1 2	UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF FLORIDA WEST PALM BEACH DIVISION
3	CASE NO. 20-md-02924-ROSENBERG
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5	<pre>IN RE: ZANTAC (RANITIDINE) . PRODUCTS LIABILITY</pre>
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8	DISCOVERY HEARING (through Zoom)
9	BEFORE THE HONORABLE BRUCE REINHART UNITED STATES MAGISTRATE JUDGE
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THE COURT: Good morning, everyone, sorry for being.

We are here on Case Number 20-02924, In Re: Zantac Multi Litigation. We are here for a discovery hearing as ordered by Judge Rosenberg. I know we have a lot of counsel who want to speak. I will have people make appearances in just a second. Let me start with some scheduling and some framing if I could.

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Let me talk first about the schedule for today.

We will take a break at 10:30, 10:45, something in that range, whenever there is a natural point for us to take a break. We will take a hard break somewhere between 12:30 and 12:45 because I have another matter that I have to handle at one o'clock on the Zoom. If we still have work to do, we will reconvene at 2:00 and we'll continue for the rest of the afternoon as long as we have to, to do what Judge Rosenberg has asked us to do. So, that's the schedule for the day.

I will remind everyone when you speak -- I will try to call on you by name before you speak so that it is clear in the record who I am recognizing, but also please identify yourself on the record for the court reporter each time you speak so that we have a clear understanding of who is speaking.

Also, I know this is hard in the Zoom hearings -- I do a lot of conferences now where people talk about the good and the bad of Zoom. One of the bad things about Zoom is it does tend to be a little less formal than standing in the courtroom.

Let me just remind everyone it is really helpful in making a record and in understanding the proceedings as they go on if everyone speaks to the Court, don't speak to each other, and also, let's refer to each other always by last name and not first name. That makes the record clear and we need to stick with that formality as well.

With that, let me start by asking the lead counsel for the Plaintiffs who are going to be speaking today to please identify themselves.

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

THE COURT: Good morning.

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MS. LUHANA: Good morning, your Honor, Roopal Luhana for the Plaintiffs.

THE COURT: Good morning. When I say lead counsel, I don't mean formally. I know that Ms. Finken has been designated by the Court to be a co-lead and Ms. Luhana is, I think, the lead discovery lawyer by Court designation. I mean the people who are going to do most of the talking today. I understand there may be other lawyers who need to speak on both sides.

Obviously, anyone who needs to speak for the parties is welcome to speak, but for now, let me stick with the people who are going to do most of the speaking. So thank you both.

Let me turn to GSK. Who will be speaking primarily

for GSK this morning?

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MR. OOT: Good morning, your Honor, it is Patrick Oot for GSK.

THE COURT: Good morning, Mr. Oot. I understand Mr. Sachse will be joining us later today. I excused him, he had a very important other matter to take care of.

MR. OOT: Correct, your Honor.

THE COURT: I also understand, Mr. Oot, you have some other members of your team available if they need to be referred to and we'll do that. Thank you.

Let me talk for a second -- I spent a lot of time yesterday and today thinking about how to structure this hearing and conceptualize this hearing because I think it is a rather unique hearing that Judge Rosenberg has asked us to have here today. In one sense it is really a working meeting to get together and discuss some issues and try to resolve as many issues as we can possibly resolve today.

On the other hand, GSK's production isn't —
substantial production isn't due until May 14th, so there is
still time for them to complete that production, but given some
of the issues that have been raised and as a matter of case
management, given a lot of the other pressures that are
involved in a big case like this, Judge Rosenberg felt it was
very important that we get together today and try to close some
gaps.

What I am going to do in a second is go through my thought process and try to identify what I think the gaps are, what I think we can realistically try to accomplish today, how I think we might be able to get there, but then I want to hear from the parties if you agree, disagree, or think there is a better way to accomplish what Judge Rosenberg wants us to accomplish.

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Also, I will say this, Mr. Oot, in particular to you, I realize there may be issues that come up that you don't know the answer off the top of your head and your team on the call may not know the answer off the top of their heads, and you may need to either confer with your client or confer with other people. That is understood presumptively in this situation.

If you need to just say, look, can we table that issue while we check into it, or put that aside, or can we deal with that after the lunch break, I will certainly entertain that request from either side, but I expect primarily it might be from the Defense side.

I want to make you comfortable up front that that is a perfectly acceptable request to make of the Court. We want to get the information and if we need a little time to get it, I would rather get it and get it right than flounder and waste time doing other things. We have plenty of other work to do.

With that, let me talk to you, if I can, for a second about what I think we are here for, how we got there, and my

thoughts on how we go forward from there.

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Starting at a very high level of abstraction, like every other lawsuit, in this case the Plaintiffs have served a request for production. When a party in a lawsuit serves a request for production the responding party has a duty under Rule 26(g) to conduct a reasonable inquiry under the circumstances to try to identify materials in their possession, custody, and control -- now that I am painfully familiar with that concept -- documents in their possession, custody, and control that are responsive to the request, and/or then to lodge objections.

The objection being we shouldn't have to look because it is unduly burdensome or problematic, or there is some legal reason why we shouldn't even have to look, or we have looked and we found some things and they are responsive to the four corners of the request, but there are legal reasons why we shouldn't have to produce them.

At least so far in this case I have not received a formal PTO 32 objection to resolve with regard to these requests for production. So, I am going to assume at least right now there are no unresolved objections sitting out there.

As I mentioned in the order setting today's hearing, if there are legal objections that GSK is interposing we want to clarify that today, and I will set a separate PTO 32 hearing and allow the parties to fully prepare and brief and then we

will resolve those issues, but that's one of today's objectives, let's identify if there are any legal issues that need PTO 32 resolution.

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Actually, before I go to the next point let me step back a second. I did want the parties to be aware, obviously I did request from and received from the special master a copy of the relevant requests for production and the objections, so I did review those.

I did indicate to the parties through the special master that if there were particular documents that the parties thought would be helpful in guiding our proceedings today, that the parties submit those to me in camera. I did receive materials yesterday from the Plaintiffs. I received them either late yesterday or this morning from the Defendants.

I will tell you, I haven't looked at them. I did receive them, so I have them, but I understand there may be some objection to how and when and where we review those, whether they are in public or not in public. So, before I even looked at them I wanted to give the parties a chance to address any of those issues, but at least I have them. We won't have to go through the logistics of you sending them to me and trying to figure that all out. I just wanted the parties to be aware of what I have seen and what I haven't seen.

Going back to where I was, there is a request for production that has been served. GSK has represented they

conducted what they believe to be a diligent search to try to identify everything that they have that is responsive to the request for production. I have no legal objections right now.

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Now, conceptually, a reasonable search under all circumstances will not necessarily yield all the documents. There will be a gap. There will be a universe of documents that are called for by a request for production that are not uncovered by a diligent and reasonable search under the circumstances.

I think that a large part of what we need to talk about today where there is uncertainty in the lawsuit right now is, what is that universe, what is in that universe, and how much of that universe should the Plaintiffs be getting and when should they be getting it. I think that is a good way to think about it.

Now, I am going to use for purpose of discussion, and discussion only, the term "missing documents." That is not to suggest that they have gone missing, they have been spoliated, that anything bad has happened, but it is a good, in my mind, way to differentiate between the documents that have been produced — and I understand there is some issue we need to resolve about Plaintiffs' ability to identify what has been produced and cross reference it, and both parties' ability to really perhaps comprehensively wrap their hands around what has been produced, because until we wrap our hands around what has

been produced, we don't know what is missing.

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That is the differentiation I am making. I didn't want GSK to feel that if I use the term "missing documents" I am casting any aspersions on them.

So, there is, apparently, a universe of documents that have not been produced that the Plaintiffs have reason to believe are responsive. Okay. And there may be completely benign reasons why something falls into that category. It just doesn't pop up during a diligent search.

It also seems to me that if the Plaintiffs have now through other means identified documents that haven't been produced that fall within the request for production, if they really do fall within the request for production and there is no objection, then they ought to be produced.

That is something we should focus on here today, and this is where I need help from the Plaintiffs. I have heard kind of indirectly at some of the hearings how you believe and why you believe those documents exist, there have been some spreadsheets maybe. I think there was something that the record indicates may have been an attachment to an email that you have looked at. There may be some other indices I have heard about. I have heard about Medmark, I've heard about PIER, but I would like to get some clarity at the beginning from the Plaintiffs about exactly what is it that leads you to believe there are documents that you haven't gotten that are

responsive.

I also understand from the prior hearings that we have had — and this would normally be the way that one would resolve the issue of missing documents. The party, in this case the Plaintiffs, says, wait a minute, this is responsive, we haven't gotten it, would notify the other party. The other party would go and look and they would come back and either say, you are right, we have it, that is responsive, we'll give it to you, or you are right, it exists, but we don't think you are entitled to it.

There would be a dialogue and it would be -- I don't know if was Mr. Sachse or Ms. Finken who used this term, but it would be an iterative process. Plaintiffs find something, they tell the Defendants, the Defendants look for it, they report back. Maybe a week later, as the Plaintiffs are going through more documents, they find something else, they go to the Defendant, and we go through this iterative process.

My sense from what I was hearing at the prior hearings, and again, something I would like to get some clarity on today, is some of the stress and concern in this case is the volume of potentially missing documents, at least from the Plaintiffs' perspective, is so voluminous that an iterative process is not a meaningful process, and that the Plaintiffs don't really have enough information to engage in a meaningful iterative process, and if they do, it is going to take forever

and that is prejudicial to them for other reasons.

My impression from reviewing the transcript and remembering what Mr. Sachse was saying is, the Defendants' position is that universe of missing documents, they don't deny that there may be some, they just don't think it is as big as the Plaintiffs think it is.

Again, I think a big part of what we need to do today is get our hands around that, like what is in that universe.

GSK can again say, yes, those documents exist and either we have a legal objection, or we are getting to it, they are going to get it by May 14th, or we don't think we have to look for that, or they already have it, or whatever, but we just need to drill down on exactly where that leaves us.

So, in that regard -- I know we probably do at some level have to talk a little bit about how we got where we are, but I really don't want to focus on how we got where we are.

As Judge Rosenberg said the other day, and I think Mr. McGlamry and Mr. Bayman stressed, we are where we are.

As I've said many times, if the Plaintiffs believe there is some other legal remedy they are entitled to because of the way that we got to where we are, they need to raise that separately by separate motion and ask for whatever relief they think they are entitled to, and I will give GSK a full and fair opportunity to respond to that.

That is not today's project. Today's project is, how

do we get from here to May 14th in a way that everyone feels like they understand what is happening and they have a fair chance to get what they are entitled or to object to what they don't think they should have to produce.

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Okay. So, let me stop there for a second and turn to the parties.

Ms. Finken or Ms. Luhana, what is the Plaintiffs' position -- do you believe I framed it right, and do you think those are really the issues we need to address today? If you do, what is your thought on the best way to go forward?

MS. FINKEN: Your Honor, Tracy Finken for the Plaintiffs. I think that you articulated it perfectly on what needs to be done here, where the confusion lies, and our inability to determine what has been produced, what is still in the queue to be produced, and what they are objecting to produce, so that we can determine whether or not we have a dispute moving forward.

Given the May 14th deadline coming up in terms of the clinical studies and preclinical studies, that is a significant — we don't want to wait until May 14th to then have to spend months trying to sift through what has been produced and determine whether or not we have it, and we haven't been able to get a clear answer on what is being produced and what will not be produced.

I think you articulated it perfectly. Thank you.

THE COURT: Look, obviously, in a normal case I would have said and I think or Judge Rosenberg would have said, well, wait until they finish their production and then we can take a look at it, but I think the whole reason we are here is this is an MDL, this is a massive case, there are other deadlines.

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Again, this is not to suggest GSK has done anything wrong, but I think it is a way to monitor and move things forward.

Ms. Luhana, did you have anything you wanted to add on behalf of the Plaintiffs?

MS. LUHANA: No. Ms. Finken covered it. Thank you, your Honor.

THE COURT: Let me turn to Mr. Oot. What is your sense as to -- have I framed the issues correctly? Do you think there are other issues we need to address?

MR. OOT: Yes, your Honor, I would like to go back to something that you raised earlier. GSK requested that the conference be in chambers and off the record. We are all aware of corporate espionage related to the pharmaceutical industry, it has been in the news. So, our concern is rolling out infrastructure information related to GSK's systems in the public, on the public record, raises serious concern.

We are going to do our best to stay within the guardrails of not going too far about different systems and how they can interact at GSK. We request that the materials that

were submitted by both parties stay in camera and under seal if necessary just so we protect against those types of issues.

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Also, another point that you raised, your Honor, we have done our best in 24 hours to bring the right people to the table here. We brought our science counsel, we brought people that are familiar with GSK systems. As you pointed out, your Honor, we may need to take a break or call our client if we need to get some answers, but I do think it would be helpful to get to a point where we are focused on a basic Federal rules approach.

We see this as, you know, exactly how you see it, your Honor, is that there is this 26(b)(1) request, we make our objections, and then we are focused on our 26(g) reasonable inquiry here.

objection to discovery on discovery. We are kind of really down in the weeds, so to speak, in what could be potential work product and what GSK has done to respond to discovery, but that said, we are being transparent, we are being cooperative. We just want to make it clear that GSK would traditionally object to discovery on discovery. I think the case law is in our favor. I could give a couple cites if it would be helpful to kind of run through it.

The bottom line is, we have acted in good faith and we have been transparent in our discovery efforts and the entire

team has really put in a significant amount of effort.

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Getting back to that Federal rules based approach with, again, the 26(b)(1), 26(g)(1)(B) focus, I think it would be helpful to get the Court's guidance on the scope issue because I think we are on the fringes of where our objections have been in the past.

Your Honor, in our prior hearing I think you said the core liability issue in this case is general causation and knowledge, does Zantac cause cancer; and if so, does GSK know or should have known about it. Some of the studies that are being requested from these PIER reports are just so far out there, and our science counsel can probably talk better to it than I can. We are expending a lot of energy to focus on things that probably don't matter.

So, relevance can't be speculative. The request must be related to a specific element of a claim. Sometimes I look at the jury instructions to see what are the elements of this claim and how does that piece of discovery relate to the elements of that claim.

Again, we can get more granular on some of these requests related to studies, but we have our existing objections, we have been cooperative. We have made reasonable and good faith efforts to locate these documents, and on top of it all, we have even been transparent about it.

Ms. Finken and GSK provided the reports that science

counsel used, our firm as well as Dechert, used to go through and identify the things that could reasonably in good faith lead to discovery. So, we gave those materials to Plaintiffs, and we can talk about this a little more when we get to the actual spreadsheets. We gave them the tools that we used to locate the documents.

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Right now, as you pointed out, your Honor, Plaintiffs have not challenged any of GSK's objections and we are left in this discovery dispute drip campaign that is really kind of wearing everybody out.

I think that this hearing will be really helpful if we can get back to the three pillars, which I think are the efforts GSK made in identifying the repositories, the efforts and burden GSK has undertaken identifying the documents, and then also one thing that I don't think you raised, your Honor, is the transparency in process that we provided the Plaintiffs.

THE COURT: Let me break that apart a little bit because you raised a couple of things that I need to address.

Is GSK objecting to this hearing on work product grounds, yes or no?

MR. OOT: No, your Honor. Right now -- well, at this point, it depends how far we get into discovery on discovery, but right now we want to get this hearing done and we want to be transparent. We want to move on to the merits. So, no, your Honor.

THE COURT: Because if you are lodging an objection, I will rule on your objection. If you are not lodging an objection, then you are waiving your objection. So, if you want to object to particular questions or particular issues as they arise, be very clear about it, but I am not accepting a general, we object to discovery on discovery, but we will go ahead with the hearing today.

I need GSK's position. The question is, we are not lodging a general work product objection, we are not objecting to any discovery on discovery, but we want to be able to make individualized objections if they arise during the hearing? I will hear you on that.

Is that what you are saying?

MR. OOT: Yes, your Honor.

THE COURT: Very well. You said you lodged objections. No one has brought any objections before the Court to these requests for production. I don't know whether that burden should have fallen on the Plaintiffs or GSK, but no one has brought those before me, and I am not — if that is going to be — I will put it this way.

If you are raising those objections today, if in the course of our discussions we start to talk about categories of documents that you believe you either don't have to produce or don't have to go look for, then I need you to make that clear on the record and, as I have said, we'll set a separate PTO 32

hearing in the very near future and I will resolve those objections. I want to make sure you reserve those objections, but assert them today, please.

MR. OOT: Yes, your Honor.

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THE COURT: Also, in terms of the confidentiality or not of documents, I did receive a request through the special master to consider whether to seal this proceeding. I looked at the case law, and my reading of the relevant Eleventh Circuit case law is that I can't seal this hearing in total. I will put the cites on the record in a second.

The Eleventh Circuit is pretty clear that there is a public right of access to judicial proceedings, and I think in a nationwide multi-district litigation involving a drug that has been on the market for 40 years where on any given day I can turn on the television for an hour and see four advertisements talking about this lawsuit, I would think the public has a substantial interest in every proceeding in this case. I think Judge Rosenberg has made that clear.

The Eleventh Circuit has said and the Supreme Court has said that sealing of a courtroom or nonpublic proceedings are the limited exception, not the rule. In particular, "that presumption can be overcome by a showing of good cause by a party." This is Newman versus Graddick, 696 F.2d 796, Eleventh Circuit, 1983, as well as Romero versus Drummond Company, 480 F.3d 1234, Eleventh Circuit, 2007.

Certainly a showing of good cause would include a party's legitimate privacy or commercial interest.

I hear you on that, Mr. Oot, and it is not my job or my goal here today to force GSK to put out anything that does not need to be out here.

If we get into a discussion of particular systems, I think there is a difference between saying this is the name, this is the details, this is where we keep it, this is how we search it, versus simply saying we have a segregated database that only contains science studies, or we have a general database where we keep all of our ANDAs.

You can certainly keep it at whatever level of abstraction you believe is appropriate, and if we need to drill down past that, then we'll address that issue and you can at that point raise the question of whether that ought to be on the public record or not.

Okay?

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MR. OOT: Thank you, your Honor, we agree.

THE COURT: Very good. Let me start, Ms. Finken, I think -- I guess there are two things we could take up first. The first thing we can take up is how do we figure out what the Plaintiffs have, or we could take up the question of the Plaintiffs have obviously looked at some -- I will call it extrinsic evidence outside -- or within the production, and from that reached an inference that there are missing

documents.

I think I probably want to take up the second one first, but I will leave it to you, Ms. Finken, which one you think is more productive to take up first.

MS. FINKEN: We can take up the second one first, that's fine, whatever your Honor would prefer. I think that is one of the critical issues that we need to determine, so I am fine with taking that up first.

As your Honor has heard from us multiple times over the past few months, we located in the document production, it was not produced to us by counsel, so to speak, it was in the general document production, a couple of spreadsheets that are index — that are indices.

One is a PIER index which your Honor has heard about quite a bit from me and Mr. Sachse over the past couple of months, and the other is this newer spreadsheet that we located in the production that is a Medtrack spreadsheet, and that spreadsheet contains human clinical trials.

The PIER index spreadsheet contains a mishmash of all different types of things, human clinical trials, animal studies, analytical testing, laboratory notebooks, stability testing, safety reports, chemistry testing, analytical testing, quite a bit, degradation, impurity profiles, and the list goes on and on. You have a copy of that spreadsheet, we gave it to you in the materials, that you can look at.

There are over 23,000 entries on that spreadsheet.

THE COURT: Let me stop you there for a second.

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Are those -- Medtrack and PIER, is it your impression that they are independent data sources or that they are like interlocking circles, that there is some information that is in both and some that is uniquely in PIER and some that is uniquely in Medtrack? Do you have a sense of that?

MS. FINKEN: My understanding, and I am sure Mr. Oot will correct me if I am wrong, is that the — this is what I have been told anyway verbally, the Medtrack data source is solely a repository of information or a dashboard of information that tracks all of the human clinical trials that were done, but it doesn't actually contain the documents. It is not a database that contains the documents, but it is a tracking, for lack of a better word, a tool that they use to track all of the human clinical trials.

THE COURT: It's like a card catalog or an index of some kind?

MS. FINKEN: That is exactly how I described it, and maybe Patrick can give some insight into exactly what that is, but that is what I asked, if it was a card catalog.

THE COURT: I will turn to Mr. Oot in a second. Your understanding is that GSK has somewhere in its files, somewhere in the universe of material that GSK has, they have these human trials, animal trials, lab notebooks, and all the other things

you just mentioned, and that Medtrack is a tool that can point you to what they have.

So, if I wanted to know what is everything GSK has, I could go to Medtrack and it would tell me here is the human clinical trials for Zantac, here is the human clinical trials for some other drug that they have done, here is this, here is that, here is the other thing. Some of that information may fall in PIER, some of that may fall in other databases, some of that may be elsewhere.

MS. FINKEN: That is my understanding.

THE COURT: Let me stop you there and let me turn to Mr. Oot. I hope this doesn't intrude too far into GSK's proprietary data structures, but can you at least clarify, are we all talking about the right thing here?

MR. OOT: Just a point of clarification, your Honor. Patrick Oot for GSK.

Medtrack, I wouldn't call it a card catalog because a card catalog gives you a Library of Congress number to go and run that book down. I would consider it kind of a project management tool or a list of studies. It is not comprehensive, it is just a list of studies that were being worked on at some point in time, so it is a list.

So, what is happening right now, during this hearing even, is we are taking that Medtrack list -- as we promised in the last meet and confer with Ms. Finken and Special Master

Dodge, is that we would go back to the production and search the production and locate the Bates numbers for the studies that are in the Medtrack report. I understand that might be over to Ms. Finken today, but that is the work that we are doing related to the Medtrack report.

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If it would be helpful, your Honor, I could talk to the PIER issue, too, or we --

THE COURT: Yes, before we leave that one behind, I just want to make sure, and I don't know if you were being precise and careful or whether this is just a term that everyone uses, but you said you are going to check the Medtrack database for the studies. Ms. Finken described a whole bunch of other stuff that she said were not studies, notebooks, testing, and safety reports.

Were you making a differentiation among those or are you saying we are going to search Medtrack database for anything that would be responsive to the request for production?

MR. OOT: Let me correct you, your Honor, I apologize. We have a list, this project management tool for Medtrack, it will give us a list of studies that are being worked on, studies that could have been started or a study that could have been canceled.

So, we take that list, and again, we don't have that Library of Congress number to go and run down the actual study

itself, but we can conduct a search in our document platform, just as the Plaintiffs can, to use key word search terms, other things, to try and locate the Bates identifiers for those studies that we can provide to Ms. Finken. So, when we talk about Medtrack, it is not a true repository where it contains information.

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Finally, your Honor, to answer your question related to does it contain other things, I understand it is just, again, a project management tool that is used to track the clinical studies.

THE COURT: Let me break that apart. This is very helpful to me.

I think as I may have told the parties, my mother used to work for a company that prepared new drug applications, so I am a little familiar with how clinical trials work. No one involved in this lawsuit, and she is long retired, but nevertheless.

So, my understanding — and it may be that these things that Ms. Finken is talking about, the human trials, the animal trials, lab notebooks, stability testing, safety reports, degradation reports, things of that nature, they don't live an independent life, they live within a particular study.

GSK decides we are going to conduct a study today of whatever -- Spalding, I am familiar with Spalding from the recent work that I have done. We are going to do a study on

whether diet affects NDMA production in the body. That is the study, this is what we are going to look at, and then that study comprises human testing, possibly animal testing, there are test results, there's whatever analysis comes out of it, then there is a final report, maybe a published report or an abstract.

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First of all, conceptually, am I correct, Mr. Oot, is that how these pieces all fit together, there is a study and then within that study, Medtrack might contain references to the global study, but also to the component pieces?

MR. OOT: Correct, your Honor. It might be helpful to also read our supplemental ESI disclosure related to the Medtrack system because it is no longer in production, that information has been put into a different production system.

THE COURT: But again, what is helpful to me is this.

Ms. Finken said there are 23,000 entries in the Medtrack

database. It may be there are only a hundred studies, and it

just means that there is a hundred studies and each one of them

has 230 component pieces. Now, that doesn't mean the

Plaintiffs don't get all the component pieces, it just may be

that in the hundred 23,000.

Am I understanding that correctly? Let me ask Mr. Oot first. Can you respond to that?

MR. OOT: Sure. I think perhaps you might have misunderstood, your Honor. The Medtrack system does not

contain the 23,000 hits. This is just a list of what I understand to be -- I would say --

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THE COURT: Let's say the Medtrack system has 23,000 entries.

MS. FINKEN: Your Honor, can I interrupt you just for one second? Because I think I can clear this up really quickly.

You are referring to the PIER index. The PIER index is the one with the 23,000 entries that has all those different pieces. The Medtrack is solely 764 entries with human clinical trials listed.

THE COURT: Okay. To your understanding, Ms. Finken, those 764 human clinical trials, were they incorporated into the studies that are in the PIER database, or do you believe those to be free-standing studies, or you don't know?

MS. FINKEN: I don't know.

THE COURT: Is that the issue that Mr. Oot is now running down for you, those 764 human clinical trials, were they produced through the PIER database or have they not been produced through the PIER database? Is that an open question?

MS. FINKEN: I think what Mr. Oot was saying -- and I apologize, your Honor, for interrupting. I think what Mr. Oot was saying is that he is taking the list of 764 studies from Medtrack and running them through the production that they have done to provide us with the Bates numbers of what has been

produced versus what has not been produced.

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And correct me if I am wrong, Patrick, but that was what I understood you to be saying. Is that correct?

MR. OOT: Correct. I understand there are 762 lines and 165 are related to Tritec and 30 are related to other products. But, yes, that is what we have asked the team to do since that came up last week, and we agreed to provide that to you in the meet and confer.

THE COURT: Okay. So, the Medtrack database at least references 764 human clinical trials and there is a process ongoing between the parties right now to determine how much of what is referenced in the -- not in the database, but they are referenced in the database, how many of the 764 studies referenced in the database have already been produced either from the PIER database or from other sources.

Am I correct that is an ongoing process? Ms. Finken, is that correct?

 $\it MS.\ FINKEN:$ I believe that is what he is representing, yes.

THE COURT: The idea, I guess, when that process is over the Plaintiffs will know you many you have, 700 of them, and here they are, or you only got 200 of them and here they are, and then the Plaintiffs will know what they didn't get. That is the end goal of that process. That seems like a very positive step to me.

MS. FINKEN: And hopefully identifying whether or not they are going to produce the remainder or not.

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THE COURT: That was my next line of questioning.

MS. LUHANA: Judge, this is Roopal Luhana for the Plaintiffs. One point that you raised that is important to recognize is that we want to know not only the study report, but whether the underlying data, the exhibits, the appendices are also being produced.

THE COURT: That is a good point. We will get to that in a second. Okay.

Before we leave that behind, let's take this one box at a time.

Mr. Oot, when do you believe you will be able to finish that process and get to the Plaintiffs at least the listing of what you believe has been produced from -- what is referenced in the Medtrack database that has now already been produced?

MR. OOT: I understand the team is working on that right now, your Honor, and I am hoping to have an update on that later today. We might have the whole thing. I should point out not every one of those entries is going to have a value because some studies were canceled, some studies didn't start, some concluded, some have a report, some don't. So, we will indicate that in the response, but we hope to get that back to Plaintiffs before the end of the week.

THE COURT: Okay, great. I take both Ms. Luhana's point and Ms. Finken's point as well. Let's assume -- you can let me know by the end of today when you will have that to them, but it is presumably going to say there are some number of these studies that you already have and you in full or you can't tell if they are in full. There is some number you don't have.

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So, then the next question is what Ms. Finken started to raise, and maybe GSK doesn't know the answer to this until you finish this process, but is GSK going to agree to produce the delta or is GSK objecting to producing the delta? I think that needs to be the next step in that process.

So, how much time after GSK produces the list will GSK be in a position to say we have now looked at what the delta is and we either agree or disagree about producing it?

MR. OOT: Your Honor, I don't think it is a question of whether we will agree or disagree to produce them, we, obviously, have to see what the studies are.

The issue is, have we done a pencils down 26(g) search to locate them and not located them, and it is not an issue of whether or not we would agree to produce them. It may be an issue where we would agree to produce those studies, but we looked and we expended a tremendous amount of effort to locate them, but did not find them.

So, I think the question might be: Would we agree to

search for them? And I think the answer most of the time is going to be yes, barring some circumstances where the study might be outside of the scope, proportionality, 26(b)(1), but the issue really does come up and kind of pivoting to the overarching extent of our search under 26(g) and how it did not locate the study, and then how do we move forward when our search does not locate what is on the report.

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THE COURT: I get it. Look, you are right, you have to do a reasonable study under 26(g), but I think once the Plaintiff points you to something that is responsive to the request for production, you can't just say, well, we didn't find it in our studies so we don't have to keep looking. You can say we object to keep looking because it is unduly burdensome, disproportionate, overly expensive, we will do it, but they have to pay for it.

So, when I say will you agree to give it to them, I wasn't saying it is a binary, either you give it to them or you don't. What I meant is, will you either — of the delta that we are talking about, it seems to me GSK has a couple of responses. One is, we don't think we should have to look for it for legal reasons, we have an objection, we don't want to look for it, or we'll look for it, and if we find it, we will give it to you, or somewhere in between the two.

What I am suggesting is, I think GSK needs to make that clear what their position is when they respond, it is to

say, look, we have given you everything and we are not looking anymore, we think it is disproportionate, we have done enough, and you come to me on a PTO 30, and I will rule on it. That's fine. Maybe between now and May the 14th you will come to some resolution of that. I don't know.

My point is, in the interest of the clarity that Judge Rosenberg is looking for, I just think it is helpful to everyone, both the Plaintiffs and GSK, to know, okay, there are 112 studies out there which GSK is objecting to looking for, or there are 112 studies out there and GSK says 50 of them we are going to go find and we will give them to you, and we're not going to look for the rest, or we can't find them, or we'll only look this far, or whatever. We just need to know are you looking or have you stopped looking, and if you stopped looking, what is your objection, and then I will rule on it.

At least then Ms. Finken and Ms. Luhana are not bothering you, and Mr. Sachse, every day going, well, what about study number 93, and you say, we already told you, we are objecting to that.

That is the clarity I'm looking for. Understood?

That is what I am going to order GSK to do. Once you provide whatever the first level response is, you have identified the differential number of studies, within -- I don't know, you may all talk about what a reasonable period of time is thereafter for GSK to figure out, maybe these are easy to find, maybe

these aren't, but within a reasonable period of time, not to exceed 72 hours, I want GSK to tell the Plaintiffs either we are objecting, we are not objecting and here's what we'll do. That's how I'm going to deal with that delta.

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I will leave that aside for the time being, and perhaps, Mr. Oot, as we move through the day, as you get more information from your team, if you can let us know when you will get that information to the Plaintiffs then we can nail that down.

Having said all of that, it seems to me, Ms. Finken, Ms. Luhana, I don't know that I need to delve into that today, have Mr. Oot on the phone with people in London saying where is study number 73, 74, 75. Do you agree, Ms. Finken?

MS. FINKEN: I agree. You summed it up precisely what we have been requesting, precisely that is what we are requesting.

THE COURT: The Court needs to know that. If there is a legal objection, they are entitled to make a legal objection, but the Court needs to know that and then the Court will rule on the legal objection. Then the Plaintiffs will stop focusing on getting the records, they will focus on responding to legal objections, but that's fine. We just need clarity, that is what Judge Rosenberg wants.

So, we have clarity now at least on, in my view, the Medtrack index and the ongoing search of the materials that are

referenced in that index and how we are going to deal with whatever materials have not yet been produced.

Agreed, everyone?

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MS. FINKEN: Thank you, yes.

THE COURT: Any objections, Mr. Oot, or any thoughts on that?

MR. OOT: No, I think that process makes sense, your Honor, to get to the specific studies that the Plaintiffs are interested in so we can call balls and strikes.

THE COURT: Good, I can put Medtrack aside. Ms.

Finken, I know you in your prior comments mentioned something about animal studies. Have I now dealt with that at least as it is referenced in Medtrack?

MS. FINKEN: Medtrack doesn't deal -- as far as I am concerned, I don't think it deals with animal studies, it's only the human clinical trials.

THE COURT: I am putting Medtrack to the side. I am determining we have dealt with that as much as we can today, other than to get a report back from GSK at the end of the day as to when they expect they will provide that information to the Plaintiffs.

Let's shift over to the PIER database then, Ms. Finken. In part, I am focusing on you and Ms. Luhana rather than Mr. Oot because it seems to me if you know it, it's not a proprietary secret and doesn't put him in the position of

waiving work product or other things.

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What else have you seen that leads you to believe that there are materials in the PIER database that are responsive to your request for production, but have not yet been produced?

MS. FINKEN: So, your Honor, we have provided you with a copy of a spreadsheet, it is listed as the full PIER -- this is our title for it just so you can differentiate the different spreadsheets. We have it listed as the full PIER index, it ends in Bates number 193 --

THE COURT: Hold on one second. I am now looking at that. For purposes of the record, why don't we mark that as Plaintiffs Exhibit 1 for purpose of today's hearing. I am going to reserve ruling about whether any or all of the exhibits should be under seal.

I don't know that -- if you need to talk about specific entries, we probably need to address that. I can see what is in here and what the columns are, so if you want to talk more generically about the general information if that informs your answer to my question.

 $\it MS.\ FINKEN:$ I think so. So, there is this index that we found in the production back in late January.

After we found that, we brought it to the attention of GSK. They provided us with a separate spreadsheet that you have that is entitled GSK PIER request. It is dated February 23, 2021.

 $\label{eq:THE_COURT:} \text{We will mark that Plaintiffs Exhibit 2.}$ It is called --

MS. FINKEN: PIER request, February 23, 2021.

And that spreadsheet, as your Honor can see, has approximately 23 -- 2,373 entries.

THE COURT: Okay. I see that.

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MS. FINKEN: It was represented to us that that spreadsheet, they were PIER indices -- or PIER accession numbers that were attributed to those documents that had been pulled, retrieved, and were in the review process for production. We were also told that GSK was continuing to search and look at the PIER indices for other responsive material.

After that, we were provided with yet a third PIER spreadsheet, which you also have, and that one is entitled Zantac PIER items de-duplicated against production list, and it is dated March 4, 2021.

THE COURT: I see that. We will mark that as Exhibit 3.

MS. FINKEN: GSK provided us with that as an updated spreadsheet. There wasn't a lot of information given to us about that particular spreadsheet until I saw some information in the materials that were sent to your Honor last night.

So, our understanding was that this was an ongoing process, that GSK was still pulling PIER documents, reviewing

them, looking for responsive material. Recently, in the past, I would say two weeks, week and a half, we were discussing information from our review of the big PIER index, Exhibit A, that we were not able to locate in the production, specific animal studies that we were looking for that were on the PIER index, but we couldn't find in the production.

During the course of that discussion it came to light that the 2300 entries, 2373 entries were the only ones that GSK was pulling, reviewing, and producing.

THE COURT: Hold on. That is exhibit --

MS. FINKEN: B -- or 2, yes.

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THE COURT: I got it. Okay.

MS. FINKEN: We had been questioning the methodology on how they were determining which accession numbers they were pulling for review, responsiveness review and production. We still don't have an answer to that today because from Exhibit 1 to Exhibit 2, it is only approximately ten percent of the spreadsheet they were looking at to be produced.

If you look at Exhibit 1, which is the full PIER index, there are a lot of — there is a lot of material in here, and the large majority of it pertains to Zantac or Ranitidine, or it might use the compound number for Ranitidine and Zantac, which is H19065, or it might use the compound number for Tritec, which is a Ranitidine containing product, just so your Honor is aware if you hear that term, which is GR

 $1 \ -- \ GR \ 122321$, and I am doing that off the top of my head. I believe that is what that is.

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Or you might see something that says H2RAs or H2B, which means histamine receptor antagonist or histamine receptor blockers. There are different acronyms that they use relating to Zantac and these types of products.

So, we are trying to determine how they decided which accession numbers they were pulling versus which ones they determined not to pull.

The same with laboratory, there are tons of laboratory notebooks in here, and when you look at them, it is a small subset that they pulled to produce and there are a whole bunch of laboratory notebooks with numbers, just numbers, that we can't tell what they pertain to or don't pertain to. We can't understand how they decided what numbers to pull and not pull.

Form our perspective, looking at the spreadsheet with all of this information, most of it seems like it would be responsive material. So, we are trying to come to grips with the methodology that was used to decide what ten percent of that spreadsheet they decided to pull and review.

The other piece of this puzzle, too, is that this spreadsheet was in a custodial file of an upcoming 30(b)(6) witness by the name of James Harvey.

THE COURT: Hold on. When you say "this spreadsheet" you mean Exhibit 1?

MS. FINKEN: Yes, Exhibit 1 was in a custodial file of somebody they have identified they are producing for a preclinical/clinical 30(b)(6) deposition. He had requested this information from their archivists.

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So, for purposes of this 30(b)(6) deposition and this individual who requested all this material and this spreadsheet was attached, it is relevant. He is obviously reviewing it in relation to Zantac recently, in the past year, and he is going to be questioned about the preclinical and clinical studies, so, from our perspective, it is relevant to that deposition and it is relevant to the case just by looking at the descriptors in the titles of the documents.

So, we are trying to really come to grips with how they decided what to pull, how they decided that they weren't going to pull the rest of it, and the response has been, you go tell us what you want and then we will talk about it.

But we can't really tell from these descriptors what it is, we can only tell that it looks relevant, it looks responsive, but that is it. We can't really tell what else it contains, what information it contains.

THE COURT: I hear you. Let me stop you there for a second. Help me out with one thing.

What is -- I am trying to understand -- I understand what Exhibit 1 is, and it looks like -- what is the relationship between Exhibits 2 and 3? I think you lost me.

MS. FINKEN: Okay. Exhibit 1 is the full spreadsheet, Exhibit 2 is all GSK has agreed to pull, review, and produce.

THE COURT: And Exhibit 3?

MS. FINKEN: Exhibit 3, Mr. Oot is probably going to have to let you know. My understanding, after reading the submissions from yesterday, is that it is just a de-duplicated list that they are not agreeing to pull, review, and produce.

THE COURT: A de-duplicated list of Exhibit 1 because it is longer than Exhibit 2.

MS. FINKEN: I don't think it is a de-duplicated list
of Exhibit 1.

THE COURT: Let me turn to Mr. Oot. If you could start, just tell me what the documents are, then obviously I'll let you respond on the merits that Ms. Finken raised.

MR. OOT: Sure, your Honor. Exhibit 1 is, again, as Ms. Finken pointed out, in the custodial file of one of GSK's witnesses. It was an initial pull that was used for the regulatory response in the EU to identify documents, so it is not that every document on that list is relevant. In fact, a refined list of documents was pulled out for that response which Plaintiffs received.

In addition to that, the work that GSK did -- and when I say GSK, we'll say GSK counsel, GSK science counsel, representatives from Dechert and Shook Hardy, representatives from Womble, who is another outside firm, all reviewed these

lists to make reasonable and good faith efforts under 26(g) to identify the things that would be worthy to pull back for a deeper analysis.

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As you remember from our discussions, your Honor, about PIER, one entry in a PIER reference is a reference potentially back to dozens of boxes or dozens of documents. It is not a one-to-one ratio. It can be one to one, but it is usually one to many.

So, for that we took a reasonable and good faith effort to go through those materials. We also went through the -- for belts and suspenders did it, sort of an additional request and identified documents above and beyond what were identified in the Jim Harvey spreadsheet and provided that whole list of here is everything that GSK pulled back from this PIER list.

We had a meet and confer that Special Master Dodge was at in February, and Plaintiffs agreed that they would identify documents on these lists that they were interested in to pull back, it is even in Ms. Luhana's notes, and we haven't received any of those requests back so we can assess whether or not it is — back to your original question, your Honor, it is worth the effort to go and seek documents that are on the master list. Not every document on the master list is going to be relevant.

If that is the position that Plaintiffs are taking, I

think that is probably something that we should set up for a hearing. I think it would a better approach for them to identify for us, as we asked in February, the specific requests for PIER pull backs that we would have to consider.

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We are still under the same constraints that we were in, that the pull back is limited, we have staffing issues, it has to get pulled back, has to go to specific scanning vendors, and it is a herculean effort to pull information out.

So, I think it would be really helpful for us if the Plaintiffs identify those specific things that they think are within the scope of discovery that they are asking for us to pull back. If it is everything, your Honor, I don't think that that is sustainable.

THE COURT: Okay. Thank you. Help me out on a more simplistic level. What is exhibit -- I heard what Ms. Finken said she thinks it is, but it is your document so I want to make sure I give you a chance to tell me. What is Exhibit 2, which looks like -- the 2,370 line spreadsheet, what is that?

MR. OOT: That is the list of items identified by the team, as I discussed earlier, your Honor, that was pulled back and items that, after looking at the list, we said, okay, this looks like it could be potentially in scope for review and analysis and worth the effort to pull out of the archives and conduct document review on.

So, that is the refined list from the -- I guess what

is called Exhibit A, the master list.

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THE COURT: Okay. And what is 3, the de-duplicated, what was de-duplicated? That's what I'm confused about.

MR. OOT: Let me get this right. It is the set considered by counsel that was not on the PIER list that appeared in the custodial file production. Exhibit 3 is information that we considered, as counsel, that was not on the original Exhibit 1.

MS. FINKEN: So it is more PIER entry --

THE COURT: Hold on, Ms. Finken, please do not talk to each other.

MS. FINKEN: Sorry.

THE COURT: Exhibit 1, as I understand it, was Mr. Harvey asked for a pull from the PIER database of some universe of documents. Counsel for GSK went through 1, Exhibit 1, and using its professional judgment, and whatever other filters it wanted to use, distilled down that what is now in Exhibit 2 is what should really be brought out of archives and you say pulled back, I assume pulled out of the archives and reviewed, processed, and produced as responsive.

Am I with you so far?

MR. OOT: Yes, your Honor.

THE COURT: Is 3 -- if I heard you right, 3 is documents that were not in Exhibit 1, but that were otherwise identified in the PIER database? Did I hear you correctly?

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              MR. OOT: Correct, your Honor.
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              THE COURT: So, that is in addition to what is in
     Exhibit 1.
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              MR. OOT: Correct.
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              THE COURT: Are the items in 3 items that have been
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     produced, are in production, or were further distilled down?
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     What is the status of the 4,079 items in Exhibit 3?
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              MR. OOT: I'd have to cross check that against Exhibit
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     2, but I don't know the answer to that, your Honor. I think
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     those were, again, items that were considered by counsel that
     were not on the original Harvey list, and the original Exhibit
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     1 was -- it was just the first list that Mr. Harvey used to
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     consider what Mr. Harvey was going to pull back from archives
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     for the earlier inquiry.
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              THE COURT: I need you to dispatch somebody on your
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     team to get me the answer to that question.
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              Have the items in Exhibit 3 been produced, is there an
     objection to producing them, or are they in the process of
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     producing them?
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              MR. OOT: I am getting an email right now, your Honor.
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              THE COURT: Okay. Thank you.
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              (Pause.)
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              MR. OOT: I am getting this in real time. Exhibit
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     2. --
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              THE COURT: Exhibit 3.
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MR. OOT: Exhibit 2 is what we agreed to produce. Exhibit 3 contains everything else that was considered that wasn't on the Harvey list, so there isn't a primer in Exhibit 3 that would say this is what GSK agreed to produce, or agreed to pull back and review from the archives.

THE COURT: That is the relevant piece of information because, again, the Plaintiffs are going to look at this and go, did we get, did we not get, are they objecting to producing. We need clarity from GSK about what is the status of the items in Exhibit 3. Are they responsive, are they not responsive, were they reviewed, are they being produced? What is going on with those documents?

That needs to be resolved.

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MR. OOT: Your Honor, we can de-duplicate, I guess, Exhibit 3 from Exhibit 2 and see what else is out there, but as for Exhibit 3, the reason we provided that refined list, it was additional information beyond Exhibit 1 that counsel considered for production, if that makes sense. I understand what you are asking.

THE COURT: I am confused by your answer.

What you are telling me is Exhibit 3 is not in Exhibit 1. Exhibit 2 is a subset of Exhibit 1. So, running Exhibit 2 against Exhibit 3 is going to give you an empty set.

MR. OOT: So, Exhibit 2 is an extraction from Exhibit 1 and Exhibit 3, if that makes sense.

THE COURT: That is not what you just told me. You told me Exhibit 2 was a distilled version of Exhibit 1, and Exhibit 3 was items not in Exhibit 1. I am confused by your answer. Which one is it?

Are the items in Exhibit 3 in Exhibit 1 or not in Exhibit 1, in whole or in part?

MR. OOT: Correct, your Honor, the items in Exhibit 3 are not in Exhibit 1.

Exhibit 2 is the list of information that GSK counsel pulled back, so the cross check I guess I would have to make is the status of what happened in Exhibit 3, because Exhibit 1 plus Exhibit 3 equals the information that GSK's counsel considered for pull back and review that created the list for Exhibit 2.

THE COURT: Okay. Now what I am hearing is Exhibit 2 contains some items that came out of Exhibit 1 and some items that came out of Exhibit 3, but Exhibit 1 and Exhibit 3 are non-overlapping sets, correct?

MR. OOT: Correct.

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THE COURT: Okay. Then there is a separate complimentary set within Exhibit 3 of items that are in Exhibit 3 that were not produced through Exhibit 2, and there is a separate complimentary set in Exhibit 1 of items that are in Exhibit 1 that have not been produced in Exhibit 2, correct?

MR. OOT: Correct. When we say the word "produced",

your Honor, Exhibit 2 is what GSK considered for pull back and analysis, not necessarily what it was agreeing to produce, just to clarify.

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THE COURT: To clarify, then, there are items in Exhibit 1 that GSK counsel made the decision not to even review, and there are items in Exhibit 3 that GSK's counsel made the decision not to even review, correct?

MR. OOT: Made the decision not to pull back and review, correct.

THE COURT: Was that decision made based upon a legal objection? What was the basis — how did you determine, for example, that notebook 7639 didn't need to be pulled back; was it determined it was not relevant, or it's disproportional, or it's unduly burdensome, did you lodge that objection? Did you tell the Plaintiffs that?

MR. OOT: What was identified, your Honor -- again, I could describe the process that GSK counsel went through the exhibits with science counsel to really identify the documents that would relate to the scope of this litigation, which is causation.

So, again, we gave Plaintiffs the very same tools that we were using to lodge our requests for extraction from the archives, so we just made reasonable, good faith judgments on how GSK was pulling these documents back from PIER.

THE COURT: I will break that apart in a second. In

terms of what was communicated to the Plaintiffs, were the

Plaintiffs told that there is a whole bunch of stuff in Exhibit

3 that we didn't even pull back and look at, we just made the determination we weren't going to do that?

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MR. OOT: Can you repeat the question, your Honor?

THE COURT: Sure. Were the Plaintiffs given the information that I was just given, which is, there is a whole bunch of stuff in Exhibit 3 that GSK has decided we are not going to even pull them out of the archives and look at? We are just going to give them the lab notebook number and we are going to make the determination that we are not going to provide that. Were the Plaintiffs told that?

MR. OOT: No, your Honor, but they were given the list of information that we agreed to pull back and review in Exhibit 2.

THE COURT: But were they given the list of items you didn't agree to pull back?

MR. OOT: Well, that would be Exhibit 1 and Exhibit 3.

THE COURT: Exhibit 1 they got because they found it attached to an email, so that wasn't given to them as an identifiable item. What about Exhibit 3, was that given to them as an identifiable item or is that something they also had to find in the production?

MR. OOT: No, that was work product that we put together to -- the goal of Exhibit 2 and Exhibit 3 was to

refine the list and identify to them what GSK considered for pull back, and then what -- in Exhibit 3, what GSK considered for pull back that wasn't on their list.

THE COURT: How would I, if I'm the Plaintiffs, look at Exhibit 3 and know whether I need to look at laboratory notebook 13463?

MR. OOT: If it is not on Exhibit 2?

THE COURT: Right.

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 $\mathit{MR. OOT:}$ That is the same information that we have, your Honor.

THE COURT: I understand, but what you are telling me is you said to them, we will give you a list, and if you want us to review any of this, you can go through the list and -- you can go through Exhibit 1 and you can go through Exhibit 3, and if the Plaintiffs want us, they can make a request that we go look at lab notebook 420, and then we'll make a decision whether we are going to do that or not.

Isn't that what you are suggesting to me as what we should be doing here? The Plaintiffs should take on the burden of going through Exhibits 1 and 3 and telling you what they want you to go look at and then you will make the decision whether you are going to object to what you are going to look at. That is the process you suggested to me earlier, did you not?

MR. OOT: No, your Honor. The process is, we

conducted our inquiry under 26(g), and we identified the set that we were pulling back under the rules in our reasonable and good faith approach. The Plaintiffs raised the issue of these additional items for PIER, and the question now becomes are there additional things that Plaintiffs want pulled back, and we have been transparent about that and we have had the discussion with them about that, so I don't think we are shifting the burden in any way. The purpose of it is to push forward the dialogue.

Again, if the issue is that we really need to raise the dispute of what the scope of the search is, perhaps that is -- you know, that is what we need to discuss, but we have been kind of open and transparent and given Plaintiffs the same tools we have to make those calls.

THE COURT: Okay, I hear you. Let me hear from Ms. Finken.

MS. FINKEN: Thank you, your Honor. First of all, there are a couple of things I want to address.

First of all, the first time that we learned Exhibit 3 was a list of accession numbers that they were not going to produce was with the timeline that was provided to your Honor last night, which listed — in that timeline that GSK provided there is an entry for March 5, 2021, and it says that these were items that were not included in any of the produced PIER exports within the production, but that counsel had considered

and determined not to request for collection from the archives.

The first time we learned that was their position on that particular spreadsheet was with this submission last night. The first time that we learned that they were not producing anything else from Exhibit 1, the big spreadsheet, was within the past two weeks in an email exchange about animal studies.

We had been told multiple times that they were still looking through the PIER index, reviewing for responsiveness, pulling documents, reviewing them, and producing them. We were not told that that had stopped as of February when they sent us the Exhibit 2 list of 2,300 entries, just to be clear about that.

The second thing I want to address is that we have consistently asked for their methodology and how they are determining what to pull from these entries.

For example, when you look at the large list, the 23,000, for example -- and I am just pulling one out. I know they said science counsel reviewed these documents, but pulling one out, there is safety evaluation documents, safety evaluation Ranitidine and breast mass.

THE COURT: I'm sorry, Ms. Finken, can you give me the line on the spreadsheet?

MS. FINKEN: It's 22,916.

THE COURT: 22,916?

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MS. FINKEN: Uh-hum.

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THE COURT: Okay. Hold on. SM Tech --

MS. FINKEN: No, wait. I am looking at the wrong spreadsheet. I want to make sure I give you the right one. If you just do a search for breast, it will come up, you will find it.

THE COURT: Okay, go ahead. I will find it.

MS. FINKEN: At any rate, my spreadsheet is sorted differently from yours, so the lines won't be the same. Safety evaluation document, safety evaluation Ranitidine and breast mass. That is not included in their list of 2300 that they thought was responsive and they were going to pull, that is one. There's multiple like that, safety evaluation documents, Ranitidine and toxicity.

I am looking at multiple of those alone, and that is literally just one tiny example. I could give you dozens and dozens of them in this larger spreadsheet that are clearly responsive and relevant and were not pulled. If the Plaintiffs don't find them and ask for them, you are not getting them has been the approach, apparently, and that is just astounding to me that we are hearing that for the first time.

So, what we had been doing, putting that aside for a minute, we were looking for animal studies, trying to wrap our arms around the animal studies and human clinical studies that were listed in this larger spreadsheet, and as we were finding

items in that spreadsheet that we could not find in the production, we were identifying those to GSK, either asking for assistance in finding them in the production or notifying them that they were not in the production and when they would be produced.

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We just heard for the first time, within the past two weeks, that those won't be produced. If they haven't been produced, they are not on that sheet of 2300, they are not going to be pulled or produced. They haven't been looked at, they haven't been pulled as responsive material and reviewed, and we can't understand the methodology that was used by Mr. Oot and his science counsel on how they determined what was responsive from this humongous list and merited pull back to review for production. It is unbelievable to me.

The other piece of this, too -- and I know that when we met with the special master -- because we have spent countless hours meeting with the special master and GSK over discovery issues in the past three months -- we had asked them if they could run specific search queries, and there was a lot of hemming and hawing about their ability to do that for us, and whether or not there were -- we had asked if there were additional fields of information in this database that could be produced, and we were given a lot of push back about that.

It has come to my attention since then, just recently actually, last night as I was reviewing some ESI disclosures

from another MDL that GSK is involved in that Mr. Oot had produced many years ago, and they are subject to a confidentiality order which I have signed, so I won't go into too much detail, but the PIER index that is disclosed in those systems disclosures indicates that there are multiple fields you can pull, there are 17 predefined fields, there are multiple queries that can be run and things of that nature that were not disclosed to us here.

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I suspect that we do not have all the information that GSK has in making that determination. I suspect that there are other fields of information that they considered that they did not produce to us, and I suspect that they somehow used the methodology to pull ten percent of this spreadsheet and produce it, and the rest is kind of up to us.

If we had not located the spreadsheet in the production, in the custodial file, we wouldn't even know about it, but it is up to us now to say, okay, this is what we want from these 23,000 entries when they are clearly responsive material to our request, they are relevant to the litigation, and the burden shouldn't be on us to find those for GSK.

THE COURT: Let me stop you for a second.

Have you had your science people look at Exhibit 1 and Exhibit 3 to see if on the face they can identify specific items listed in Exhibit 1 or Exhibit 3 that you haven't gotten that you believe would be within your request for production?

MS. FINKEN: We have been going through it to do that, but we were not under the impression that the 2,000, the 2300 was all that was being produced. So, we have been identifying things that we have not gotten, and identified those to counsel, but we were just told in the past two weeks that they are not producing anything else beyond that spreadsheet that is Exhibit 2.

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THE COURT: I assume, Mr. Oot, that is based on a legal objection, that it would be unduly burdensome and disproportionate to have to produce anything other than the 2300 that you have already produced.

MR. OOT: Correct, your Honor, and that is in our written responses and objections, first and foremost.

I would like to touch on a couple of things, your Honor. There has been an ongoing meet and confer that dates back to February on this issue that Mr. Sachse has also been managing.

So, I can't say that the production list that we gave them, that this is the first time yesterday they knew that was the list that we were producing from. I would have to go back through my email and check, but I think we provided that list and told them in the meet and confer, where Special Master Dodge was there, this is the list we -- that GSK selected.

Again, I just have to underscore, your Honor, this was reasonable input from national counsel, discovery counsel,

outside counsel, science counsel, experts, and the archivists that really came up with these searches both for Mr. Harvey and also for counsel.

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I think to say that we have been unreasonable in how we track things down and how we analyze these sheets, I don't think that is fair and I don't think that is appropriate. We have also been transparent with telling them the information that we pulled back, or we requested from PIER, and we have been giving them those updates on the productions as we are getting that information in the system.

So, to your point earlier, your Honor, we do have some additional runway on those things that we are pulling back, so -- and we have been open and transparent about that process.

The other thing I would like to raise, your Honor, Ms. Finken raised safety evaluations. Those are in adverse event reports, so PIER is not the only place where this information exists, there are other locations where information could exist, and a primer for something that is in PIER could be in a more accessible location and produced through the safety production process, medical information letters have been produced.

So, there is more that relates to safety that is beyond the PIER report that we produced here. I would like to raise that, too.

If it would be helpful, your Honor, to have a further

discussion on the process, we could do that, and we could get science counsel involved but --

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THE COURT: Here is what I think ought to happen: Ms. Finken, file a Motion to Compel. You served a request for production, I am looking at their objections, it is a vague objection, not entirely specific, but they did object on the grounds of disproportionality and burden. File a Motion to Compel. I will have a hearing quickly.

It seems to me -- GSK can assert whatever defense it wants to assert, that it would be cumulative, they could find this information elsewhere, they conducted a sufficiently reasonable search, and therefore it would be disproportionate for them to conduct additional searches. They have every right to assert their legal defenses and I will hear it and I will rule.

And it may be you say -- if your request is I want them to produce all 23,000 as opposed to a more targeted approach, I don't know, but it seems to me you have all been dancing around these issues since February, enough is enough.

File a Motion to Compel, and I will rule. If the ruling is GSK is going to have to go back and pull another 10,000 items, then it is going to be expensive, there may be other remedies, but that will be the remedy. If the remedy is, no, I think GSK has done enough, then Plaintiffs can (inaudible) that will be the ruling, I don't know.

We have at least identified where we are, you have clarity. You know what they have agreed to give you, you know what they are objecting to give you. It doesn't seem to me you are going to reach agreement that what you think you should get they are going to agree to give you. So, when we reach that point it is time to file a Motion to Compel.

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MS. FINKEN: Your Honor, I appreciate that.

The one thing I would respectfully request your Honor to give GSK guidance on is if we could get this spreadsheet, Exhibit 1, with all of the data fields that can be included on it from the PIER index versus just the limited subset that we received, so that if there is other identifying information or descriptive information, or things of that nature, we have the benefit of looking at that as well.

THE COURT: Mr. Oot, I don't want to get too deep into what is in that index right now, but are there other data fields that might enlighten the Plaintiffs as to more information about these studies so they can make a more informed request?

MR. OOT: Your Honor, I am not sure, this is the same list that we used. I will go back and ask the client.

THE COURT: If you can find that out for me before we are done today, I would like an answer to that question.

It seems to me if there are other data fields and it would help focus the request, that is to everyone's benefit,

otherwise, if they make a request for all, it doesn't help you. If they can target their request, maybe it helps everybody. So, if you can get that information before we leave today, that would be helpful.

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That is all we -- unless the parties feel otherwise, I think I have done all I can do with at least the PIER database.

Ms. Finken or Ms. Luhana, do you think there are other issues related to the PIER database that we haven't pulled up and looked at?

MS. LUHANA: Judge, I just wanted to provide additional context in terms of Exhibit 1. This was in Jim Harvey's custodial file, who is the Director of Research and Development, and it was part of the product incident review committee where he asked for all studies that related to Ranitidine, and Exhibit 1 is what was produced. This is why we think it's relevant.

So, Exhibit 2 is the culled down version that GSK has come up with that they said they are willing to look into and may potentially produce. There is an overlap of 2100 or so entries. Right?

So, we are wondering how did GSK decide those other 20 something thousand entries are irrelevant or too much of a burden if they haven't even pulled it back and reviewed these documents? What is their methodology? That is what we are asking for. We are asking for the clarity on these objections

that they have. PTO 32 requires that clarity in the objections and I don't think we have received those yet.

THE COURT: Well, Mr. Oot has at least inferentially asserted that is their work product. I am not sure he is going to agree to tell you what their methodology is.

Am I correct, Mr. Oot?

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MR. OOT: Your Honor, I would like to address one thing before I answer your question. First, the list that Mr. Harvey generated is not a list that was specifically related to clinical studies. It was a list for — a broad search for everything related to Zantac, the compound numbers, the product names were searched.

And secondly, your Honor, related to your question whether or not, you know, we are going to discuss how we considered that, I think we can discuss with Plaintiffs off line a sort of more specific approach of how we analyzed the document. As I said earlier, and I will repeat again, we pulled in science counsel, we pulled in global counsel, we basically pulled in all of the subject matter experts to decide line by line through these spreadsheets whether or not it would be worth pulling back.

I agree, your Honor, it makes sense for us to deal with this in a motion.

THE COURT: Okay. A couple of thoughts. One is, I hear you both, so on the one hand, I hear Mr. Oot saying, on

behalf of Mr. Harvey, we just did a very, very broad pull of anything that was tangentially connected to Ranitidine. I accept that premise.

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I accept the premise that you engaged in what you believed to be a meaningful and deliberative process to try to cull it down to those items on that list that were responsive to the request for production in proportion to the needs of the Plaintiffs. I accept that premise.

I also accept the Plaintiffs' belief, at least looking at a list of 23,000 and then it reduces to 2,000, there is an argument that the right number was somewhere greater than 2300, even if it is less than 23,000. It would be helpful for them to understand how you winnowed it all the way down to 23,000, then 2,300, and it isn't 7,500. I don't know how individualized we want to get.

So, to that end, first of all, if there are additional data -- Ms. Finken, what was it you were asking for on the spreadsheet?

MS. FINKEN: Fields.

THE COURT: -- data fields that could be provided to the Plaintiffs, that would help inform them and perhaps allow them to make a more targeted Motion to Compel. Maybe then they come and they go, okay, we see this, we can see a theme here, and perhaps once they see those data fields, if they exist, and have a conversation with Mr. Oot and his team and Mr. Sachse

and they are told, look, if you look in column 17, which you didn't have before, we understand it, the lawyers didn't have it either, but you can see why we wouldn't have done this, because it says incomplete study, so we didn't pull the incomplete study.

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And Ms. Finken or Ms. Luhana might say, okay, if it is an incomplete study, we don't need that, and we're not going to include that in our Motion to Compel. I don't know.

Ms. Finken, you can ask for all 23,000 in your Motion to Compel, I don't care. I will rule on them.

I already made the order with regard to the additional data fields. I want to know if they exist and we can -- unless there is some objection that is meaningful, I am going to order those to be produced.

Separate and apart is this question of methodology. It do recognize that at some point it touches up against possible work product claims, but I appreciate Mr. Oot saying, look, we can have a more meaningful discussion about that, we are happy to tell them off line, we don't want to do it on the public record. But I think that dialogue also needs to happen sooner rather than later. Again, that might help inform the motion that Ms. Finken and Ms. Luhana would file.

Here is what I am thinking, we are going to take a break in a few minutes and another break at the lunch hour because I have to handle this other matter. At that point in

time I think you should have the discussion Mr. Oot just mentioned.

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Even if it is at a very high level, Mr. Oot, give them a little more guidance as to how that winnowing is done, what parameters were applied. You don't have to get all the way into the work product, but I think you can safely share with them some very general parameters.

In candor, if we have a Motion to Compel and you are going to have to justify why it is disproportionate to do more, you are going to have to put on testimony of what you did as a practical matter. I am not making an evidentiary ruling if you want to make an objection to that.

It seems to me as a practical matter, if you are going to try to sustain an objection that it is disproportional because it would be a waste of time for us to do more of this, you are going to have to put on some evidence of what you did in the past. So, you are not going to be able to stand fully on we don't have to tell anybody anything about our methodology, and I don't take you to be doing that. All right.

That is going to be my order, is that over the lunch break I am going to order the parties to confer on that particular issue.

It is now 10:35, it is a good time to take our morning break. I would ask each of you independently to think about

what is the next topic to cover. We have dealt with the Medtrack issue, we have dealt with the PIER issue. I will probably go back to you, Ms. Finken and Ms. Luhana, to identify what is left that you feel you don't have clarity on and what can we do to get you that clarity.

Let's take a break until 11:00 o'clock and come back and reconvene the hearing. You can turn off your cameras if you want to. I am going to mute and turn off my camera and I will see everybody back at 11:00 o'clock.

MS. FINKEN: Thank you, your Honor.

(Thereupon, a brief recess was taken.)

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THE COURT: All right. Before we go forward, let me circle back on one topic that, as I looked at my notes from earlier, I was unclear on one thing.

If I am now understanding, Mr. Oot, and I think you have made this clear, there is kind of a filtering as I see it. There were the materials that were requested by Mr. Harvey, that is Exhibit 1 from the PIER database. There were other materials from the PIER database that were also at least identified separate and apart from Exhibit 1, that's Exhibit 3.

Counsel and GSK went through Exhibit 1 plus Exhibit 3 and distilled out Exhibit 2 and determined these are the documents we are going to actually pull from archives and conduct further review on.

And then from that, the 2300 items in Exhibit 2 is

what distilled down to what was actually produced to the Plaintiffs, am I correct? Not all of what is in Exhibit 2 was produced, it was some subset of Exhibit 2, am I correct?

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MR. OOT: Or in the process, your Honor, correct.

THE COURT: Okay. Ms. Finken and Ms. Luhana, to the extent you are filing a Motion to Compel, you are not limited only to — it is anything that you believe you haven't gotten that you think you should have gotten so far. Okay. I didn't want you to feel like you were limited.

Likewise, we had talked about the Medtrack data. I understand there is no data -- well, there is data, but there's no documents, the Medtrack related materials which GSK is going to provide some further clarity on and will determine whether there is a delta or not. Again, the Plaintiffs are not precluded from separately moving to compel that.

If you feel like you want to expedite what I'll call the PIER data and get that in front of the Court under a PTO 32, I am not going to make you wait until you have had a chance to review and process whatever you get related to Medtrack because possibly the Medtrack may be negotiated out and you haven't had a chance to do that.

I see Mr. Sachse is in the waiting room. Shall I let him in, Mr. Oot?

MR. OOT: Invite him to the party, for sure.

THE COURT: He is invited to the party. Okay.

Again, just reviewing my notes from where we have been so far, I think I had directed GSK to let us know before we conclude today timing on what I am calling the Medtrack data, to get us some information about whether other data fields exist in the PIER database, and — I guess the other question for the parties is, now that we've talked about Exhibits 1 through 3, we have been very careful not to talk about the substance of Exhibits 1 through 3, we talked about them conceptually and kind of big picture.

Are those marked as confidential pursuant to the confidentiality order that was entered in this case?

MR. OOT: They are, your Honor.

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THE COURT: So, is there a request by either side that those be sealed at the present time?

MR. OOT: For GSK, yes, your Honor.

THE COURT: Ms. Finken or Ms. Luhana, any objection if I seal those exhibits for purposes of this hearing?

MS. FINKEN: No, your Honor.

THE COURT: I will do that. Under the case law that I previously referenced, the Eleventh Circuit does make a distinction between discovery materials, purely discovery materials, and materials that are used in furtherance of obtaining a court ruling.

So, if you attach discovery materials, for example, to a Motion for Summary Judgment, they are analyzed under a

different standard.

As I thought about today's hearing, no one has filed a motion, no one is asking the Court to rule today. I believe, at least for the time being, those documents would fall under the more protected classification that the Eleventh Circuit has recognized. It may be that if we have to litigate a contested Motion to Compel we will be in a different place and I will revisit the question of whether those or any other documents that are used during the contested Motion to Compel have to be in the public record, but at least for purposes of today, I will grant the motion to seal Exhibits 1, 2, and 3.

All right. Any other loose ends from what we have already discussed today, either Ms. Finken or Ms. Luhana?

MS. FINKEN: Your Honor, there is one other issue that is tangentially related to these issues we discussed today, and that is our ongoing inability to ascertain whether or not there are other systems or hard copy repositories or anything like that where these documents might be located.

Like I said earlier, we were unaware of the Medtrack tool until March, and we had been asking for a master list of clinical studies for many, many months and were told that it did not exist.

So, what we would ask, your Honor, is a couple of things. One, we were provided with systems disclosures by GSK by letter in May and then recently an updated one. We would

request a full and complete systems disclosure from GSK that is verified, that is a full and complete list of all electronic sources of potential information and/or hard copy archives where Zantac, or Ranitidine, or Tritec information or documents can be located, just so that we know that we are working with the universe of potential places to be looking for responsive information.

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We had gone this route in lieu of a 30(b)(6) deposition back then because we were trying to work through this more informally than taking 30(b)(6) depositions. So, we would either request that we get a full systems disclosure and hard copy archive disclosure with a verification, or they produce an ESI witness to testify in relation to ESI and hard copy archives that would not count to our caps on depositions, so that we can get to the bottom of the totality of where we are looking for information.

THE COURT: What it seems to me you are asking for really is for an additional interrogatory, that you want them to take that letter they gave you and just verify the letter in a manner that they have now bound themselves in a way that you can use in court and that is verifiable. Am I correct?

MS. FINKEN: Correct.

THE COURT: Mr. Oot, any objection to responding to an interrogatory that asks for the same information you already have given them?

MR. OOT: Yes, your Honor. Just a point of clarification, the full and complete language would be pursuant to 26(g). So, obviously, it would be what we have done after reasonable inquiry, and as I put in my letter to Ms. Finken, we would agree to supplement as we interview witnesses and find out about new systems, but I think that the 26(g) standard should apply and not a full and complete verification that Ms. Finken is asking for.

THE COURT: Hold on one second. I think 26(g) by its terms applies to any response to discovery. Hold on, let me look. Rule 26(g)(1) applies to every discovery response or objection. A response to an interrogatory, it would seem to me it would apply as a matter of law.

Let me do it this way, I will authorize the Plaintiffs to issue an interrogatory, a systems driven interrogatory that will not count or be in addition to any limits on interrogatories that have already been imposed in this case.

Welcome, Mr. Sachse. Mr. Oot, if you and your client object to the phraseology of that interrogatory, you can object to the interrogatory, or if you can work out with Ms. Finken ahead of time the verbiage that you can live with, please do.

It is my reading -- if I have to ultimately rule on it formally, I will, but my quick reading of Rule 26(g) suggests that I don't know that you need to reserve that, just like you don't need to always say we will amend. You are required as a

matter of law to supplement. I think if they just ask you, please provide us a list of all systems where science studies could be found -- I will let her write it the way she wants to write it -- you can answer that.

It is understood that that is based upon a reasonable inquiry and subject to being supplemented later. So, if they try to jam it down your throat at a later proceeding you can invoke Rule 26(g) as a defense. That is how this works.

Okay, we resolved that issue.

Mr. Sachse, how did your moot go, is the student ready to go?

MR. SACHSE: Your Honor, she is, she is going to do your alma mater proud. She is excellent.

THE COURT: Although, as I tell people, the law school that is on my diploma doesn't exist anymore since they changed the name last year, but good for you. Working with law students is always very gratifying, so thank you.

I think we now have tied up all the loose ends from this morning and that last issue.

Ms. Finken and Ms. Luhana, what else can we try to accomplish today? I know there was some discussion at one of the prior hearings that — there was some issue about cross checking and making sure that there is a common understanding between you and the Defense of what you have. Perhaps that is what is being resolved through what we talked about with the

Medtrack data, but is that a continuing issue?

Is there anything there that I need to get involved with?

MS. FINKEN: Your Honor, I think at this time the cross checking really was pertaining mainly to the PIER and the Medtrack spreadsheet and data source issues to make sure that we know exactly what you articulated earlier today, which is what was produced, what is not going to be produced, what is in the queue to be produced, where the objections lie. The majority of that was covered already today in terms of different categories of information.

I don't know -- Roopal might correct me if I am wrong and I am missing something, but I think that was the main source that we were really struggling with in terms of clarity.

THE COURT: Ms. Luhana, anything to add?

MS. LUHANA: No, nothing further on that issue, your Honor.

THE COURT: Okay. Were there other issues that the Plaintiffs wanted to raise today? You have my attention. I am happy to rule on things, or guide you, or whatever else we need to do, or would it make sense — that is a two-part question. That is an open question. Ms. Finken, while you are thinking about that — I can see you thinking and desperately checking your computer to see how many emails you got about from other people on your team telling you what to say.

I am also open to the idea that if it makes sense for us to, as I said earlier, maybe recess this morning and then reconvene at 3:00 o'clock, 2:30, give you a chance to talk between now and then. Maybe Mr. Oot and Mr. Sachse and their team can get answers to a couple of issues that we had raised this morning.

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If there are still issues to resolve, if we come back later today, there are still a couple of hours in today's working day, we can try to accomplish Judge Rosenberg's goal of tying up every possible loose end that can be tied up today. If there are issues to put on the table right now, let's put them on the table right now.

MS. FINKEN: I guess another overlapping issue that pertains to the PIER indices that we already talked about in terms of the laboratory notebooks — I know that you ordered Mr. Oot to provide us with the additional fields from the PIER indices that might help us ascertain what those entries are.

One of the questions that has arisen is in relation to those laboratory notebooks because the way that they are identified is just by a laboratory number. We have been trying to figure out if there is some type of way to relate those laboratory notebook numbers to the actual studies or the data that link the actual final study report to the laboratory notebook.

We were told there was no way to actually do that, and

I am just wondering, if there is no way to do that, how they identified the laboratory notebooks that would be responsive for purposes of the PIER index.

I can't imagine it was just randomly selected numbers, we are going to do 25 of these numbers, and those are the ones we will pull and look at and forget about the rest. There has to be some way to identify what those laboratory notebooks pertain to. That is something that we are struggling with here.

THE COURT: Just to be clear, I don't believe I ordered them to produce to you all of the PIER data fields. What I said is, report back what those fields are, and if they feel they need to lodge an objection — there could be a column in there that says attorney notes for all we know, or attorney review, and they have to reserve the right to object to that.

What I said is, my sense was that would be helpful to both sides, if there are additional fields, to facilitate, but I didn't want Mr. Oot or Mr. Sachse to feel that I had ruled that they have to produce all of them because I don't believe that I did.

In terms of the lab notebooks, Mr. Oot, Mr. Sachse, is there some -- whether it is in the PIER database, is there some mechanism by which to connect the lab notebook and say, okay, this is a lab notebook for a study on Tagamet, this is a lab notebook for a study on Santac, this is a lab notebook on some

other study?

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MR. OOT: Your Honor, there is not a connection of the lab notebook back to this particular study name that I am aware of. I could definitely go back to the client and ask. We did pull hundreds of lab notebooks for evaluation, and we can identify that list if that would be helpful, but again, it is going to be lab notebook numbers that were evaluated by the review team for production, so we just don't have that connection.

THE COURT: I understand that. Ms. Finken's question does sort of resonate, how does one know even which lab notebooks to pull if -- I am not saying you have to say lab notebook 1, 2, 3, 4 ties to study A, B, C, but is there a way that you can just look at lab notebook 1, 2, 3, 4 and say, well, that was -- there is a way to do that because when they did the pull for Mr. Harvey -- Mr. Harvey made a request for all things related to Ranitidine and he got a list that had a bunch of lab notebooks in it, so there clearly is some data source somewhere that allows GSK to say these lab notebooks relate to Ranitidine.

Now, there may be another level of that, which is, we can't say which study it goes to, again, it is unduly burdensome to figure it out.

Mr. Sachse, you are nodding your head up and down.

MR. SACHSE: Let me jump in here, Judge. I will say,

as with much of PIER, it's -- you know, this is a little bit of art and a little bit of science. So that index -- sorry, that report that you referenced, which is Exhibit 1, it does contain authors that -- in some instances authors associated with the lab notebooks.

The process that we used was, and it is a bit laborious, but we tried to cross reference between names of scientists at Glaxo or GSK who were working on Ranitidine and pull those lab notebooks for further review. Some of them end up having Ranitidine information, some of them end up not, but that was essentially the process. It was and is a very technical review certainly.

I can't even read the handwriting, frankly, it looks like doctor's handwriting often, but it is a process that requires specialized reviewers, which is why it took us a little bit more time to get through those, but that was the process.

THE COURT: If I am hearing you correctly, and maybe this is one of the data fields that isn't apparent on Exhibit 1, but that will become apparent if you supplement that, there is an author line and you can look at the author and say — just like I could look at your law firm, probably, and look at the list of partners and go, well, this person is in the tax division, they are very unlikely to be working on the Zantac litigation, as opposed to here are all the people in the pharma

litigation group, it is pretty highly likely they are working on it, so we'll focus on them.

Is that essentially the methodology?

MR. SACHSE: That is the methodology, and I do think, your Honor, that Exhibit 1, unless I am mistaken, I think it does include that author field, so we were able to narrow the list of the universe of notebooks that we would pull for review using that.

THE COURT: Ms. Finken, you got an answer, it may not be a satisfying answer, but at least you got a partial answer to your question.

And again, on that I would just encourage, as we talked earlier, Mr. Sachse, before you got on the phone -- I think Mr. Oot is going to have a conversation about some of the methodology for how things were shrunk down. To the extent that you can share that sort of information with Ms. Finken and Ms. Luhana, I think that will inform them. Again, to the extent there may be other data fields maybe everybody can work off of.

Ms. Finken, I got you an answer to your question. As I said, whether it is a satisfying answer, I don't know, but that is the answer.

MS. FINKEN: Thank you, your Honor.

MS. LUHANA: Judge, I think the data fields are imperative, and we were talking about Exhibit 3. Those are the

studies that GSK has concluded they are not going to produce. That is lacking that field. We don't have the author field or any other field that is helpful to identify the basis for them not producing that information.

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THE COURT: Very good. I already told Mr. Oot I am not letting GSK go today until we know whether there are data fields and what they are. If they already know or they can get it quickly, that may be something you can confer on over the lunch break. Unless there is some privilege that needs to be asserted over the data fields, I am going to order them to produce the data fields, but I can't order them to produce what doesn't exist.

What else, Ms. Finken, anything?

MS. FINKEN: I was referencing before a list of outstanding issues that we have had ongoing with GSK that we have been trying to resolve.

I know that there are a couple of items that are not necessarily ripe for today. We have the batch manufacturing deadline for tomorrow that we are trying to work through. If you would like an update on that, Ms. Luhana can give it to you today. I don't know if we are going to get to an agreement by tomorrow or not. I think the ball is in GSK's court to get back to us on our proposal and we are waiting on them to do that.

There is an issue that -- well, there are a couple of

issues. One, we have an issue with our tranche 2 custodial file production. We have identified back in February a number of people we were requesting additional information on to determine whether or not we wanted to request their custodial file. The basic information was basically their title, how long they worked at GSK on Zantac, etc. We are still waiting for that information to determine who our tranche 2-B custodians will be.

We had already agreed upon tranche 2-A, so that is something that is pending, that is holding things up. Until we can get that information, we can't identify our tranche 2-B custodians.

THE COURT: Let me stop you there for a second. I am happy to take up any issues that the parties want to take up today. My sense of what Judge Rosenberg was really pointing us to today was the repeated discussion that there seemed to be a lack of clarity between the parties.

On the tranche 2 custodians and the batch documents, I don't sense that there is a lack of clarity. You know what the batch records are, you know where they are. There is just a legal question, perhaps, as to how much of them should be produced or not be produced.

If that is in the final phases of some negotiation, I don't know that I want to dip my -- put my finger on the scale there other than to say -- not to make more work for myself,

but I think, particularly in this litigation, I really do applaud the fine work that the special master is doing and the parties' continued willingness to have really meaningful meet and conferrals, but there does come a point when coming to court and getting a ruling is more efficient and faster than trying to work it out yourselves, and I sense we are reaching that point with a lot of the issues here, not just with GSK, but with some of the other Defendants as well.

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I will put that out there to you, but you tell me, is the tranche 2 issue and the batch issue kind of a clarity, we are confused, we don't have enough information, or the issue is joined, but we just need to resolve it or get a ruling on it?

MS. FINKEN: We have been seeking information on it so that we can actually get to a point where we determine whether we have a dispute or not. That has been outstanding for a couple of months now, so that is kind of a lingering issue.

THE COURT: When you say that, the batch issue or the tranche 2 issue?

MS. FINKEN: The tranche 2 issue.

THE COURT: Let's take that up next. What, from your perspective, is the tranche 2 issue?

MS. FINKEN: Well, we had identified a number of custodians in January that we have been referring to as tranche 2-A, so to speak, and then there was a separate list of custodians that we weren't necessarily identifying yet, but we

just needed some additional information on to determine whether or not we wanted to identify them as potential custodial file requests. We have been waiting for that information from GSK so we can make that decision.

2.4

Some of them have been outstanding since February, and others we provided to them probably a month ago at this point that we are still waiting for. It's simple information, title, length of time they were employed, if they are current or former, when they worked on Zantac, their role. That is holding up that process.

THE COURT: If I can stop you there. The issue is, you sent them a list of names and it might say Tracy Finken, who is she, we have seen her name in some documents, we are tying to figure out who she is, or John Smith, who is he. That is really the level of discussion that you are trying to resolve?

MS. FINKEN: Correct, so we can then determine whether or not we want to request any of those for tranche 2-B. Yes.

THE COURT: I understand. If you get somebody who was a scientist there, but they were there for three weeks, you may not want them, versus he was the lead scientist on Zantac for five years, or she was, you might want to. How many of those have you fired over to them? How many people are in that tranche 2 queue?

MS. FINKEN: The ones requesting information, I think

less than 30. It's not that many people. I can check my spreadsheet on the break, but it's not a very large list.

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THE COURT: I know the other day when Mr. Watts was talking at the hearing, there was some discussion about they wanted to depose a hundred or something people, and there was some dispute about that. So, I just wanted to get a volume.

Let me turn to Mr. Sachse and Mr. Oot. Is there any holdup on getting that information to the Plaintiffs? I am sure you are going to tell me you haven't prioritized that because you have been busy with other things. Where are we?

MR. SACHSE: Stop stealing my lines, Judge, but you are correct. We are working on that list, I think it's -- I should be clear that there was a request that came over in late February, the 18th or 19th, that had some custodians that were identified as for discussion, and then we got an updated list in April that coincided with the request the Plaintiffs made for depositions in the U.K.

Obviously, for all of the witnesses who are being deposed, they are now custodians, and so we are assuming that those depositions go forward, and so we are collecting those custodial files and we will be producing those.

We had previously agreed to an additional 17 custodians, some of whom are in this batch of witnesses, and those we are on track to get over to the Plaintiffs by the end of this month.

The sort of challenge -- and I acknowledge that Ms. Finken and Ms. Luhana are waiting for information from me, and we will get that over to them as quickly as possible.

We are also waiting for information from them. From the beginning we have made the request that we would like to understand kind of what is the universe, because I think that when we approach custodians in a sort of piecemeal fashion, it is very easy for the parties to maybe not make the tough decisions early on, and from our perspective, when we are getting to, you know, a total request of custodial files that enters — or approaches triple digits, there is a real question about diminishing value and proportionality, and is this really going to be core at this point.

The ask that we have made repeatedly was, all the people you are seeing in our documents that you think are potential custodians, let's put them all on the table and let's have a conversation and let's try to wrap this up once and for all, and I appreciate that — I think Ms. Finken will say, well, we are still working through the documents, we have not gotten all of them until recently, and that is all fair.

But I have also consistently told Ms. Finken and Ms. Luhana that this is not going to be forevermore, you are never adding another name to the discussion list. The challenge, from my perspective and my client's perspective is, if I have a list of 30 now and we go through it, and not to be

too pessimistic, but my suspicion is that of the 30, the Plaintiffs will end up asking for 20 or 25 of those custodians, and then we are into the 60s, the 70s, we are getting up in the range, and then if I get another list of 30 or 50 or more in a month we are going to be producing custodial files until the cows come home here.

2.4

That is kind of the process that we are trying to engage in, and I don't want to lose sight of the fact that at this point, by early to mid May, they will have custodial files for, you know, 50 some-odd, you know, custodians and they will have either taken or they will have scheduled something like 20 depositions when you include -- maybe even more than 20 depositions when you include the 30(b)(6)'s. So, we are sort of coming to the end of what they can do in terms of witnesses without leave. So, that is kind of the perspective that I bring to this.

Again, let me end where I began, which is happy to work with Ms. Finken and Ms. Luhana about this, and we had a meet and confer two days ago where we said we were finishing up that information, that kind of what I'll call HR information about these witnesses to the extent that we can figure it out, and we are going to get that over to them, but I do think this has to be part of a broader conversation.

THE COURT: I think you are talking past each other, because it seems to me this is a perfect project for two LDC

lawyers. Get an LDC lawyer and an HR person at GSK, they can pull 30 names and say, Will Sachse was at the firm from this date to this date, this was his title, and he left on this day.

2.4

That is without prejudice to you then coming back later on behalf of GSK and saying, no, that is not a proper custodian, no, you don't get their custodial file, but perhaps once Ms. Luhana and Ms. Finken get that information they may say, okay, we don't need that person, he was not there very long.

I hear you and I think your point about the burden of producing custodial files is well taken and is a serious question that needs to be considered.

I don't see the burden in literally going to the HR department and saying, who was this person, how long did they work there, and when did they leave, and producing that information relatively simply and quickly.

MR. SACHSE: Your Honor, I agree with you on the burden point. You're right, just getting the basic biographical information, that is not the holdup. The holdup is more that, as you know, we are dealing with custodians going back decades. I will say, curiously, most of the custodians of interest to the Plaintiffs are people who only worked on this product in the last few years. That aside, when we are talking about more historic custodians, one of the things we need to do is ascertain whether there are reasonably likely to be

custodial documents, whether it is electronic or whether it is paper, because that is also part of the information that needs to go into this discussion.

THE COURT: I hear you, but I think that is the second level of discussion. The first level of discussion is simply who is this person, how long did they work there, and what was their job. It seems to me that can be done quickly and easily and simplistically.

Everything else you're saying makes perfect sense and you are reserving your right to make all of those objections and to have that dialogue, but the only issue Ms. Finken seems to be raising here with me today is what I am calling the level one question, which is just tell us who they are and when they were there.

That, seems to me, I could order you to do that in two weeks, and there shouldn't be any reason you couldn't do that in two weeks.

MR. SACHSE: Your Honor, you're absolutely right, and I think, frankly, we might be able to get that to them this week. We probably have collected that information already for most, if not all, but let me check on the status of that. That is something, as I said, that we said we would get to them.

THE COURT: Why don't you look at that. We are going to have a lunch break in a little bit. Why don't you look into that and talk to Ms. Luhana and Ms. Finken once you have that

information and come up with an agreed date. I will enter an order that requires GSK to provide that information by a particular date, without prejudice to all the other things you have talked about.

All right. Ms. Finken, I think I just dealt with your tranche 2 issue. You said you had an issue with the batch documents. Let's go to that one.

MS. FINKEN: Thank you, your Honor, I appreciate that, that was very helpful. I haven't been on the ground floor on the batch records as much as Ms. Luhana has so I will let her field this one.

THE COURT: Again, Ms. Luhana, what I am focused on is I'm not -- I didn't put anyone on notice to this, so I am not going to rule on whether batch records have to be produced, if they do, which ones, and all that. We will reserve that for another day.

I am here today dealing just with transparency. As we just did with the tranche 2, is there baseline information that the parties need so that they can at least join the issue and start talking about the merits?

MS. LUHANA: Understood, Judge. At the Court's direction, we have been meeting and conferring regarding batch records. We had a meet and confer for about two hours last Tuesday, so we submitted a list of questions to GSK on Monday and Tuesday and we are waiting on their responses as to what

they are willing to produce. These are very basic questions, and our requests have been -- we made an effort to refine our request for batch records.

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We appreciate the burden here that there are hundreds of thousands of possible batch records. We are not looking for those. For example, Mr. Sachse and I discussed it on Tuesday, and what I have asked is only 16 batch records, specifically the chromatograms from the residual solvent testing for API that GSK manufactured from 2009 to present. It is only 16 and we are waiting for a response from him as to that data.

Mind you, that data isn't in hard copy, it is in an electronic database that we have recently learned about because GSK has updated their ESI disclosures.

In addition to that, we are looking for SOPs as to stability testing that GSK does, and importantly, not just the stability testing, it's what they do when their products fail stability testing, what additional investigation and testing they do. We are looking for that. The goal and the hope is to focus only on those batch records, those chromatograms, and that data.

So, that really narrows the pool and focuses on the issues here. If GSK is willing to produce that information for us, I think we will have an agreement on batch records, but we are still waiting for their response on this.

THE COURT: Okay. Again, Mr. Sachse, I am not asking

you to respond on the merits if you don't want to, but I am certainly happy to hear any response you want to make.

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MR. SACHSE: I feel like I must because Ms. Luhana did not constrain herself. So, let me start positive and then we can maybe get into a little bit more of the granularity.

I think we had actually quite a productive conversation on this point on Tuesday and I acknowledge that the ball is, as you would say, in our court on this. I have somebody working right now to answer the questions, you know, I think it is relatively — for this litigation at least it is a handful, but I think at the same time, you know, there are some issues that we still need to work through because some of the information that the Plaintiffs are requesting, it will be incredibly burdensome for us to essentially resurrect it, it is all decommissioned archived information.

The conversation we had on Tuesday was the Plaintiffs said, well, we looked at the ads for the testing equipment and the manuals, and we think it is easy. We go and we do our investigation, that is not what we hear, but suffice to say we are working through that.

One thing I don't want to lose sight of here is the massive amount of information that the Plaintiffs already have on the testing that the company did on a batch level. So, Ms. Luhana referenced, oh, there are these 16 batches, we are just asking for 16 batches, the chromatograms. They already

have all of the numerical values, all of the numerical data for those 16 batches. What we are really talking about is the picture that accompanies — the actual picture of the chromatogram that accompanies the numeric values.

So, they have kind of like the export out of what is called the lift system that includes all of the numeric batch level values for -- or testing results for this 2009 to 2017 time period, and we are just trying to get to this last little piece.

Now, going back in time it gets much harder for us because we don't have sort of the comprehensive numeric values for all of the testing at our fingertips. That is what we would have to resurrect at great expense.

But what we do have and what we have provided to the Plaintiffs, and what we have identified by Bates range, are something called PPRs, which are essentially like — think about it as a report card for the manufacturing process, and for a particular year and a particular facility it says how did you do when you were making Ranitidine. Then at the back of these PPRs they have pages and pages and pages of batch by batch were your results kind of within the appropriate range or did you deviate.

We have also given the Plaintiffs information about those instances when batches did deviate, and what happens there is the batch doesn't get released, but the Plaintiffs

have that information and I acknowledge -- Ms. Luhana said they are asking for some help finding some of that information that we have referred to, and that is exactly the sort of work that we are doing right now.

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The last thing I will say about the batch record issue, and I don't know if Ms. Luhana feels the same way, but going back to the meet and confer, Ms. Bogden (phon) joined us, and she knows quite a bit about these tests and was very helpful in moving the conversation along, and I think that we can hopefully either get an agreement or greatly narrow the dispute, but as you know, Judge, we are sort of under -- we have that sword hanging over our heads with the deadline tomorrow, and I am not sure -- I don't think we are going to get there on an agreement by tomorrow.

So, one thing that I did want to talk to Ms. Luhana about on the break is whether she thought we were making sufficient progress that maybe we could come and ask the Court's permission for a few more days to see if we could nail down this issue or at least narrow it.

THE COURT: Okay. I am happy to -- that is my order, so I can modify it, so I'll be happy to entertain that if you all want to confer on that.

Again, I don't think I ever addressed batch records directly with you two on the GSK, I think I addressed it in a separate hearing relating to Mexico, BI, and sort of the idea

that -- my sense is they are at some level relevant.

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Now, whether, as Mr. Sachse said, getting the actual picture is relevant or having the numbers is relevant, I don't know, not what I do, but I think there is a level at which that information is relevant. There is also a level at which that information becomes quite cumulative.

I can only imagine how many batches of Ranitidine have been manufactured by these Defendants collectively over the last 40 years. I don't think Ms. Luhana wants to go look at every batch of every manufacturer. Some good sampling data would be advised, and it sounds to me like you are having the right discussion, let me put it that way.

I don't know if there is anything I need to jump in on here other than to say it sounds like you are having the right discussion. If you think a couple more days will help you reach resolution, I am happy to consider that.

Ms. Luhana, let me hear from you if there's anything further.

MS. LUHANA: Judge, I was just going to say that we are honing in our request are narrowing in on a subset of the data. No chromatograms and data have been produced to date, it's only summaries of the data. The underlying data is key because when you hone in and narrow the scope and the picture, you are not seeing the full picture, and that is what the chromatogram tells us. It tells us the full picture and the

full story.

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So, that is why the data for just those 16 batches -we are not asking for the hundreds of thousands of batches that
have been produced for almost four decades, it is a small
subset and highly relevant. I believe it makes sense to
continue the discussion with counsel and agree to an extension
to continue meeting and conferring on the topic.

THE COURT: Okay.

MR. SACHSE: If I may, Judge, let me just say in response, disagree with the substance, but agree very much if this is easy, I am not going to fight it. We are going to give them the 16 pictures, but if it turns out to be as hard as it sounds like it is, then we have to make that decision about whether this is a dispute or not.

THE COURT: Okay. Remind me, the deadline for tomorrow, is that GSK specific or is that batch records for GSK and BI? I don't remember how the order was crafted.

MR. SACHSE: BI is in the soup with us, too.

THE COURT: Do you know what their position is? Do they want some more time? Maybe you can talk about that over the lunch break.

MS. FINKEN: They are probably going to want some more time as well since we just found out this morning that they have electronic sources of batch record testing that we previously did not know about until today.

THE COURT: I don't know if BI's counsel is on the call, I don't know. Why don't you all confer with them -- my inclination is, I am going to keep going and deal with the issues that you have raised this morning. I have to take a break for my one o'clock hearing, but I was going to take a break whenever we're done and ask everyone to come back at maybe 3:30, four o'clock, and then we'll close the loop on everything that we can.

2.4

Perhaps during that break period everyone can confer with BI and if there is a joint request by the Plaintiffs, GSK and BI to extend the batch records deadline, as long as it is a reasonable extension, I am inclined to grant that. So, put that on your agenda of people to talk to.

What else, Ms. Finken or Luhana? Any other clarity issues or things that need to come into focus, or deadlines you want to ask for extensions on while you've got me softened up?

MS. FINKEN: I think the ones that we want to ask for extensions on next probably won't be in front of you. It might be a good time to break. I think that we covered a lot of ground this morning on some of the outstanding items that have been really troubling us for the past few months, and depending on when you want to reconvene, we can circle back around and see if there is anything else outstanding on the break.

I don't believe, off the top of my head, that there is anything that is urgent that needs to be addressed today. It

will give us time to talk amongst ourselves and see. We can discuss what you advised us to discuss with GSK and hopefully we will have some answers on some of the inquiries that you had posed to Mr. Oot this morning.

THE COURT: Very well. Mr. Sachse, Mr. Oot, anything else you would like to raise? I am happy to take a break and tell me what time you would like to come back this afternoon for a check-in.

MR. SACHSE: I obviously have the benefit of ignorance, but it sounds like you made a lot of progress this morning with your help, Judge, so thanks for that.

THE COURT: One might argue we made a lot of progress when you were not here, but I won't say that.

MR. SACHSE: Fair point.

THE COURT: I do have to say this, I know the parties, both sides, ran around feverishly to get ready for this morning and to gather information and get a lot of people pulled together, and I know that was not an easy process. That's why I am trying to make as best use we can of today because you do have everyone's attention. I want to thank you all for doing that.

Why don't we come back at 3:30. If it turns out, Mr. Oot, Mr. Sachse, you are still waiting to hear back from your compatriot — London is ahead of us, so they will be well past pub time in England so you should have answers from them.

Let's come back at 3:30, and if it turns out you say at 3:30, look, Judge, can we wait another hour, I am here.

We will be in recess until 3:30. Thank you, everyone, I'll see you back at 3:30.

(Thereupon, a recess was taken.)

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THE COURT: I don't see Mr. Sachse. I see Mr. Oot and I see Ms. Finken and I see Ms. Luhana. I am happy to wait if Mr. Sachse is joining us.

He just joined, very good. If counsel want to come on their screens here.

Okay. So, we are reconvening the matter of In Re:

Zantac (Ranitidine) Product Liability litigation, case number

20-2924. I recognize Ms. Finken and Ms. Luhana on behalf of
the Plaintiffs. I see Mr. Sachse and Mr. Oot on behalf of GSK.

I was going over my notes from this morning and trying to make sure what was left hanging out there. Here is what I have, and then you can tell me if this needs to change or if there is anything new that has come up, or maybe you have settled everything on this issue and I can go home.

The first thing is granting leave to seal the orders. I sealed the exhibits pursuant to local rule 5.3.

I want to get an update from GSK on what I will call the Medtrack delta, kind of what is relating with Medtrack, and I do want to set a deadline for GSK to let the Plaintiffs know, if there is any delta there, whether you are going to provide

it or whether you are going to object. That is up to you.

2.4

You are free to object if you want to object, but I think the Plaintiffs should know which road you are going down. That's number two.

Number three is, I do want to set a date for GSK to provide job titles and employment dates for potential tranche 2 custodians who have already been identified. Mr. Sachse, I know you said you could do it very quickly. I was going to give you a week. That seemed like enough time to me. I will hear you if you think a week is not enough time.

Presuming that BI is on board, I am prepared to grant you an extra week on the batch record issues, until next Friday, if that is what the parties believe would be appropriate and helpful.

And then finally, setting a deadline for GSK to provide an updated Exhibit 1 that would include the additional data fields from the PIER database.

Lastly, I am going to calendar a followup status hearing for next Friday, the 30th, at 1:30 p.m. If you don't need it, you can notify my chambers that you don't need it, but I think it is helpful to keep it on there. That would be right after we have had the lunch with the LDC members, so you can make one of them handle it and have an early weekend maybe.

Those are the topics I had. Let me turn to Ms. Finken or Ms. Luhana on behalf of the Plaintiffs. At least as to the

five or six items I just laid out, any issues, or any problems, or any modifications or concerns?

MS. FINKEN: No, your Honor, I think that covers pretty much everything. I do have a quick update on the Medtrack spreadsheet.

During the break, Mr. Sachse sent us a spreadsheet that identified the clinical studies with Bates numbers that are in the production. It does not identify what exactly was produced, but it gives Bates numbers associated with those clinical studies. It looks like there are 213 of the 764 produced, there are 14 in line for production, and there were 535 that were not produced and are not in line for production.

So, just to give the Court an update on that and where we are with Medtrack.

THE COURT: Okay. Do you now have the information you need? Is it clear now that as to the other 4 or 500, whatever it is, they are going to assert a legal objection, and if you want to challenge that legal objection, you can, or is there still any ambiguity as to that?

MS. FINKEN: My understanding, your Honor, from talking to Mr. Sachse is that they are going to undertake a search, a reasonable search for those clinical studies, and I will let him speak for himself on that so I am not misrepresenting. I want to make sure we get it crystal clear on what he is going to do.

THE COURT: Before I turn to Mr. Sachse, let me go down these quickly with Ms. Finken. I appreciate the update on Medtrack. I will circle back on that.

2.4

Any problem if I give them, Ms. Finken, a week to get you the employment and job data that you wanted for those approximately 30 potential tranche 2 custodians?

MS. FINKEN: That is fine, your Honor. They did provide an initial spreadsheet that just gave us dates, whether they were active employees, or dates that they left GSK, which is not quite what we were looking for, but a week is fine to get back to us.

THE COURT: Okay. Obviously, if they can do it sooner, that is fine. I really meant what I said before, this seems like a good project for LDC lawyers. You all get paid too much and work too hard doing other important things, so maybe you can delegate this to someone, but I will leave that to you.

Ms. Finken, by the nodding of the heads, do I presume that there is agreement amongst the Plaintiffs, GSK and BI that you want the additional week on the batch records?

MS. FINKEN: Yes, your Honor.

THE COURT: I see Mr. Sentenac. Are you here on behalf of BI?

MR. SENTENAC: Yes, your Honor, Mark Sentenac on behalf of BI and an LDC number. BI is in agreement on a week.

THE COURT: Very good. I will grant that request.

1.5

Let me go back to Mr. Sachse or Mr. Oot. Mr. Sachse, you are up first here. Medtrack, it sounds like you provided some of the information. I hear what Ms. Finken is saying that you maybe have not yet reached the fork in the road to decide whether you are going to object or provide the differential; is that correct?

MR. SACHSE: Yes, your Honor. So, first of all, let me confirm Ms. Finken's report in terms of the numbers of what is already in the productions, what is in the pipeline to be produced, and what is not yet in the productions because we have not found or identified those studies.

We did have, I thought it was a very good conversation with Ms. Finken and Ms. Luhana before this conference, and I think we still need to huddle up on our end and figure out exactly the process for next steps, but our next steps are to conduct additional investigation, see if we can find studies, find the studies that we have not yet located on the list.

And I think we are in broad agreement that, A, this is high priority, obviously; and B, we are going to stay in close contact on this going forward to make sure that we are making progress and keeping each other updated.

And C, in terms of prioritization, something that I floated to Ms. Finken and Ms. Luhana, and I think they agree, is there are a number of different categories of studies

identified on the sheet, and I think we are going to start our focus on studies that are listed as report complete, because we think it is more likely that we will be able to find completed reports for those studies.

1.5

The good news there is, by the way, that there is about 287 entries that are listed as report complete, and we, I think, have produced already about half of those. So, I think that is a good sign of progress that we are hoping to make going forward.

As I said, this is going to be a high priority, and we are going to be working closely with the Plaintiffs on it.

THE COURT: I appreciate that. Let me ask Ms. Finken.

Ms. Finken, is this something where realistically I should just say let it ride until May 14th, that is three weeks from tomorrow, that is the deadline for substantial production of everything, or do you think it would be helpful for me to set a soft interim deadline, understanding that the parties are going to keep talking and really in good faith, if GSK needs more time we will revisit that. What is your preference?

MS. FINKEN: I would prefer a soft interim deadline. I think that just keeps us all moving along, and I think that checking in next week with your Honor on Friday is perfect, but I think a soft interim deadline would be helpful so we can ultimately get the clarity we need on where we might have a disagreement.

THE COURT: Okay. What I was thinking in that regard, since it is 21 days from tomorrow, I will just split the difference and set a soft deadline for whatever the Wednesday is from the week after next. That is halfway in between.

2.4

As Ms. Finken points out, that is strategically placed so that if we met next Friday and, Mr. Sachse, your position is we are doing it, we're working on it, we're making progress, we have been transparent with them, we are not going to make it by Wednesday, but all systems pointing in the right direction.

To Ms. Finken's earlier point, I am mostly concerned about the clarity. If there comes a point where GSK is going to say we are going to make a legal objection, and the Plaintiffs need to file a Motion to Compel, I just want them to have enough time to do that. On the other hand, if they are never going to have to file a Motion to Compel, that's fine, at least we have transparency.

So, that is what I'm going to do, whatever that is, if someone can figure out what that date is, May the something.

It looks like May 5th, Cinco de Mayo. I'll set a deadline, but I am telling you right now that is a soft deadline, Mr. Sachse.

We'll check up on where we are next Friday, and if that deadline has to be adjusted, we will adjust it. So, that is Medtrack.

The other question was, have we determined whether there are other data fields in the PIER database; and if so,

any issues or any materially complex problems in providing an updated document to the Plaintiffs that would include those data fields?

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MR. OOT: Your Honor, Patrick Oot for GSK. I spoke with Ms. Finken on the break and identified the report that she was referencing, identified the employee that was responsible for that statement. Unfortunately, he is in the U.K.

I just want to make sure that I have an understanding of what these fields are. Right now, I would say there is no objection to providing an update. I just don't know what the what is, and I want to make sure that when we come back there isn't anything in there that would be objectionable or irrelevant, or what have you, not helpful to conducting the search. I just need a little more time to talk to the person overseas to make sure that we can do that pretty quickly.

THE COURT: Okay. Here is what I will do. As long as we are all here and I am entering a written order anyway, I am going to set a deadline to provide that, and again, that is without prejudice to GSK asserting legal objections based on undue burden, confidentiality, or anything else you want to assert an objection to.

I suspect there are certain fields that are going to be meaningful and really, really helpful to Ms. Finken and Ms. Luhana, and some that are going to be completely unhelpful, and it may be that the ones that are most sensitive to GSK are not

the ones that are going to be most helpful and vice versa.

Maybe you all can reach an agreement, but I will set a deadline for that just to provide them with the updated spreadsheet.

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Again, would a week be -- as you sit here right now,
Mr. Oot, I understand you haven't talked to your colleague, but
do you think presumptively a week is good enough, and if there
is a problem, we can talk about it next Friday?

MR. OOT: That should be plenty of time, your Honor.

THE COURT: Okay. I will set next Friday at 5:00 p.m. for the production of that report. Obviously, if you can get it sooner so we can have a meaningful discussion if we need to on Friday, that would be great.

MR. OOT: Agreed, your Honor. I will shoot for early next week.

THE COURT: That would be great. Ms. Finken, I should have asked you first, but any objection to giving them a week to provide that spreadsheet to you?

MS. FINKEN: I don't have an objection per se, I just would — the sooner the better, because that is going to inform any Motion to Compel that we need to file in relation to that PIER production index. So, the sooner that we have the fields and can actually make an informed decision in looking at that, the better.

THE COURT: Why don't we do this. Maybe this is the way to balance both of those concerns.

Mr. Oot, by close of business on Tuesday, can you just give them what the fields are, not necessarily all the data that would then go into the spreadsheet to fill in those fields, but let them know there is a field for author of the study, there is a field for number of pages.

2.4

Then, Ms. Finken and Ms. Luhana, maybe that will help you focus on at least knowing that outline.

MR. OOT: Agreed, your Honor, bound by the same sort
of scope discussion --

THE COURT: Of course. I'm just making a note to myself, Tuesday, COB for the fields themselves, and then Friday COB for the completed spreadsheet, which will have the data that fills in those fields.

All right. Let me turn back to the Plaintiffs, anything else that has come up since this morning that you think we should take up while we have the time today. I think those are all of the issues that I had left hanging.

MS. FINKEN: I don't believe so, your Honor. I am
looking at my notes. Thank you.

THE COURT: Sure, take a second and do that. I will turn to Mr. Sachse or Mr. Oot and ask them the same question.

Any either new issues you wanted to raise or clarifications on the issues we have discussed?

MR. SACHSE: Nothing from me, your Honor. I think we have been ruthlessly efficient in this afternoon's session.

 $\it THE\ COURT:$ Yes. Like the Spanish Inquisition in Monty Python. We try.

2.4

While Ms. Finken is reviewing her notes, Mr. Sachse, what is the oral argument that the student is doing?

MR. SACHSE: It is actually something that might be of great interest to you. The question involves a magistrate judge's jurisdiction — it is really the intersection between 636(c) and the judge's ability to screen prisoner cases under the IFP provision of the PLRA.

The specific question presented is, our client consented to jurisdiction, but the Defendants never consented before the judge dismissed the case under the IFP screening, and so that is the question presented.

THE COURT: Interesting. Who is the trial judge?

MR. SACHSE: The magistrate judge who dismissed the case is Judge Pesto in Pennsylvania. He is a part-time fencer as well as being a judge.

THE COURT: Having clerked for Judge Shapiro, which is the whole reason we have the PLRA, I am very sensitive to the PLRA.

Ms. Finken, did you have a chance to review your notes and make sure we don't have any other topics while we're together today?

MS. FINKEN: Yes. I don't believe that we do. I don't know if Ms. Luhana had anything else that she needed to

raise. 1 2 THE COURT: Ms. Luhana. 3 MS. LUHANA: Judge, I would just raise one thing in 4 terms of the field headings that Mr. Oot is going to produce by 5 COB Tuesday. If they are technical field headings, just an 6 explanation of what those headings represent will be helpful. 7 THE COURT: Okay. I am not going to be that granular 8 in my order, but that is my expectation. I think that is a 9 reasonable question and a reasonable question that should be 10 answered. I won't get that detailed in my order but, yes, that 11 is my expectation. 12 MS. LUHANA: Understood. Thank you, your Honor. 1.3 THE COURT: If there are abbreviations, you have to 14 know what the abbreviations mean, or technical terms, you have 1.5 to know what they mean, otherwise it is not really helpful. 16 Great. Unless either side has anything else you 17 wanted to talk about today, I think we have done a lot. I appreciate everybody's work. 18 19 One last chance. Anything else, Ms. Finken, 20 Ms. Luhana? 21 MS. FINKEN: Not at this time, your Honor. Thank you. 22 THE COURT: You have a window of time, you can go

MS. FINKEN: It is still early.

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spend time with your family and friends and loved ones since I

didn't take up the whole day, or do you have other work to do.

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THE COURT: I have work to do, too, so I will excuse
 1
 2
     you with the Court's thanks. Have a great week, everybody, and
 3
     I will see you back next Friday.
 4
              MS. FINKEN: Thank you.
 5
               THE COURT: Have a good day.
 6
          (Thereupon, the hearing was concluded.)
 7
 8
               I certify that the foregoing is a correct transcript
     from the record of proceedings in the above matter.
 9
10
11
           Date:
                      April 27, 2021
12
                      /s/ Pauline A. Stipes, Official Federal Reporter
13
                                 Signature of Court Reporter
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