UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
WEST PALM BEACH DIVISION

CASE NO. 20-md-02924-ROSENBERG

IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION. . West Palm Beach, FL . March 23, 2021

MOTION HEARING (through Zoom)
BEFORE THE HONORABLE BRUCE REINHART
UNITED STATES MAGISTRATE JUDGE

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THE COURT: Good afternoon. I think I have all counsel who are speaking.

Let me formally call the case. It is case number 20-2924, In Re: Ranitidine Multi District Litigation. We are here for a motion hearing on GSK's unopposed motion to extend certain discovery deadlines.

Let me have appearances, please. Let me start with counsel for the Plaintiffs.

MS. FINKEN: Tracy Finken on behalf of Plaintiffs.

THE COURT: Good afternoon, Ms. Finken.

MS. FINKEN: Good afternoon.

THE COURT: On behalf of GSK.

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

THE COURT: Good afternoon. As we always do, let me remind both of you that each time you speak -- I will try to recognize you ahead of time, but each time you speak, if you will make sure to identify yourself for our court reporter so we can have a pristine record.

The matter that is before the Court this afternoon is GSK's motion for -- unopposed motion for extension of certain discovery deadlines which was filed at Docket Entry 3044. I did review the motion. I reviewed the exhibit that was appended to it at Docket Entry 3044-1.

I reviewed the response that was filed by the

Plaintiffs at Docket Entry 3062, as well as GSK's reply at Docket Entry 3080. This matter was referred to me by Judge Rosenberg by order at Docket Entry 3076, which gives me the authority to modify the PTO 47 deadlines that have been requested here which relate to the brands, specifically to GSK.

So, with that as a windup, let me confer with Mr. Sachse.

So, as I read the motion and the materials, there is really three dates that are now -- you are requesting. One is, I guess, a week from tomorrow, which would be March 31st, for a large chunk of the categories; then April 16th for certain materials relating to sales and rebates and things of that nature, chargebacks; and then May 14th for production relating to science and science reports and apparently very old, crinkly, very tender documents.

Am I right about the three categories and the three dates that you are requesting, Mr. Sachse?

MR. SACHSE: Yes, Will Sachse for GSK, that is correct, your Honor. I should also mention, of course, that we are making multiple rolling productions in those categories every week.

THE COURT: We will talk about that in a second. I just wanted to make sure that I know what I am shooting at.

I also noticed in your materials, and I did want to discuss this at some point during the hearing today, there is a

reference to temperature related data that you are investigating. I just want to get my hands around at some point what that means and what it is and what the timeframe looks like to get that produced. There was also some reference to ongoing meet and conferral relating to batch data, batch reports, things of that nature.

I want to get my hands wrapped around that, although I do understand from the special master that may be a legal issue that is not necessarily restricted only to GSK, that there may be other brands from whom that sort of data has been requested. I want to make sure, if I am going to make any rulings on that, that everybody who needs to be heard on that gets heard.

So, as far as I can tell, those are the topics that we need to discuss this afternoon. Obviously, if there is anything else the parties want to discuss, I will be happy to hear them on that.

Let me start, then, with the different dates and -- let's start with Ms. Finken.

Ms. Finken, it is your position you don't object to the requested deadlines that GSK is asking for; am I correct?

MS. FINKEN: Yes, your Honor, that is correct. We have been meeting and conferring with Mr. Sachse for the better part of two months with the special master on these issues, and as a result of those discussions, we do believe that the request is an appropriate one, which is why we did not object

to it.

However, we reserved our right to be able to respond to that request so that we could make a record as it related to the prejudicial effect it has had on our ability to obtain the material, review, analyze it, meet and confer with Mr. Sachse on any followup issues, and feed the material to our experts for purposes of expert reports which are due in four months.

So, we wanted to reserve our right to respond to it and make sure that the record was preserved on that issue so that we could address the scheduling issues under PTO 30.

THE COURT: There is no issue before me and it certainly has not been referred to me and not been raised to me, an issue to modify PTO 30, and I don't have that authority.

I read your response and it is clear you are making your record and you are certainly permitted to do that.

At least in terms of the specific remedy that they are requesting here with respect to the three dates I mentioned with Mr. Sachse, you are not objecting to those; am I correct?

MS. FINKEN: That is correct, your Honor.

THE COURT: All right. Very good.

Let me start with this: Certainly the March 31st dates are very reasonable. I will grant the request as it pertains to the March 31st dates that were requested.

Mr. Sachse, help me out on the April 16th proposed documents. I don't have a feel for what they are, what they

are relevant to, how voluminous they are. Can you just give me a sense, a better feel for those?

MR. SACHSE: Sure, your Honor. Again, this is Will Sachse for the record.

So, the April 16th -- again, it is rolling to complete by April 16th. Those documents -- or that data really, it is data, are sort of historic sales and pricing records that actually are held by an outside vendor who GSK has used in previous litigation and previous other settings, and so this is -- we sort of learned that this was going to be a source of historic data that we were not able to locate within the company itself that would, I think, give a more complete picture of the sales and pricing information.

I should mention that we have -- I believe we have already produced some sales and pricing information held by the company and some more of that is coming in the next week, but this outside source is going to be kind of a more comprehensive historic look at that data.

THE COURT: Let me ask Ms. Finken. Ms. Finken, if I understand, that sort of sales and pricing data would be relevant to the consumer class action claims primarily?

MS. FINKEN: Yes, your Honor.

THE COURT: All right. Now I have a better feel for what that is.

Talk to me, then, about the 230 or so -- maybe it is

less than last week since you are doing a rolling production -- science reports that are yet to be produced, Mr. Sachse. Are those all over in the U.K.? I read in your papers that was a big issue, given the U.K.'s Governmental restrictions under COVID, that was impeding GSK's ability to produce those any faster.

Can you bring us up to speed as to where we are on that?

MR. SACHSE: Sure, your Honor. Again Will Sachse.

You are correct, these are archived documents, often hard copy documents, that are held in the U.K. What has happened is, the company has an archivist who has to go back -- or an archivist team who goes back and queries the records and pulls these hard copy documents and then scans them, makes them available for our review teams. Of course, if it is an electronic version of a document that is within the archive, pulls that electronic copy and then makes it available to the review team.

That process has been in sort of fits and starts, unfortunately, due to the pandemic, but that has been ongoing for more than a year, or for about a year.

And I think we are now at a point where we are close to done with the actual scanning of hard copy documents and a number of the documents have already been loaded through the system. I know that there have been some substantial

productions of science-related materials in the last few weeks and there are more to come.

Sitting here right now, I couldn't tell you exactly what is the number of documents remaining, but I know that we do expect it is still a substantial amount of information that is coming through the pipeline.

I think we feel more confident that we are coming to the end of what we call lab notebooks, these are the actual notebooks that some of the scientists were using historically and even today. We have produced most, if not all of those, but to just be as thorough as we possibly can, we have made multiple queries of this, what we call the PIER, which is sort of an archive system, and we are looking for Ranitidine related studies that we have not yet located.

And the process, in essence, is to pull the documents, look at them, see if they are, in fact, responsive, sometimes they are just not, and then get them over to the Plaintiffs as quickly as possible.

THE COURT: So, help me out in terms of process. Where is the major bottleneck? Is the bottleneck that it just takes a long time for the archivists to find these things; is it that once they are found, figuring out if they are Ranitidine related is the problem, or is it getting them physically scanned in, and then once they are scanned in, the review process could be more efficient, or is it the review

process that is the bottleneck, or all of the above?

MR. SACHSE: I will put review to the side, but I think all of those other pieces have certainly contributed to the challenge.

The bottleneck starts, of course, in the U.K. If the GSK employees are not allowed to access the facility, or are only allowed to access it for very limited periods of time, there is only so much they can do.

And then the scanning has been quite challenging, and you mentioned the crinkling documents, which may have been partially in jest, but I can assure you partially not. There have been some real challenges with the age of some of these documents and making sure that they are handled properly.

I think, from our perspective, once they get into our review platform and they are available to the reviewers -- I think we have reported that we now have a team of roughly a hundred reviewers, so we can get through material relatively quickly once it is there. It is just getting it there that has been the challenge.

THE COURT: What has happened in the past, has happened in the past, it is what it is. As we sit here today, where is the current bottleneck? How many people do you have working on it in the U.K.? Is there an opportunity or ability to expand that number? That is what I am trying to get a better sense of.

It sounds to me like once it is in the platform, the U.K.'s COVID restrictions cease to be the problem. I'm assuming the review platform is, like everything else in the world these days, in the cloud, and anybody sitting anywhere in the world can access it.

So it seems to me, at least if we accept COVID as the problem, it means you have to get the stuff scanned, so help me out there.

MR. SACHSE: I think that you are exactly right, your Honor, once it gets into that the review platform it gets moving quickly.

The bottleneck, though, that remains at the U.K. facility is just a matter of their safety protocols dictated by public health that even with a little bit of relaxing, I think they moved from one person allowed to go into the archives at a time to three, and there had to be kind of shuffling musical chairs even to allow that to happen, and then the scanning.

What we looked at really was an estimate that we thought we would have the documents on the platform for review by the end of this month, and I think we are on track to do that. Then, just in terms of the volume and getting through the sort of responsiveness review, we expect that we will be able to get through that in April.

THE COURT: Okay. I hear you. Let me ask a last kind of factual question. Were any of these studies, to your

knowledge, included in materials that were submitted to the FDA, or the regulators? I know at some point GSK sold -- I don't know if you sold directly to Pfizer, or if you sold Ranitidine business to somebody. Are these reports available elsewhere or is it really just this one facility in the U.K.?

MR. SACHSE: That is a really good point, your Honor. Thank you for making it for me. Let me take a step back.

There are by our count something like 600 studies that we are talking about here relating to Ranitidine. We, of course, shared that list, our list, with the Plaintiffs, they had an interrogatory to that effect. We have shared that with them.

Based on our review and based on the documents that we have produced to date, the Plaintiffs have roughly two-thirds of those, if not more, because they were in fact studies that were submitted to the FDA in whole or in part.

We have been following up with the Plaintiffs, and I know they have been sending us lists asking us whether we have produced various other studies and we are continuing to investigate that.

The bottom line is that we think, once we get to April, end of April or early May, we will be through the remaining documents from this archive and we will see if we can locate the other studies or not. We might not be able to locate all of the studies, I just can't say that right now.

Just big picture, I think that the Plaintiffs have a significant amount of information in their hands already.

THE COURT: You say you are estimating about 630 that exist, and you think they got about 400 or so.

Do you at least have a catalog of what they have and what they don't have? Is there a division there?

MR. SACHSE: Yes, your Honor. Again Will Sachse.

We do have a sense of what they have. I think it is 420 of the studies that we were able to identify in the FDA file, in the submissions to the FDA, which is, of course, something we have produced already.

MS. FINKEN: Your Honor --

THE COURT: One second, Ms. Finken. One last question for Mr. Sachse, then I will let him off the hot seat for a minute.

How do you come to the 630 number? Is that just based upon reviewing some index of the archive? How do you arrive at that number?

MR. SACHSE: It is actually more -- there is no real index to the archives, it is more you run a query and you see results, but that is actually an imprecise measure because, as I mentioned before, there is no real good meaning conventions or things like that.

So, we could not go and look at a comprehensive index from this archive and say, okay, let's tick off everything that

we need, it is a much more involved process.

The way we came up with the list of studies was, frankly, it was a little brute force. We went through the regulatory submission, which is significant in this case because it is a product that was on the market for 40 years. I think it was a two and a half million page production, and we went through and identified the studies that were in there.

We identified studies that were referenced for which we did not find final study reports, and that is how we have that delta between the 400 plus studies that we know are in this production and the 200 plus where we have seen reference to them, but we do not have the actual study in hand.

THE COURT: All right. Thank you. Ms. Finken, let me turn to you. You have been very patient. I know you wanted to say something. Let me hear from you.

MS. FINKEN: I just want to chime in on the studies that Mr. Sachse had indicated they produced as part of the regulatory submissions already, and I think Mr. Sachse would agree with me on this, that a large number of them have been produced as not study reports, but they might just be a paragraph or two paragraph summary that is contained in a regulatory submission.

Some have been produced in their entirety, study reports, but I don't believe that Mr. Sachse is saying that all 400 have been produced in their entirety, unless they have been

produced in the past two weeks and something has changed. I don't believe that that is what he is intending to say.

There have been mentions of studies in regulatory submissions, there might be a paragraph or two about a study that we don't have a full study report on. As we have been digging through the production so far we have been identifying missing information. We have been reaching out to Mr. Sachse so that he could followup on it and see if they have the study report.

We have located some indices that Mr. Sachse had turned over as part of a custodial file production that contained a large number of studies, and have been crosschecking that index with what has been produced and also what was listed in our interrogatory responses that we received from GSK, and as we determine deficiencies in what is produced we are reaching out to Mr. Sachse so we can get followup on those and production.

One of the things that Mr. Sachse had mentioned was the laboratory notebooks that were recently produced in the past two weeks. I can attest, having looked at some of them, quite a few of them over the weekend, they are very dense, very old and in handwriting. So, they are quite a challenge to review, and this is somebody who I feel like I am relatively up to speed on the science in this case, so they are not something that you can just give to any old reviewer and say, have at it.

They are very, very technical and require some level of science-based knowledge to review those laboratory notebooks.

They are also really highly relevant to the case. They involve studies involving nitrosamines and nitrosation back 20, 30 years ago. They require very, very careful review, and they are going to take some time to get through. I just wanted to make that clear for your Honor.

Like I said, we are working with Mr. Sachse in identifying missing pieces of studies or missing studies altogether and trying to wrap our arms around the historical body of science that GSK has in relation to this product.

THE COURT: Understood. First of all, the purpose of my question about whether some of these studies might have been available from other sources was not to suggest it excuses GSK having to produce them if GSK has a better copy. It was simply trying to, in my own mind, think about how we might prioritize, or other things I can do to help GSK get through this and the Plaintiffs get through this more efficiently.

It wasn't meant to suggest, Ms. Finken, you have to give up your right to get something from them if you got a portion of it from somebody else. So, I didn't want you to feel that way.

MS. FINKEN: We appreciate that, your Honor.

THE COURT: Mr. Sachse, back to you for a second. On the delta, as you call it, the difference between what you

think they have already and what you think you have to produce, is your understanding, though, that anything that would be responsive is in the U.K.? Is that the only repository for this data for GSK?

MR. SACHSE: Your Honor, I think that is correct. I think just based on where these archives are physically located, that would be correct.

THE COURT: Okay, okay. Anything further, Ms. Finken?

MS. FINKEN: No, your Honor.

THE COURT: Okay. Mr. Sachse, anything further on that topic?

MR. SACHSE: No, other than to say you have seen a good peek into how the sausage is made, and it is quite an involved process, but I do say that Ms. Finken and I have been working to try to work through this iterative process cooperatively.

THE COURT: The Court always appreciates that.

As I think I may have told the parties before, my mother, in her career, worked at a company that developed new drug applications, so I am familiar with what new drug applications looked like in the '70's, '80's, and '90's, when they had literally Ryder trucks full of paper that we'd drive down to Maryland and hand it off because it couldn't be scanned. I am aware when Ms. Finken talks about what those notebooks look like and the volume of information that got sent

to the FDA for this product, I can only imagine. Two and a half million pages is probably less than I thought, Mr. Sachse, so thank you.

MS. FINKEN: For the record, I have volunteered to Mr. Sachse that I would go to the dungeons of GSK and look at the paper files if that would expedite things to try to move things forward.

THE COURT: We appreciate that. Okay. Here is what I am going to do. I am going to grant the request to extend the deadline for the production of the science materials until May the 14th, but with a couple of caveats.

One is, I am going to formally order a weekly rolling production on or before noon on Friday of whatever materials have been -- completed their review process. I certainly don't think, Mr. Sachse, that you and your team are going to wait until the last day and send Ms. Finken a truckload of things on May the 13th, but just to be sure, I am going to order you to do it once a week in that regard.

The other thing I am going to do is, I am going to set another status hearing just to get us all back together probably in three weeks or so, just so I can get a feel for how GSK is doing. Maybe Mr. Sachse will be moving faster and hopefully we can maybe accelerate that date from May the 14th, or maybe things have really gone downhill in the U.K. and, unfortunately, we have to revisit that date. I don't want to

lose track of this, so I am going to set another status conference in approximately three weeks.

I will let you two talk and talk to the special master about your availability and when you think would be a fruitful time. I know you have a lot going on right now, Ms. Finken, you have a lot of depositions coming up, so I don't want to pull you away from something that important for what I hope will be a very brief status conference, but I do want to keep my finger on this particular process.

At least as to the formalities of the motion, I will grant the motion with the provisions I just said and will get a written order out in that regard.

While I have you, though, I did want to also turn to those other couple of topics just because I want to get my hands around those and get a sense of whether I should expect to see some sort of a PTO 32, or if not, how quickly -- I respect the fact that everyone is meeting and conferring. Sometimes the process of the meet and conferral with each other with the special master is a little slower than the Court might like, but I respect the fact that you have a lot going on.

On the other hand, I do want to get my hands around what might be coming my way if I can.

Mr. Sachse, talk to me further about the temperature related data, whatever that is, that is referenced in your paper.

MR. SACHSE: Sure. Again for the record, Will Sachse.

So, broadly speaking, I think the area where the parties, frankly, have plenty of room still to meet and confer is in the storage and distribution topic or subject area.

And there is a few different kind of categories or buckets of information that the Plaintiffs have requested, some relating to testing at a batch level or an individual product level of Zantac, and also, the sort of temperature control data to show that Zantac was stored in, you know, appropriate conditions.

So, we've taken -- GSK has taken the position from the beginning that we start with summary level information, that there are certain reports -- this should be of no surprise, there are sort of periodic reports that show how the factory is doing, how the warehouse is doing, are you in temperature range, outside of temperature range, is your product passing its tests, or is it failing its tests.

So we have been focused on -- in the first instance, we have been collecting those sort of reports, those periodic reports, to the extent they are available, and we have produced those to the Plaintiffs.

The Plaintiffs are interested in getting at least a sample of more kind of granular data, and that is something that, you know, like I said, we did not agree at the outset that we were going to do that, but we have been willing to meet

and confer and talk to them about that.

We are in the process of collecting some testing data that will show the testing results for the lots from 2009 forward, the lots of Zantac that went to the U.S.

The challenge for us, and I think the challenge for many Defendants, is as you go back further in time the availability of these data becomes spottier, and the hope is that if we can keep it largely to a summary level, which again would show any deviations from spec, deviations either in terms of testing or in terms of temperature, we would submit that is sufficient information for the Plaintiffs for purposes of what they are trying to show at this point.

The question about whether a particular Plaintiff is going to want to show that a particular batch that was shipped to -- I will pick Philadelphia since I am in Philadelphia -- was compliant or not compliant, we think that that is something that could wait for a later stage of this case, if at all.

I don't know that it really adds anything if you have the policies, and you have the sort of summary level testing that shows that product that is outside of range either temperature or outside of range in terms of testing, doesn't get shipped, doesn't make its way into the market.

But that is a conversation that we are having with them, and it is another one of these iterative processes where

they need to look at the documents that we have been producing over the last month or so, get a sense of what is in there, what they think isn't in there, and then we will have those followup conversations.

THE COURT: Understood. If I understand, though, your objection, if you have one -- I am not saying you have lodged one, but if I am going to see an objection, it sounds to me like it is going to be a proportionality burden, not that it is not relevant.

Obviously they have a claim in this case that is highly dependent on the theory that Ranitidine was not kept at proper temperatures and that causes the molecules to degrade more aggressively. Ms. Finken knows the science better than I do. But essentially, if you keep it for too long in too hot of a temperature, it increases the cancer risk. How about if I stay at that level.

So, am I correct, Mr. Sachse, that likely, if I am going to see a legal objection, it is going to be more of a burden proportionality argument and not a relevance argument?

MR. SACHSE: I think that is exactly right. It really does go to what information they need and what information they will have available or they already have available to them at a summary level that would show if there is a routine deviation outside of the sort of agreed temperature range that this product should be stored at.

THE COURT: Okay. Let me turn back to Ms. Finken.

I am not going to rule on this today, but my primary question to you is -- and it sounds to me like this is probably an issue that some of the other Defendants are going to have with you as well. I know storage and transport is a big issue for them. Start with that. Am I correct about that, that this is kind of a cross-cutting issue that will involve more than just GSK?

MS. FINKEN: There is a good possibility, your Honor, that it will.

You hit the nail on the head in terms of the claims and why it is necessary, and it is not something that -- like Mr. Sachse said, we have been meeting and conferring on this. I don't know that it is ripe for resolution right now because we have been under discussion on how to get at what we need in a way that makes sense and gives us what we need in the timeframes that we have available.

I don't know that it is ripe for resolution right now, but it is certainly something that is cross cutting. It will be cross cutting, I suspect anyway, across multiple Defendants, but it is also highly relevant to the claims.

THE COURT: Again, that's why I was asking Mr. Sachse. It seems to me the objection we are going to get from GSK, I am not binding anybody else, but likely from the other Defendants is, it is relevant at some level, however, there is a

difference between saying on Thursday at four o'clock we ran the four o'clock batch and this is what it showed, and at five o'clock we ran the five o'clock batch and this is what it showed. Those numbers add up very quickly. There is a difference between that and, well, once a year we -- here is our summary for the year. That may be too far in the other direction.

So, there is some sweet spot between those two extremes, and I respect the parties' ability to try to reach that sweet spot on their own, but I would ask you to be mindful that it is a cross-cutting issue, so don't let it linger too, too long because I don't want it to become -- it's like a cut on your finger. I don't want it to get infected. So, let's tee it up sooner if we can and make sure that we are involving all the necessary parties in the discussions.

To the extent it is a burden issue, GSK had -- we said this before, GSK had the product for 40 years, and Sanofi had it for two, so the burden argument there may be very different. On the other hand, the proportionality argument may be very much the same, that we are generating 10 or 12 of these a day, and we should have the result of the 10 or 12.

In any event, I appreciate knowing a little bit more about that, but I would hope that the parties don't let it linger too long and fester too long.

Is that similarly related -- I sort of mushed the two

together, but there is a discussion of batch and batch data. Is that, Mr. Sachse, more or less the same thing, just not relating to temperature, but relating to other manufacturing conditions?

MR. SACHSE: That is exactly right, your Honor. Again Will Sachse.

When we talk about batch data in this context, I think we agree that we are talking about the testing that companies do of each batch of product to make sure that it is within the specifications.

There is a battery of tests that get run, and again, our position to date has been that there are summary level data, or sort of periodic reports that are sufficient to show that these products are sort of within range, within spec, and that we don't need to go down -- drill down to show that here is each batch that passed, because actually when you drill down to each batch, all you will see is pass, pass, pass, pass, pass, so it doesn't really add much.

But those are the discussions that we are having right now.

THE COURT: Okay. Ms. Finken, anything further on that issue?

MS. FINKEN: Yes, your Honor. Without getting too much into the weeds on this particular topic today since we didn't necessarily come prepared to talk about the scope issue

as it relates to these types of documents, it is relevant because of the temperature piece of it.

There are also chromatograms that are involved in the batch testing and degradation and things of that nature that are also highly relevant to the claims, and while it might not affect a batch that -- there are batches that pass and batches that don't pass, but there is a lot of gray in the middle there in terms of what they are subjected to and what is showing up in terms of the impurity testing and degradation. Without, like I said, getting too far into the weeds on that, from our perspective, it is highly relevant.

I understand what you are saying about a proportionality argument, but that is something that is difficult, from our perspective, to address in terms of proportionality when we are dealing with a product that has been recalled and it contains a carcinogen, and that every single Defendant on this Zoom's client has admitted it contains a carcinogen.

So, from our perspective, and putting into light that we have 80,000 people with cancer in the registry, we have a hard time with the proportionality argument coming out of the Defendants in this particular case.

THE COURT: I hear you. Obviously I am not ruling on that. I will let you all meet and confer, and I am sure you are talking about this. This at a very high level, from what I

am hearing, might be ripe for some representative sampling as a starting point and then drilling down further, as Mr. Sachse and Ms. Finken both said, more of an iterative approach. Rather than just give us everything or give us nothing, let's come up with some representative sampling, almost like ESI -- I hate to us this analogy, but almost like search terms in the ESI discovery.

Let's come up with some very broad parameters, timeframes, or batches, or -- get your statisticians in line, they can figure this out better than I can, but some representative sampling that would have statistical significance that you can then work off of going forward from there.

Again, I will let you continue your discussions along those lines.

MS. FINKEN: Thank you, your Honor.

THE COURT: Sure. Just to circle back -- well, one last thing before I circle back up.

Ms. Finken or Mr. Sachse -- let me start with Ms. Finken. I know those were a couple of discovery topics I happened to notice in your pleadings. Is there anything else that is bubbling out there that you anticipate you might need the Court to get involved in in the relatively near future?

I am not asking you to point fingers at each other or cast blame one way or the other, but are there issues that are

bubbling that I ought to be aware of? Ms. Finken, anything?

MS. FINKEN: Your Honor, I don't know that there are issues per se that are ripe and bubbling, so to speak. We have been under discussions about different categories of information.

For example, Mr. Sachse mentioned the PIER database and those indicis. I don't know that we necessarily have a dispute at this point, but certainly if there is one, we will bring it to your attention in a speedy manner. So far, we seem to be working through those issues in terms of scope.

THE COURT: In terms of custodial production, I know we are on target. Are we in phase two now? We are in tranche two custodial already. Is that moving forward productively, Ms. Finken?

MS. FINKEN: I don't believe that the tranche one custodial file production is complete at this point. For purposes of GSK, we have discussed a tranche two custodial file list. We have a preliminary list that is agreed upon. We haven't discussed the deadlines or dates for production of those particular documents.

I think that they were in the schedule. I think -- Mr. Sachse, correct me if I am wrong -- he put a proposed date in the schedule for production of those documents that was submitted to the Court.

THE COURT: Okay. I looked at it last week, I didn't

look at it more recently. If it is in there, I don't remember it being in there, so I apologize.

MR. SACHSE: Will Sachse. Just to sort of give you the timeline, Ms. Finken is right that we -- by agreement with the Plaintiffs, we went back and actually did a new collections for our first tier custodians up through December of 2020. Those materials we are reviewing and we are on track to get those completed by the end of this month, so, next week.

And the second tier custodians, or second group of custodians are in the hopper, as they say, and the plan is to get those produced in April.

THE COURT: Very good. One last question, Mr. Sachse. Sorry, I was checking my notes and it wasn't clear.

Are you at least now satisfied -- I am going back now to the materials in England, the 600 and some reports in England. Are you at least satisfied that you now have identified as best you can everything you have there and it's just a matter of producing what you have found, or do you believe that it is possible you are going to find a hundred, 200, 300 more studies there that you don't know about yet?

Are you pretty satisfied you have drilled down and you got, I won't say everything, but substantially everything?

MR. SACHSE: It think, your Honor, we are satisfied that we are looking in exactly the right place. Who knows if we are going to get everything or get substantially everything,

but that is the intent and that is what we are looking at in this PIER archive. That is precisely where the materials should be if they exist, so that is what we are looking at.

THE COURT: I think maybe you and I may be talking past each other. I apologize.

What I am saying is, given that you have looked where you think everything is, do you think you have at least now found everything that should be there, or is it possible there is a whole bunch of other stuff -- you are looking in the right place, but you haven't found it?

MR. SACHSE: I just want to make sure I am answering your question.

We think that we are looking in the right place and we think that, you know, at the end of this process, at the end of -- by May 14th, if not sooner, we will be able to say to the Plaintiffs, here is what we found and here is what we were unable to find, and we do not know of other places where we could reasonably look for the information we could not find.

Does that answer your question?

THE COURT: I think so, but maybe my question could have been better phrased this way. What I don't want to run up -- I am making decisions today based on the assumption that there are approximately 220, 230 more -- at most, 220, 230 more studies that have to be processed, reviewed, produced.

What I want to make sure I am not going to hear is,

Judge, between now and then we just found 300 more studies that we kept looking for and now we have -- your deadlines are unreasonable because we now have a thousand to produce, not 620.

I just want to make sure that the 620, 630 number is -- is that an accurate number of what we fully expect is the right number?

MR. SACHSE: Thank you for that clarification because I need to clarify to make sure that the record is clear here.

The PIER materials, the science materials that we are currently reviewing, pulling, reviewing, scanning, they will include, to the extent that they are in there, the 200 studies, but they include other things as well.

There are other science-related materials. For example, we have been talking about those old lab notebooks. The lab notebooks, we found them -- we located many of them through this PIER archive, so those wouldn't be technically studies, but they clearly are materials that we thought were responsive to Plaintiffs' request and should be produced.

I think that the short answer is, we think when we get to May 14th, we will have substantially completed not only the studies, but other science-related materials that we found through this process, this iterative process.

THE COURT: Again, just to make sure we are talking about the same thing, forget the word studies. There is a set

of information that is in your PIER database that you agree is producible. It includes these studies, it may include other things.

I am just trying to make sure that you at least feel that you have now -- as we sit here today on March 23rd, you have identified that entire universe, or pretty close to that entire universe, and all that is left to do is process it and produce it, that you are not still engaged in the process of trying to figure out how big that universe is, and it could be two or three times larger than what we think it is. That is the concern I have.

MR. SACHSE: That is exactly right, your Honor. I apologize if I was sort of missing the gist of the question before.

Yes, you know, from our position, we believe we have now identified the universe, as it were, of the materials that are responsive and we are processing those, reviewing them, and getting them to -- I should say potentially responsive, and we are processing, reviewing, and getting those to the Plaintiffs.

THE COURT: Thank you, you have answered my question.

MS. FINKEN: Your Honor, can I just chime in on that particular point for one minute? I don't know that it is quite accurate that there are only 620 potential studies.

There were 620 that were identified in our answers to interrogatories, roughly. I am approximating the number. We

have been identifying additional studies through the PIER indicis that are not in that initial listing of studies that we have requested in terms of animal trials as well as human trials, and we just recently found a spreadsheet that was produced in the production of human clinical trials that totaled almost 800.

I don't know that that is a complete list and I was actually in the process of getting that out to Mr. Sachse today so that we can have further discussion about it.

So, to answer your question, I do not believe that the 620 is the universe of studies out there. I think it will be higher than that from what we have seen in terms of the production so far.

THE COURT: Okay. I appreciate that. My concern and the basis for my ruling is my understanding that there is a universe of scientific data, studies and other, that GSK concedes it will produce and that it must produce, and GSK has identified that entire universe as best it can, and all that is left to be done from today until whenever is to process that material, confirm that it is, in fact, relevant and discoverable and produce it, that we are not in a process any longer of trying to identify responsive materials.

Again, Ms. Finken, I understand your point, it is an iterative process. You may learn from some other source that there is some other piece of information that did not pop up on

Mr. Sachse's process on his end. I understand. Again, it is never a perfect process. It is like using search terms, you are going to catch some noise and you are going to miss some of the signal. I understand that.

I just wanted to confirm from Mr. Sachse that they have at least identified what they can and I am satisfied with that.

I am giving the extension to no later than May the 14th. Obviously, the Court's hope and expectation is that if resources can be reallocated and that can be done sooner, it will be completed sooner. Like I said, we will have a status conference in a couple of weeks so I can just check in and make sure we are making the progress that we need to make.

With that, Mr. Sachse, anything further this afternoon on behalf of GSK on any matters?

MR. SACHSE: Nothing from me, your Honor. Thank you for the time.

THE COURT: Ms. Finken, anything further from the Plaintiffs this afternoon?

MS. FINKEN: No, thank you, your Honor.

THE COURT: Thank you both very much. We will enter a written order. Ms. Finken, I will certainly see you on Thursday. And Mr. Sachse, I think we will see you, but I don't know to what extent we will see you or somebody else from GSK on Thursday. We will get back with you through the special

master.

MR. SACHSE: Good chance you will be seeing me.

THE COURT: Very well. Thank you both very much. Have a good afternoon, everyone.

MS. FINKEN: Thank you, your Honor.

MR. SACHSE: Good afternoon, bye.

(Thereupon, the hearing was concluded.)

* * *

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

Date: March 24, 2021

/s/ Pauline A. Stipes, Official Federal Reporter

Signature of Court Reporter