objection, and the witness' answer was, "I don't know," I will order GSK to provide an answer to that question. It can be a written answer by declaration, but they have to answer the question. Okay. They didn't object in real time, you've got to answer the question. If the witness couldn't answer the question, you've got to answer the question now.

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

Let me address the privilege issue. I appreciate, Ms. Finken and Ms. Luhana, that you were working off of my words from the last hearing, so I don't fault you for that. Sometimes I say things I probably shouldn't say without thinking them through all the way, but in reading through the transcript at least $I$ didn't see that many privilege objections. I think there were maybe four or five in each 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, but instructed the client to do, why shouldn't those be privileged? Ms. Finken or Ms. Luhana, I don't know who wants to address that question, but why isn't that a valid privilege assertion? If you tell your client, go search for this, why isn't that the lawyer's thoughts and opinion work product?

MS. FINKEN: Well, your Honor, first of all, let me draw your attention to an example of one of the privilege objections that Mr. Cotton asserted. For example, Ms. Mitchell, who was the witness who testified about the MedTrack spreadsheet, of which your Honor probably never wants to hear about again --

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

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

THE COURT: But my question is this: Whether -- first of all, you asked two questions. One was, when did you do the search. I don't think that is privileged. When you did the search is not privileged, but what filters did you apply, if in fact she got those filters from counsel, whether you know that 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
applied. I certainly didn't ask what filters had been applied, or what she had been told. It was a simple question on whether or not any filters had been applied when she pulled the data.

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

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

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

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

THE COURT: Okay, I understand.
MS. FINKEN: Your Honor -- I'm sorry, I didn't mean to interrupt.

THE COURT: Go ahead.

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

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

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

MS. FINKEN: Yes. Your Honor, I am looking at another one on page 160 where $I$ said: Sitting here today, can you tell me where GSK looked for these particular studies? I was referring to the MedTrack spreadsheet he asserted a privilege 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.

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

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

We have also since requested, because Ms. Mitchell did cite to a retention policy for the PIER database during the 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.

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

THE COURT: I understand, but my recollection from the transcript is, you did ask those questions, and her answer was, "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 page, we can double check that, but to the extent my recollection is correct, I have already ordered them to answer those questions for you, so you are going to get that 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.

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

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

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

I actually have a list, $I$ have it for you.
MS. FINKEN: I appreciate that. Thank you.
THE COURT: Let me also do this. I am going to sustain the privilege objections that were asserted and to the extent perhaps -- as I read the questions -- and again, in real time maybe we are at the margin here, but as I read the question -- any question that had to do with what searches did GSK do, what searches did GSK affirmatively choose not to do, if that thought process was informed by counsel and counsel's input, I believe that is privileged. Any objection that goes to that, whether it was a scope objection or a privilege 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.

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

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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.

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

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

THE COURT: I hope so. Before I forget, let me also address -- I do want to make a specific ruling on this question, which is on page 167. I will read it to you so you 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
if the truth of the matter is we have a policy that we keep all Zantac stuff for as long as we ever sell Zantac, that is very different from, I think she has testified we destroy it after 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. 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 question.

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

MS. FINKEN: Your Honor, Tracy Finken on behalf of 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 $30(\mathrm{~b})(6)$ 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.

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

Mr. Watts is trying to speak up. Mr. Watts, what is the date?

MR. WATTS: September 29.

THE COURT: Okay. I will take that under -- we will set a date before you go.

Mr. Sachse, Mr. Cotton, did you want to be heard?

MR. SACHSE: Yes. Let me respond to that quickly. First of all, obviously we will have a followup conversation with Ms. Luhana and Ms. Finken and now Mr. Watts to figure out exactly what really matters, timing of all of that.

I think that all of the Fell questions are not really related to the depositions that are happening in the U.K. at the end of this month, so maybe we can do this in a staged manner so that they get the answers to the clinical trial questions in advance of those depositions, which $I$ think is fair, and then we can kind of work on the batch testing questions or batch system questions sort of after we finish the Ms. Mitchell questions. That is what $I$ would recommend.

THE COURT: Ms. Finken, does that make sense to you?
MS. FINKEN: Your Honor, I believe we are scheduled to take another deposition that week as well of a gentleman by the name of Giuseppe I deposition, who the chromatogram issue may have some bearing on that deposition. So, I would appreciate if we could get all the information in a timely manner.

THE COURT: I'm sorry, one more time, Mr. Watts, the
deposition is on the 29th?
MR. WATTS: The $30(\mathrm{~b})(6)$ is on the 29 th, Mr. Giuseppe is on the 28th.

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

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

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

MR. COTTON: Your Honor.

THE COURT: Yes, Mr. Cotton.

MR. COTTON: I am not sure how many questions we are talking about, but we certainly will take your guidance and go 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 question to --

THE COURT REPORTER: I am having a problem.
MR. COTTON: Sorry. I will just repeat, Judge, I am not sure what all you heard.

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.

THE COURT: Again, to the extent the objection was to 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.

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

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

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

THE COURT: Yes.

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

THE COURT: Yes.

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

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Fell's deposition is, there were notes produced the night before the deposition, similar to Ms. Mitchell, and Mr. Fell, who was designated to testify about Lift and Empower, setting aside the predecessor systems, he said he could not provide any further testimony but for what was in his notes.

He was essentially an IT administrator that just installed software and he created user I.D.'s and formatted reports, but he couldn't talk about where data was stored. He couldn't speak about how searches were conducted. He couldn't speak about the interplay between the systems.

I could cite to the specific language if you would like. If you take a look at 22 , 36 , he says --

THE COURT: Hold on. Page what?
MS. LUHANA: 22, line 3.

THE COURT: Hold on. 22.

MS. LUHANA: Line 3.

THE COURT: Okay.
MS. LUHANA: He says: I can only talk to Empower 3, but only to the information $I$ prepared in my notes. That is 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 20, I ask him: What about any other information aside from what is in your notes about Lift? He says, no, I don't have any further knowledge on Lift other than what is in my notes.

So, repeatedly throughout the deposition there continued to be objections as to scope when they were clearly within the scope of the deposition, as to data and --

THE COURT: There is no scope objection there. MS. LUHANA: No, no, it is to form there, but my point 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 notes and that is it.

In addition to that, when $I$ asked questions about data that was stored in the systems, when I asked about the interplay of these systems, when I asked about how searches could be conducted, Mr. Cotton repeatedly objected to being outside the scope. Even looking at GSK's objections, they didn't object to those areas of inquiry.

THE COURT: First of all, Ms. Luhana, all I read were the things that you highlighted in yellow for me. That was, to my mind, the only things that were at issue here.

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 it. You say he kept repeatedly making scope objections. At least in what you pointed me to in this deposition that is not
true. He made a bunch of scope objections as to your questions about the predecessor chromatogram systems. That is at pages 56 to 65, and there was an objection on page 50 to the Statistica (phon) and I think some predecessor systems like that. Beyond that, if there were multiple objections based on 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.

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

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

The remedy you have asked me for is, compel GSK to produce an adequately prepared $30(\mathrm{~b})(6)$ 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 can't rule on things that don't happen.

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.

We will meet and confer with GSK per your ruling and
come before the Court if there are any other issues.
THE COURT: Thank you.
The Plaintiffs have also raised the issue that they wanted sanctions, including, but not limited to, a negative inference.

I guess the first question is, what other sanctions? Because including, but not limited to doesn't really limit it. MS. FINKEN: Your Honor, I think we were referring to the costs associated with the deposition that we took and prepared for that we were unable to actually get adequate answers to the questions that were posed that were well within the scope of the notice.

THE COURT: Okay. I will allow you to file a written motion for sanctions and $I$ will let GSK respond in writing within the time set by the local rules as to that.

MS. FINKEN: And -- sorry, your Honor.
THE COURT: No, go ahead.
MS. FINKEN: I was just going to clarify, in terms of the negative inference, that is something that we wanted to put on your Honor's radar. I don't know that it is something that is ripe at this point in time, as we still have depositions to take with the $30(\mathrm{~b})(6)$ clinical trial witness, and some questions now that have arisen based upon this hearing.

Mr. Sachse just represented that there were only 17 studies that have not been produced. That is news to me, so I
would request an updated MedTrack spreadsheet with the Bates numbers of the studies and where they were produced in the record, because the last time $I$ checked it was 380 or so that had not been produced, and we were not limited to 17.

So that would be just another request, your Honor, and then --

THE COURT: I am done micromanaging that list. If GSK says they produced what they have produced and they are not producing no more, and the Plaintiffs don't like that answer, you can file the appropriate motion and seek the appropriate relief. I am not going to not micromanage yours and Mr . Sachse's list anymore.

MS. FINKEN: Okay. Thank you, your Honor.
Then the last issue $I$ would just raise is if we would have an order to compel production of the SOPs that relate to the document retention policies for the clinical trials that were referenced in the transcript, please.

THE COURT: I think I did order that, because I ordered them to answer the questions. Yes, to the extent the questions related to the production of SOPs, Mr. Sachse, Mr. Cotton, what is your position on that?

MR. SACHSE: Your Honor, I think maybe we should take this step wise. I agree that you have ordered us to answer the question about the GSK policies and the SOPs, and we will do that. Then maybe sort of the next step is, if there is a
request for the actual underlying documents, we can see if we can reach some sort of agreement on that; and if not, we can brief that for the Court as well.

And the reason $I$ am just sort of thinking it makes sense to do this in a step wise fashion is that we are talking about 40 years, and we are talking about -- I don't think it is really easy to paint with a broad brush and say we want the "GSK policies and the SOPs relating to retention." It is a 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 the narrative responses sworn on those issues, and then we can kind of follow up and obviously identify, to the extent we can, the source of that and then we can follow up on what makes sense in terms of documents.

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

MR. SACHSE: Okay.

THE COURT: All right. Anything further on the
$30(\mathrm{~b})(6)$ deposition issue from the Plaintiffs?

MS. LUHANA: Nothing from me, your Honor, thank you.
MS. FINKEN: No, your Honor, thank you.
THE COURT: From GSK?

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

Ms. Finken, what else is there out there that you are waiting for or that $I$ have ordered you to get that you haven't 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.

One of them -- and Mr. Watts, I am glad that he is on this call because he may want to weigh in on this. We had been discussing a deposition of a former GSK employee who is overseas. We had an agreement that the deposition would move forward on October 5th with Mr. Sachse, and we were advised a 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 going to do, but that process takes approximately four months. We had asked Mr. Sachse if he would be willing, for the purposes of that witness, to take that deposition after the December $20 t h$ 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.

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

Mr. Sachse, if you have anything you feel compelled to say, I will be happy to hear you, but I am not going to get 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.

THE COURT: If I understand what Ms. Finken is saying, this is not a current employee, this is a former employee.

MR. SACHSE: Retired.

THE COURT: I see. Because they are not a current employee, you are taking the position they are not within your control and you can't voluntarily produce them, they have to be served through other means?

MR. SACHSE: Actually the Swiss law is that -- there are actually two issues. Let me back up. Maybe we should talk about it.

The two issues were, we will be in Europe, in the U.K., I guess not in Europe anymore, in the U.K. in a couple of weeks for these other depositions that we have been talking about. At the time, to try to be efficient, we were talking about trying to do this witness, the Swiss witness, remotely.

At that time I said, well, look, I don't know whether we can even do a remote deposition in Switzerland, I don't know what the laws are about what a witness -- how you go about doing a deposition in Switzerland, but go ahead and notice it, and we can deal with that later.

What I learned subsequently is, good news, we can do remote depositions now under Swiss law; bad news, you do have to comply with the Hague, and it is not a waiveable thing. It's not like we can lean on this guy, or the witness could say, oh, sure, come over to my house and do my deposition. The

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.

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

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

I can tell you from my view, let's just put it politely, these designations have been over used, if you will. So, there will come a time, and frankly, I just don't have time 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 not occasional, it is pervasive in a way that $I$ don't think complies with Federal law or Florida Sunshine law. It is 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.

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

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

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THE COURT: When you are ready for me, I am here. MR. SACHSE: Mr. Watts, you assume that I am going to be handling the confidentiality issues.

MR. WATTS: Well, I can assure you that Mr. Sachse is not the one filing these because he would not do it with a straight face, but we will get there.

THE COURT: Anything else that the Plaintiffs wanted to put on the table today? I am glad to hear you are not 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. MR. WATTS: Judge, one other thing. I had sent out notices of depositions for $30(\mathrm{~b})(6)$ with respect to knowledge of NDMA, and we achieved a stipulation with Pfizer. I believe we have agreements with Sanofi, BI, and now Mr. Sachse at GSK to do short half-day notice of $30(\mathrm{~b})(6) \mathrm{s}$ tagged along with witnesses we have already taken. They are not going to count on the limit, but $I$ agreed to keep it to half an hour -- half a day, rather, and we will get all of those done, but that is now resolved as far as I am concerned.

THE COURT: Very good. Great.
MR. SACHSE: I am glad Mr. Watts just raised the knowledge of NDMA deposition because maybe, Mr. Watts, that is a way that you can get into that nitrosation document, you don't even have to bother this poor retired doctor in Switzerland.

MR. WATTS: Maybe so. Okay, we will talk about it. THE COURT: I would expect, knowing all the lawyers in this case, that if it is really a matter of just laying an evidentiary foundation for some documents, that the parties -I don't know that $I$ have ever seen a case lost on the inability to authenticate a document. Mr. Watts and his team will figure 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 get it in. The parties tend to work those things out.

All right. Thank you very much. Mr. Sachse, anything else from GSK?

MR. SACHSE: Nothing for today, your Honor.
THE COURT: Thank you. Mr. Shortnacy, I have you on my agenda, so I don't know whether, on behalf of BI, you had anything you wanted to report, ask, raise, anything like that. MR. SHORTNACY: Nothing, your Honor. Thank you for checking in.

THE COURT: Mr. Beroukhim, because you made the mistake of appearing earlier for Sanofi, let me call on you. Anything from Sanofi that you wanted to raise?

MR. BEROUKHIM: No, your Honor.
THE COURT: Thank you. Pfizer has strategically managed to not even show up here on the screen, but let me ask. Speak now or forever hold your peace. If there is anyone on behalf of Pfizer who wanted to raise an issue, please introduce
yourself and speak now.
MS. SHOWALTER: Your Honor, this is Annie Showalter with Williams \& Connolly for Pfizer, and I have no issues to raise.

THE COURT: Thank you very much, Ms. Showalter.
All right, everybody, thank you all for your time. Is there any issue that anybody wanted to raise today that $I$ have not ruled on, not waiving any objections anybody may have to a ruling I may have made?

All right. Hearing none, $I$ will thank the parties and excuse you. Thank you very much.

MS. FINKEN: Thank you, your Honor.
(Thereupon, the hearing was concluded.)

*     *         * 

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

Date: September 14, 2021
/s/ Pauline A. Stipes, Official Federal Reporter

Signature of Court Reporter

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