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

CASE NO. 20-md-02924-ROSENBERG

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

- July 15, 2021
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STATUS CONFERENCE (through Zoom) BEFORE THE HONORABLE BRUCE REINHART UNITED STATES MAGISTRATE JUDGE

FOR THE PLAINTIFFS: TRACY A. FINKEN, ESQ.
Anapol Weiss
One Logan Square 130 N. 18th Street Suite 1600 Philadelphia, PA 19103 215-735-1130

ROOPAL P. LUHANA, ESQ.
Chaffin Luhana LLP 600 Third Avenue 12th Floor New York, NY 10016 888-480-1113

PAIGE N. BOLDT, ESQ.
Watts Guerra LLP 5726 W. Hausman Road Suite 119 San Antonio, TX 78249 210-448-0500

FOR THE DEFENDANTS: MICHAEL B. SHORTNACY, ESQ.
King \& Spalding LLP 1180 Peachtree Street Suite 1600 Atlanta, GA 30309 404-572-4600

WILL SACHSE, ESQ. CAROLINE POWER, ESQ.
Dechert LLP Cira Centre
2929 Arch Street
Philadelphia, PA 19104
215-994-4000

Official Court Reporter: Pauline A. Stipes
HON. ROBIN L. ROSENBERG
Ft. Pierce/West Palm Beach, Fl 772.467 .2337

THE COURT: Good afternoon, everyone, this is 20-md-2924, In re: Zantac (Ranitidine) Product Liability Litigation. We are here today for a discovery status conference. I don't think it is going to be a lengthy hearing, but we are here today for a discovery status report on two matters.

We will start with the -- we have the BI lawyers up, so we will start with the $B I$ matters first. Let me have counsel make their appearances, please.

Counsel for the Plaintiff.

MS. LUHANA: Good afternoon, Judge, Roopal Luhana for the Plaintiffs.

THE COURT: Good afternoon. And for Boehringer Ingelheim.

MR. SHORTNACY: Good afternoon, your Honor, Michael Shortnacy of King \& Spalding for Boehringer.

THE COURT: Good afternoon to both of you.
We were together two weeks ago, and I just wanted to get an update. I said at that hearing I was going to try to set a deadline based upon the developments that have happened since then, but just to circle back and make sure that $I$ am remembering this correctly, this started out as a discussion about materials that were in Mexico at the Promeco facility.

My understanding is BI has now, hopefully, been able to access everything they need to, and they are just making a
mass production of all the materials that they are recovering there. All may be a little too strong, but they are making a virtually complete production of whatever is in the batch records that are in the Promeco facility.

I understand the Plaintiffs have told them they don't need all that stuff, and that the Plaintiffs have given some alternative suggestions for not producing everything. I understand BI's position is, no, while we have access and we have been asked for it all, we are going to give you it all. I understand the Plaintiffs' position is, we don't want it all, and please don't come back later and claim that because you have given us a bunch of stuff that we don't want, it is now disproportionate to give us the stuff that we really do want.

I understand those are the positions on both sides and no one is compromising on any of their views on those two positions. That, to me, is not an issue here today, but I did want to say it on the record, that I have heard both of you, I understand those positions, and no one is compromising on either of those positions in any way today.

What is on the agenda today is my understanding that there were some documents that were within -- this was our Venn diagram discussion a few weeks ago. There are some manufacturing related documents that are in electronic format, some of which may fall within the circle that is the batch records, some which may have fallen outside the circle that is
the batch records, but are nevertheless manufacturing documents in electronic format.

What the parties had been doing over the last month or so is trying to identify that universe of electronic documents and which of those documents the Plaintiffs want, prioritization of the production of those documents, and to the extent that BI has an objection to producing those documents based upon burden or other concerns, that at least we are all pointing to the same things and trying to move the ball forward.

So, my understanding at our last hearing was you all had started moving in that direction and $I$ just wanted to get a quick update as to whether that process is continuing and what your best estimate is at to how quickly we can reach the inflection point where everybody sort of agrees that the Plaintiffs know what are there, the Plaintiffs have asked for what they want, and BI has either said we are going to give it to you, or we are not going to give it to you.

That's a long lead-in but, Mr. Shortnacy, let me turn to you and have you respond, please.

MR. SHORTNACY: Thank you, your Honor. Michael Shortnacy speaking.

You are right, and to your point about the paper records, your Honor, we are making what we believe to be, hopefully, the final production of those records to make it
complete at the end of this month, with another one going out tomorrow in fact.

Right, with respect to the Venn diagram, I think your Honor has said it correctly. In fact, the batch records themselves are also partly how you narrow into what is there and what the Plaintiffs are asking for.

So, what we have been pushing for, what we have been working with the Plaintiffs and the special master is to really have the Plaintiffs provide us with a narrow and specific ask pointing to specific records that will allow us, BI, to be able to respond and to say, if you are looking for these investigation records, now we are talking about a specific thing that we can respond to.

I think that is really the critical component for us, is being specific, and also that once you identify the what, you really can then get into the why and whether or not the information can be provided, for example, by a question like was there even this equipment used at the facility. That may answer and resolve questions.

Those are the kinds of conversations that are having with Plaintiffs, and again, $I$ think from our perspective, pushing at all times to be as narrow and specific as possible so we can respond, identify what is being asked for specifically so that we can ask the next question, which is: What is the burden and what is it going to show and is the
juice worth the squeeze from our perspective?
THE COURT: I understand that is the dialogue from your perspective. I understand as well, and Ms. Luhana made this point the last time we were all together, it is hard to say what we want if we don't know what you have. I understand that is a circular argument.

I broke the log jam and I told the Plaintiffs to go first, understanding that there is going to be some ebb and flow there and that just because they didn't ask the precisely right question or push the exactly precise right button, BI is acting in good faith and if it is clear this is what they are asking for and there is some record out there that they haven't directly asked for, but it is really responsive to their ask, we are going to tell them.

Understanding that is the flow, is that process going forward, are requests being made, are disclosures being made, are the Plaintiffs -- I will turn to Ms. Luhana in a second.

But from BI's perspective, are you starting to at least get a feel for what they are asking for such that you can start to make your evaluation of is the juice worth the squeeze, are we going to agree to produce this, et cetera? Do you feel that process is moving?

MR. SHORTNACY: Yes. This is Michael Shortnacy speaking again.

I do think the process is moving. We have engaged
with the Plaintiffs, we have pointed them to certain documents, they have provided questions to us, we have iterated on that process at least twice. Our mission is to try to make it as specific as possible, and to your point, your Honor, it is in our interest to help frame that question because, you know, we are interested in moving this along and having it reach the inflection point your Honor is talking about.

We certainly are willing to say, you know, if you didn't say this magic word, we think you are thinking this. We pointed Plaintiffs to certain Bates numbers of reports that contain records that we think they are interested in. So, I do think that process is working and we encourage it to be as focused and narrow as it possibly can.

THE COURT: I agree. I will come back to you in a second. Let me turn to Ms. Luhana. You have been very patient, I appreciate that. Let me let you respond to anything that has been said.

MS. LUHANA: Sure, thank you, Judge. The Plaintiffs have worked to narrow the scope of our request, we got those over to BI. BI, in turn, on July 5th, as Mr. Shortnacy mentioned, did provide us with a list of information. So, they provided us with about 50 spreadsheets from TrackWise, and that was covering about 2,500 batches of Zantac, and it was all of their out of trend, out of spec testing results, and they also provided a list of their annual product reviews for the time
they have had Zantac.
So, the spreadsheets are voluminous, they contain thousands upon thousands of cells of data, and sometimes it is in paragraph form. So, what we have done, once we received it on July 5th, we sent it to our team in Puerto Rico to do all the translations. So, it has been a huge undertaking and our team just got those documents back to us yesterday morning.

So, now we are going through them, sifting through the data and ascertaining exactly which batches we want to focus on and what testing and data we want. That is the next step, the ball is in our court to get that over to BI, and we plan to schedule another meet and confer shortly to go through some of those spreadsheets to narrow our request.

THE COURT: Great, that is very productive. I appreciate hearing that.

Let me ask you, Ms. Luhana, what is your sense of timing on all of this? As I said at the last hearing, I just want to set a deadline. I think deadlines are helpful, understanding, let's be clear, what a deadline in this context is going to drive. It would be similar to what I have ordered to GSK, which is a date by which BI has to say we are giving you -- we have completed our search, you have everything, we have completed our search, it is coming and here is when it is going to come by, or we have done all the searching we are required to do and we are not going to look any more.

At which point the Plaintiffs would then react either by doing nothing, or by requesting a PTO 32 to try to -essentially file a Motion to Compel. So, that would mean there would be a window of time after whatever the date -- the deadline would be in BI's written response, during which we would schedule the PTO 32, and the parties could certainly continue to negotiate and continue to meet and confer and perhaps resolve issues or narrow issues.

So, the reason I lay that out is, I want the parties to be aware that the court understands that that sort of a deadline is a triggering point, but not an ending point to discussion. So, when I ask you how much time do you need for me to set for that deadline, $I$ want it to be in context.

Ms. Luhana, what do you think is a good period of time to allow this process to continue on to a point where you feel like BI should be able to give you an answer and also give you an answer in a way that this process can come to an end such that the Plaintiffs have the documents that they are going to get, with enough time to do what they need to do this fall?

MS. LUHANA: That's a very good question, Judge, and I think a fair timeline would be sometime at the end of August, because we will be able to run through the data, work on a proposal, we should be able to work with BI on these meet and confers to get some of these answers. Bear in mind that we have the $30(\mathrm{~b})(6)$ coming up soon.

So, we are going to ascertain where the data is housed, what exactly is maintained, where it is maintained, how accessible it is, how easily it can be retrieved and what format. We will have all those answers to those questions so we will be able to fairly assess where we think we should push on some data versus other data. So, we will be well informed to make that decision, make that call by the end of August.

THE COURT: Okay. Mr. Shortnacy, I will allow you to respond.

MR. SHORTNACY: Thank you, your Honor. One point of clarification. The spreadsheets that we pointed Plaintiffs to because they asked a specific question and the response was these sheets were, in fact, produced in March, and they have been out there a long time. So, I just want to clarify that that has been sitting and what we are hoping is happening on the Plaintiffs' side is that things are not sitting like that and that we can try to move this process along. That is the first point.

As to the second point, for the $30(b)(6)$, 1 think that is something to flag for your Honor. That is another example where we have topics, as Ms. Luhana suggested, that are squarely about sort of electronically source testing information that is, in part, part of the batch records, that is true.

We've asked for as many written questions in advance

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as sort of narrow and focusing that we can do, as your Honor suggested with GSK and their issue about making a $30(\mathrm{~b})(6)$ ESI deposition be efficient and allow for preparation. So, we have asked for that and hope that that will happen.

Also, they have asked topics on 13 different systems, and so we are working with Plaintiffs to try to narrow those requests as well because, as your Honor can appreciate, 13 different systems have 13 different people, and so on and so forth.

I agree that the long-range plan of end of August makes sense. I only mention those things because we do want to keep anchoring back to the what and the why, why is this necessary and can it be focused, because I think that informs the burden analysis which we are all here to really, at the end of the day, make.

THE COURT: Okay, I hear you.
A couple of things. First of all, I am not going to fault the Plaintiffs necessarily that in the truly mountains of discovery that they have gotten in this case they didn't notice these spreadsheets back in March. There has been a lot of moving parts here and $I$ know everybody is scrambling. Maybe at some point in the future that becomes a relevant fact in some analysis that I have to do, but at least as I sit here today, I don't find that particularly problematic or troubling to me.

In terms of the $30(\mathrm{~b})(6)$ depositions, as $I$ said the
last time, $I$ think there is a push and a pull there.
The more focused information that the Plaintiffs can give to the Defendants about what the topics are going to be -as I said the other time, if they would just give you their list of questions, you can definitely prepare people. I don't expect them to actually do that, but $I$ also expect them not to just show up and say here is a very high-level topic, we want to ask you about manufacturing.

So, I appreciate that you all are working through that and going through that process. Look, if other issues come up in the interim, I will address those.

If the parties both agree that you think late August is the right time to land this plane, at least preliminarily land this plane, I will trust you. You are closer to this than I am.

Looking at my calendar, I am looking at Friday, August 20th, that is toward the end of the month. That way we don't ruin Labor Day weekend for anybody and those sorts of things. That is close to 45 days away. Or would you prefer even later, like -- immediately before Labor Day, like Thursday, September 2nd, or Friday, September 3rd?

Ms. Luhana, do you have a preference?
MS. LUHANA: Why don't we shoot for September 2 nd. THE COURT: Mr. Shortnacy, does that date work for you?

MR. SHORTNACY: Yes, that works for us, your Honor. THE COURT: Okay. You have already seen the order I did on GSK. My expectation is $I$ will cut and paste, so it will be the same directive as to that. Great.

Do you feel there would be value in having a scheduled status check-in sometime between now and September 2 nd on this topic, or is it better for me to just leave it to you two, and if you need me you can always either formally request a PTO 32, or informally through the special master say we have some topics we would like to talk about, getting guidance from the Court would be helpful, and we can do that on an ad hoc basis.

Ms. Luhana, what is your preference?
MS. LUHANA: I think if we can informally reach out to the special master and to when we need your intervention, that would make sense to do it that way.

THE COURT: All right. Mr. Shortnacy.
MR. SHORTNACY: I agree, your Honor, and that's right. If we feel like we need to exercise PTO 32, we have that availability, and otherwise can reach informally out to you through the special master, that works, and I appreciate that, your Honor.

THE COURT: Very well. So, I am not going to schedule another interim status check-in. I appreciate where you all have gotten to. It sounds to me like you have gotten to the point where we need to be where there is some transparency for
the Plaintiffs, they sort of know what is there. There is transparency for $B I$, they are starting to get a focus on what is being asked for. Everybody is iteratively focusing more and more. If you tell me you need about 45 days to finish that process, I have no problem with that.

That's all I had on this topic. Ms. Luhana, anything else relating to these issues that you wanted to raise today?

MS. LUHANA: I just wanted to raise one issue. In terms of the $30(\mathrm{~b})(6)$ notice, we have provided very specific detailed topics to address to BI, and we have requested that, to the extent they have questions about those topics, to address those with us, but $I$ think we have gotten detailed enough in terms of the topics that we intend to cover.

THE COURT: Again, I am not seeing it, and you know my practice is I generally don't rule on that ahead of time. Emphasis on the word "generally". I am not saying it never happens, but generally speaking. Again, I trust you all have a good relationship. I know the special master is available and I trust that you will be as focused as you need to be.

Look, if what happens is, BI shows up for the deposition, Plaintiffs ask certain questions, the BI witness -I do allow BI to instruct the witness not to answer a question at that time, or perhaps the witness says, I am not prepared to answer that, and if then we have to address after the fact whether the witness should have been able to answer the
question or should have had to answer the question, that is what I get paid for, and I will adjudicate that on a developed record after the fact.

So, you all will get as close as you can get. I don't expect we will get through an entire $30(\mathrm{~b})(6)$ deposition in this case without some disagreement about, well, you should have been able to answer that, well, no, we shouldn't have. That's okay, that is not -- my expectation is not perfection. My expectation is what you are doing, so I appreciate it very much. Thank you very much, Ms. Luhana.

Mr. Shortnacy, anything further?
MR. SHORTNACY: Nothing further for us, your Honor.
THE COURT: All right. Thank you. Then I will excuse you folks relating to the BI issue and I will ask the parties who are speaking on behalf of the GSK issue to turn on their cameras, please.

Good afternoon, Ms. Power and Ms. Boldt.
If $I$ could ask counsel for the Plaintiffs to enter her appearance, please.

MS. BOLDT: Paige Boldt on behalf of Plaintiffs. Good afternoon, your Honor.

THE COURT: Good afternoon, Ms. Boldt. On behalf of GSK.

MS. POWER: Caroline Power of Dechert on behalf of GSK. Good afternoon, your Honor.

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THE COURT: Good afternoon to both of you, too.
Again, to just circle up and to make sure we are all looking at the same target here, last time we were together GSK reported that they had identified approximately 750 boxes of what they think -- if the human clinical trials exist anywhere, they are going to be somewhere in those 750 boxes most likely. Again, there are no absolutes in this case.

They were going through those boxes, and I set a deadline for an inflection point to either produce what you are going to produce, or say you are not going to produce any more. Ms. Power, if you could bring me up to date on how you are doing in the process of going through the boxes and if there is any further discussion or any other topics that need to be addressed.

MS. POWER: Yes, your Honor. I think the high level take-away here is that the process is ongoing. We have boxes collected in both the U.S. and the U.K., those are being done with a first-level review to determine if any responsive documents are worth scanning, and then a second-level review before production, and that process has been going on on a rolling basis. We have been making productions of additional responsive studies.

We anticipate that the complete step one and step two process will be done, or close to done enough to have that inflection point that your Honor mentioned by the end of the
month.

And, your Honor, you previously set a request for a report on July 22 nd. Based on the current status of scanning, we would request a five-day extension to that, that we could provide a report on July 27th. Your Honor, this is the day before the scheduled GSK ESI $30(\mathrm{~b})(6)$ deposition.

THE COURT: Refresh me just so you and I are talking about the same thing, Ms. Power. What is it that you -- you say a report on -- did I order a report or is that the date I ordered by which GSK had to amend its responses to the request for production?

MS. POWER: I will have to get back to you on the details of that, but $I$ understand that by the 22 nd, we were going to make a final disclosure of where we stood, whether we believed we had done all that we could do, and have that inflection point to determine whether or not there is a dispute remaining.

THE COURT: Hold on just one second. I think what I had ordered, Ms. Power, was -- the procedural format for you to provide that notice was to file amended responses to the request for production which conformed to the local rules and to my standing discovery order in terms of format and which contained a Rule $26(g)$ certification.

So, if what you are asking is for an additional five days to provide that certification and that response -- am I
correct that is the ask?
MS. POWER: I believe so.
THE COURT: I see Mr. Sachse is hiding on the call, I know he is over in England.

MS. POWER: I am here with him. He will jump in if he thinks he needs to.

THE COURT: I didn't mean to call you out, Mr. Sachse. Ms. Power is doing a great job and I hope you are both enjoying being in England.

Mr. Sachse, $I$ just want to make sure, there was nothing else $I$ had ordered you to do by the 22 nd that $I$ am not remembering, is there?

MR. SACHSE: No, your Honor. This is, for the record, Will Sachse.

Yes, you are correct that we are to update or amend our responses just so that we can crystalize, clarify whether or not there is a dispute remaining.

THE COURT: All right. That's fine. Let me turn to Ms. Boldt.

I'm sorry, Ms. Power, had you completed your report?
MS. POWER: Your Honor, the only other thing I wanted to mention was the upcoming ESI deposition and how we are continuing to produce the exemplar batch records as requested by Plaintiffs.

THE COURT: Very well. Let me turn to Ms. Boldt.

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MS. BOLDT: Good afternoon, your Honor. THE COURT: Good afternoon. MS. BOLDT: As far as we were aware, there were no issues and, frankly, we have a deposition, as Ms. Power mentioned, on the 28th, so we would object to an extension for these productions when that deposition is a $30(\mathrm{~b})(6)$ on ESI issues, and while we are doing ongoing meet and confers, our understanding was that things were moving smoothly for next week's clinical production deadline.

THE COURT: Let me turn back to Ms. Power. Perhaps we can pull this apart into two pieces.

There is a difference, I think, between when are they going to get the documents and when are you going to file whatever certification that you have now given them, whatever it is.

So, is your request to just have additional time to make the certification and they are still going to get the documents by the 22 nd, or is your request to have additional time to actually produce the documents?

You are on mute, I apologize, Ms. Power.
MS. POWER: (Inaudible) is the point at which to make the assessment. As I mentioned, there are collection professionals who are pulling those boxes off of shelves and going through them in order to assess whether they are responsive or not. What volume of potentially responsive
documents comes out of that process will inform the time necessary to get it processed for electronic production in the case.

It is correct, your Honor, that we are hoping to have all of that production done -- excuse me, to have our certification and that they would have the production beforehand.

THE COURT: Yes, I am looking at my order here. For the record, it is at Docket Entry 3735, I don't think I have ever had to say that before, on the docket. It says: GSK shall substantially complete its production by the 22 nd.

Again, I am not necessarily sure what the disagreement is, Ms. Power. If you are saying you are engaging in a rolling production, you are going to continue to engage in that rolling production, there will be some materials that will be produced after the 22 nd, but before the 27 th, but maybe it is not substantial -- again, if you could clarify that for me.

MS. POWER: If we have the five extra days it would allow us to make a more accurate representation to Plaintiffs about how complete the production is. We do intend for it to be substantially complete, but so that they can have an accurate view on what we are seeing coming out of that PIER process and what can be expected over the next few weeks.

THE COURT: Okay. So, Ms. Boldt, if I am understanding, the request, and what $I$ would consider doing, is
giving them additional time to make the certification, with the understanding that whatever production schedule we are on is going to be the production schedule that we are on and that is not going to be modified.

It was always anticipated there could be some additional production after July 22 nd, but $I$ am not extending the July 22 nd date for the substantial completion, $I$ would just be giving them additional time to formalize that through their certification.

Does that inform your decision any better, Ms. Boldt, or do you want to confer with your colleagues if you weren't expecting this question?

MS. BOLDT: This is the first time we are hearing of this extension request, even though we spoke with them this morning regarding this production as well.

MS. FINKEN: Your Honor, it is Tracy Finken for the record. May $I$ jump in for one moment?

THE COURT: Sure.
MS. FINKEN: Thank you. Your Honor, as Ms. Boldt just indicated, we had not been advised of the request for an extension despite having spoken directly before this conference, so it came as a bit of a surprise to hear that.

Given the July 28th ESI deposition that we have on this specific topic, we would just request that we get those responses well enough in advance of that deposition so that we
can meet and confer, we can discuss it, analyze it, and be prepared for the deposition. So, we would actually object to that request for an extension and had not had a chance to discuss it with them ahead of time.

THE COURT: Okay. Let me turn back to Ms. Power to give her the last word.

MS. POWER: Your Honor, if I understand Plaintiffs correctly, that they would like more time to discuss this with us, we are certainly open to that. I am not prepared to withdraw our request today, but we can have those conversations and circle back to the Court if additional conversations would be helpful.

THE COURT: Here is what I am going to do. I am going to deny that request without prejudice at this time. You all can continue to talk and if the parties reach an agreement that additional time or an additional process would be helpful, I am happy to entertain that. File whatever formal motion you need to file. If the parties need to have another status conference to talk to me directly, $I$ am happy to do that as well.

At least at this point, I am not prepared to extend the deadline, but I will give you the chance to meet and confer, and if at that point GSK wants to request that, $I$ will hear you on that.

Anything else, then, Ms. Power, that we need to do this afternoon?

MS. POWER: Nothing from me, your Honor.
THE COURT: What time is it there in England?
MS. POWER: It's 6:30 here.
THE COURT: I hope Mr. Sachse will take you out to a nice dinner.

MS. POWER: We are actually in quarantine, so it will be a nice dinner in.

THE COURT: Okay. I'm sorry. Ms. Boldt, anything further that we need to take up from the Plaintiffs' perspective this afternoon?

MS. BOLDT: No, your Honor, thank you.
THE COURT: All right. I thank you all. I will
excuse everybody, wish everyone a one day belated happy
Bastille Day and a good weekend. I will wait to hear from you all as you need me.

Thank you, everybody. We will be in recess.
(Thereupon, the hearing was concluded.)

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

Date:

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\frac{\text { /s/ Pauline A. Stipes, Official Federal Reporter }}{\text { Signature of Court Reporter }}
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