| 1 2      | UNITED STATES DISTRICT COURT<br>SOUTHERN DISTRICT OF FLORIDA<br>WEST PALM BEACH DIVISION       |
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| 3        | CASE NO. 20-md-02924-ROSENBERG   |
| 4        | TN DE GANGAC (DANIERDINE)  |
| 5        | IN RE: ZANTAC (RANITIDINE) .  PRODUCTS LIABILITY . West Palm Beach, FL LITIGATION May 26, 2021 |
| 6        | • Hay 20, 2021   |
| 7        | <u></u>  |
| 8        | STATUS CONFERENCE and ORAL ARGUMENT (through Zoom) BEFORE THE HONORABLE BRUCE REINHART         |
| 9        | UNITED STATES MAGISTRATE JUDGE   |
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THE COURT: All right. Good morning, everyone. This is case number 20-2924, In Re: Zantac (Ranitidine) Products
Liability Litigation. We are here this morning for a status conference on one matter and for oral argument on a second matter.

The first matter I would like to take up is the status conference relating to proposed modifications to PTOs 54 and 60. Who will be representing the Plaintiffs for purposes

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of that matter?

MR. McGLAMRY: Your Honor, Mike McGlamry on behalf of Plaintiffs.

THE COURT: Good morning, Mr. McGlamry.

MR. McGLAMRY: Good morning, your Honor, thank you for having us.

THE COURT: Good to see you. On behalf of the brand Defendants?

MR. SACHSE: Your Honor, Will Sachse on behalf of the brand Defendants. Good morning.

THE COURT: Good morning. On behalf of the generic Defendants?

MR. HENRY: Good morning, your Honor, Terry Henry representing Apotex on behalf of generic manufacturers.

MS. THOMPSON: Good morning, your Honor, Sara Thompson also on behalf of the generic Defendants.

THE COURT: Good morning, Ms. Thompson. Good morning,

Mr. Henry.

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Any other groups of Defendants who I have mistakenly ignored here who are represented by counsel? Apparently not.

Counsel, this matter started about a month or so ago, a little over a month ago, the Plaintiffs submitted a request for modifications to PTO 54 and 60, the Defendants responded, Judge Rosenberg referred the matter to me. Then the parties indicated that they thought perhaps some conferral might narrow the issues or crystalize issues, and so we have been checking in periodically, and I just wanted to see where you all were.

I do want to bring this to closure at some point, but again, if you are making good progress and you think there is a reasonable likelihood you will reach agreement in the near future, that is fine. If not, I do want to set a date down for us to bring this to closure.

Let me start with Mr. McGlamry on behalf of the Plaintiffs. Mr. McGlamry, from your perspective, where are we? I don't necessarily need to get into the weeds of what you have agreed on and what you haven't agreed on or what the debates and issues are, just kind of a sense of what is the path forward from here.

MR. McGLAMRY: Thank you, your Honor. Again, Mike McGlamry on behalf of Plaintiffs.

Your Honor, as you have kind of indicated, although as I recall, initially the Court asked the parties, both sides, to

submit edits to those two PTOs. We submitted edits to both, the generics submitted edits to PTO 60 and the brands objected to our edits of the PTO 54, but we have, as you indicated, had discussions with the special master now for several weeks, including meet and confers and exchanging drafts of sort of a potential modification of PTO 60, and I think we are at an impasse, your Honor. We would ask you to set something.

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I think what we will do Friday in our reply brief as relates to PTO 30, is that we will make reference to this in the context of the schedule as an overall issue, but we believe we are at an impasse.

THE COURT: Thank you for clarifying. Your recollection of the history is more accurate than mine.

Are you at an impasse as to both PTO 54 and 60, or one or the other? I just want to be clear.

MR. McGLAMRY: Sure, your Honor, and that is a good question. It's PTO 60.

As I recall, and I pulled out the transcript from our last conference when Will was not available, May 11th, and we talked about essentially that we were only focused at this point on PTO 60, and that Ms. Horn had made a comment about that, and then I had responded to say, your Honor, with regard to PTO 54, we believe that we should look at that sort of systemically and we would be in touch with Ms. Horn about that.

Nothing has happened further on that, but in terms of

sort of the discussions with the special master and the parties, it has only been between us and the generics as per PTO 60.

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THE COURT: So, at least at this point, there is no ripe issue before the Court as to PTO 54; is that correct?

MR. McGLAMRY: That is correct, your Honor.

THE COURT: Okay. Thank you for that guidance.

Let me turn to Mr. Sachse. I will let you go first on behalf of the brands. Maybe you are not a party to this, this is PTO 60, but I will hear you anyway.

MR. SACHSE: Sure, your Honor, and I will just echo,
Mr. McGlamry is right, we are not ripe on a PTO 54 dispute. I
still am optimistic that maybe if 60 gets resolved, litigated
or resolved otherwise, I think the 54 issues might fall away as
well.

THE COURT: Okay. I hear you. Let me turn to Mr. Henry.

MR. HENRY: Thank you, your Honor. Well, in our view, the issue that was raised by the Plaintiffs at the case management conference that started this discussion involved the timeline in which the generic Defendants needed to produce noncustodial documents related to 30(b)(6) depositions. Your Honor, I think we have an agreement on that issue.

The reason we are at an impasse, at least from our perspective, is because Plaintiffs have sought to make other

changes that, number one, we don't think are needed at this time, and number two, that would impact all parties with respect to, for example, PTO 54. So, we do think we are at an impasse on those other issues.

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Maybe, as Mr. McGlamry suggested, and maybe I am reading too much into his comments, it makes a lot of sense to us as the generics that maybe we postpone or at least put off until after the PTO 30 issue is resolved whether PTO 60 gets amended as well, because we think whatever happens with PTO 30 is going to have an impact on what happens with PTO 60.

By the way, the impasse that we have reached at this point is not holding up discovery. Discovery is continuing at a pace, over the last two weeks multiple generic Defendants have continued to produce documents, we have continued to have depositions. Apotex had a deposition just yesterday, there are 28 more depositions on the calendar through the end of June, so that nothing is holding up discovery, but perhaps the resolution of the PTO 30 issue will help give us all guidance on what the next step is.

THE COURT: All right. I want to circle back on the PTO 30 issue in a second, but let me hear from Ms. Thompson.

MS. THOMPSON: I don't have anything to add beyond what Mr. Henry said, your Honor.

THE COURT: Very well. Let me turn back to Mr.

McGlamry and Mr. Henry. I understand there is a connection

between PTO 60, resolution of whatever issues you still have and PTO 30 modifications. What I want to understand, and I will ask Mr. McGlamry first, if the PTO 60 -- which one needs to go first, I guess is my question. If PTO 60 resolution is going to affect one of the factors Judge Rosenberg has to consider in assessing PTO 30, I want to try to resolve PTO 60 sooner.

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If what you are telling me is whatever Judge Rosenberg does on PTO 30, then we can work out PTO 60, then we can go the other way.

If what you are telling me is we have to get Judge Rosenberg to come up with a new scheduling order with new deadlines, those deadlines that she is going to put in place in PTO 30 as modified are going to be affected by how we resolve PTO 60, then I would need to know that because I want to do that first. I apologize, that is probably a convoluted question.

Mr. McGlamry, to the extent you could understand that question, can you respond to it, please?

MR. McGLAMRY: Yes, your Honor, Mike McGlamry for Plaintiffs, and maybe I will give a convoluted response.

I sort of would start with it depends. Mr. Henry indicated that one of the issues was the timing of the generics' production, and they have given us some dates by which they say is their drop dead back end production dates,

which we have said we can't use because, if so, we cannot go with the schedule we proposed to the Court for PTO 30.

On the other hand, as you have indicated, if the Court were to rule on PTO 30, as it might typically happen, that would then dictate what the parties had to do, whether that is us or the generics, in terms of getting things done within the time that the Court took into consideration as part of the PTO 30 issues.

That is why I had indicated when I first started that we intend to include this in our reply on Friday, because I do believe it impacts what the Court's consideration would be about PTO 30.

Look, your Honor, I am happy to go either way you want to go with that.

THE COURT: Okay.

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MR. McGLAMRY: Or do both of them sort of concurrently. Either one is fine with us.

THE COURT: All right. Ultimately, we all work for Judge Rosenberg, and I will do what she tells me, but I did want to clarify that on the record.

Let me hear from Mr. Henry on the same issue.

MR. HENRY: Your Honor, I think it is instructive for us to look back at PTO 60 for a moment and remember that what we did there was negotiated that agreement somewhat in the dark, we set deposition dates before we really understood the

scope of discovery. That has kind of set up this problem we have had where we are trying to shoot to produce documents in advance of depositions that had already been scheduled. Right. So, that was a bit of a problem.

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We are working through that, but we are trying to avoid that in this second iteration. Right? So, now we are trying to set up to make sure that we can complete the discovery, but what we don't know is what is the ending. Right? That is why, in our view, having PTO 30 resolved will help us set that schedule and get everybody on board.

And to be fair, many of the generics are moving forward and getting this discovery done. It is really the folks that have a lot of ANDAs over a lot of years, have a lot of documents that are struggling to keep apace, just as you would expect in any kind of race.

THE COURT: I understand. We have heard this theme before in the PTO 30 discussions with Judge Rosenberg. I think everyone in good faith sat down a year ago, tried to come up with a schedule, negotiated a joint schedule for this case trying to look into the future and anticipate what the world was going to be like and their ability to access documents, their ability to produce, their ability to review documents, the Plaintiffs' ability to prepare timely for depositions.

Sometimes when we predict into the future, we hit it on the bull's eye and sometimes we miss. I think part of the

discussion that we have been having collectively over the last few months is we got some of it right and may have missed on some of it. So, collectively the Court and the parties are trying to reboot and rejigger and figure out a better mouse trap here.

MR. McGLAMRY: Your Honor --

THE COURT: I'm sorry, Mr. McGlamry, go ahead.

MR. McGLAMRY: Your Honor, I apologize, I wanted to respond in this sense.

THE COURT: Yes.

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MR. McGLAMRY: I understood we were not going to get into the weeds, and I don't want the record to reflect that I agree that discovery has proceeded without delay. I disagree with that, and we can go into that in great detail if we wanted to.

Ultimately, my concern is this: Whatever time it takes us to get PTO 30, those issues resolved, in my opinion we still have to come back to the generics which, in my opinion, is a very difficult group to get to do anything timely.

And so, all of this, you know -- and part of our impasse is the generics say, well, it is premature to discuss this issue, this issue, this issue, and our response is, well, if we don't deal with that now, there is no more time left.

And so, my only concern is, I would not want to just wait for whatever length of time it is to get to PTO 30 to then

have to circle back, depending on whatever that ruling is, to go back to the generics and say, okay, now that the Court has ruled this, because that may say to them and to us we have to adjust ourselves accordingly, I just think that that is going to lead us down the road to further delay.

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THE COURT: I hear you, I understand that. Here is what I am going to do -- well, here is my proposal, unless anybody feels strongly this is not the right direction to go in.

Obviously, what was originally the issue that brought this matter before the Court, seems there has been negotiations and maybe some of those issues have resolved and the issue that needs decision at this point may be different from what you have already briefed for the Court.

I think it would be very helpful if the parties could file submissions to the Court laying out what is currently in dispute and what are their current positions as to what is in dispute. Maybe it is very different from what you said before.

I think once that is filed, I can look at it and Judge Rosenberg can look at it in the overall context, now having had full briefing on the PTO 30 issues, then the Court will be fully advised on the PTO 60 issues, and the Court can make a decision on the order of operations, how we want to address this, how quickly we want to address it.

My personal inclination is I want to get the briefing

in from you and then I would be inclined to just set a hearing and resolve the PTO 60 issue in parallel, and if Judge Rosenberg hasn't gotten to the PTO 30 issue or Judge Rosenberg wants to wait for me to resolve the PTO 60 issue, she can do that.

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On the other hand, if Judge Rosenberg wants me to wait, I will wait, but I don't think she and I can make that decision unless we know what is the current issue, not what was the issue a month ago, what is the current issue.

So, anybody disagree that that is a good way to go forward and at least make sure we are focused on the right thing? Mr. McGlamry?

MR. McGLAMRY: Your Honor, I am fine with that. In fact, if you think we should do that, which I think is a good idea, I think we should do that concurrently with filing our reply brief on Friday so that we don't have to spend time in our reply brief dealing with this. It could be a separate submission, as you have indicated.

THE COURT: I am fine with that.

Mr. Henry and Ms. Thompson, do you feel that gives you enough time to -- I assume you know what your position is and you can articulate it well, but you only have -- what day is today, Tuesday, Wednesday? I can't remember. You have a couple of days, so if Friday is a little tight for you, I will give you a little more time, but I have no problem doing this

as a separate round of briefing.

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Mr. Henry, what is your thought?

MR. HENRY: Your Honor, that sounds like a very smart way to go. Maybe if we had until early next week, that way we get to see the Plaintiffs' submission and respond by Monday or Tuesday of next week. I think we know what the issues are, but it is always good to see how they have articulated them in order to respond.

MR. McGLAMRY: Your Honor, I object to that. We have been negotiating back and forth these submissions, they know our position, we know their position. If we are going to wait until early next week, let's all wait until early next week.

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

MS. THOMPSON: I agree with what Mr. Henry said, your Honor.

THE COURT: Okay. Here is what I am going to do. I am going to have the parties file simultaneous submissions. I am not going to have serial submissions.

By five o'clock on Monday, close of business next

Monday, five o'clock Eastern time on whatever day that is -- I

can't do Monday because that is Memorial Day. Tuesday, by five

o'clock, the parties can just submit their position papers as

to just identifying what still is in dispute in PTO 60 and what

your respective positions are on that.

1 As Mr. McGlamry says, you can probably anticipate each 2 other's positions. If, once the briefing comes in, someone feels strongly that there is something that they must respond 3 to, they can respond to that by Thursday at five o'clock. 4 way, within a week or so we will have it fully briefed, and I 5 6 don't believe PTO 30 is going to be resolved before then, so 7 that will give me and Judge Rosenberg the information we need. 8 That will free everybody up to be completely focused 9 on the Motions to Dismiss and then we will go from there. Anything else relating to the PTO 60 issue that the 10 Plaintiffs think we should talk about today, Mr. McGlamry? 11 12 MR. McGLAMRY: No, your Honor, thank you for this. 13 THE COURT: Very well. Mr. Henry? 14 MR. HENRY: No, your Honor, that covers it. 15 you. 16 THE COURT: Ms. Thompson? 17 MS. THOMPSON: No, your Honor, thank you. THE COURT: Mr. Sachse, you don't really have a dog in 18 19 this fight quite yet. To the extent you and your clients want 20 to weigh in on this, I will certainly allow you leave to file 21 something on Monday or in response to either side's position. 22 MR. SACHSE: I think you're right, Judge, we don't 23 have a dog in this fight just yet, so we will wait to get to 2.4 54.

Before I sign off, I did have one other GSK specific

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issue, more of a scheduling issue to discuss. I don't know if you want to wait until the end of this conference to handle that.

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THE COURT: No, let's take it now, we are all here.

As long as Mr. McGlamry and Ms. Finken are the right people to respond to it, let's take it up.

MR. SACHSE: Yes, and Ms. Finken is aware of this. I just wanted to alert the Court, you asked earlier, inquired about my health status, so I would say we are at half time right now. I am actually going to be going back out on Friday, I have a surgery scheduled, it will keep me out for at least a few weeks.

I did have a meet and confer with Ms. Finken and Ms. Luhana yesterday because we have some deadlines coming up. We have, of course, as you know, what I call the batch record check—in and we made some really good progress in that regard yesterday and got some homeworks from them that we are running down, and I believe we also have technically — I shouldn't say technically, there is a deadline to substantially complete 30(b)(6) depositions of most of our 30(b)(6) deponents by the end of this month.

We have conferred with the Plaintiffs and agreed that we are scheduling those for the June and July period because our 30(b)(6) witnesses are based in the U.K., and there is -- as you may have heard, there is a European vacation -- I

shouldn't call it a vacation, a European work trip upcoming in June and July for all of the parties.

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I wanted to raise both of those issues with your Honor because I know that we do have, as I said, that reporting deadline on Friday. If we could get an extension of that deadline, and we are happy to submit a joint request in that regard, and I just wanted to sort of alert the Court to what I would consider the resolution of the scheduling, the deposition scheduling issue for those 30(b)(6)'s.

THE COURT: I apologize, I hadn't focused on it. The deadline for this Friday was to report in, file a notice relating to the batch record issue. Is that what it was?

MR. SACHSE: That is correct, and it is a deadline that applies both to GSK and to BI. I can't, obviously, speak on behalf of BI, but on behalf of GSK, I can say that I think we are making progress. We are not there, but we are making progress and we have been getting them additional information.

THE COURT: Okay. I want to keep on top of that. I will set another date for a notice from you.

How much time do you think is reasonable to come back around and update the Court on where you are on that?

MR. SACHSE: This is the tricky part. I'm not sure exactly when I am going to be back up and running.

We can say -- let's say two weeks. Would that work,
Ms. Finken? And if for whatever reason I am still laid up, I

will try to get a proxy who can report.

THE COURT: Ms. Finken, what are your thoughts on all of this?

Let me put it this way -- first of all, Mr. Sachse, I think earlier I said you and your client could file something on Monday. Obviously Monday is a holiday, so Tuesday is what I meant.

Secondly, as far as this week is concerned, you don't need to file something, you have just given me your report.

You both have lots of other work to do this week, so you don't have to file a notice by this Friday. I will excuse you from that.

The only question is whether I should set another date for another notice or whether you all want to kind of trumble along and then let me know if there are issues. I sort of prefer the first, but I understand the logistical problems or challenges, Mr. Sachse.

Let me hear from Ms. Finken.

MS. FINKEN: Tracey Finken on behalf of Plaintiffs.

Your Honor, I think it is fine to set a date for another two week check-in. We have contacts at Mr. Sachse's office that he was kind enough to supply us yesterday that we can reach out to in his absence. I told him he does not need to be texting and emailing us from the hospital bed this time.

We are making some progress, we did have a productive

meet and confer yesterday, so I would agree with Mr. Sachse on that.

As far as the 30(b)(6) depositions go, we do have dates certain for some of them in June and July in the U.K. currently. We will see if it sticks, whether they are actually live and in person in the U.K. or they end up being on Zoom, but they are scheduled for the most part.

I agree with Mr. Sachse, I don't know how you want us to approach that deadline that is in, I think it is PTO 63, in terms of getting those depositions done by the end of the month.

THE COURT: I don't recall. Again, I wasn't prepared so I didn't look at PTO 63. There is a deadline to complete GSK's 30(b)(6) depositions by the end of the month?

MS. FINKEN: Correct.

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THE COURT: If the parties just want to submit a proposed modified order extending that deadline, given your agreement, you can just submit that, a joint motion to extend that deadline, and I will review it.

I will just push back the reporting deadline on what we have called the batch record issue until June 11th, which is two weeks. In the interim, if something happens — it is just a written notice, and the notice can simply be we continue to work, or Mr. Sachse is still in the hospital, or we found someone else competent at Dechert who can actually work on

this, so we have actually made more progress. I don't know, I don't know where it will land. That is fine as well.

If you want to incorporate that, Ms. Finken, into the proposed PTO 63 modification, we can do one order for that as well.

MS. FINKEN: Thank you, your Honor.

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THE COURT: Mr. Sachse, the order of the Court is that you are to prioritize your health. This case will go on with or without you and you need to prioritize your health.

MR. SACHSE: Judge, I promise I will follow that order. Thank you very much.

THE COURT: Just in case your partners start to complain, you have an order from the Court now.

MR. SACHSE: I will let them know. I do not want to be held in contempt, so I appreciate that.

THE COURT: I don't want to send the Marshals to the hospital room to get you.

Is there anything further on these issues before we turn to the Sanofi related issues?

MR. SACHSE: No. Thank you, Your Honor.

THE COURT: I thank all of you. I will excuse the parties on the PTO 54 and 60 matter. I look forward to getting your briefing next week.

At this time let me turn to the second issue that was set for hearing today and that is what we have been calling the

Sanofi clawback issues. 1 2 Let me recognize counsel for the Plaintiffs on this 3 matter. MR. TROPIN: This is Daniel Tropin on behalf of 4 5 Plaintiffs. 6 THE COURT: Good morning, Mr. Tropin. 7 MR. McGLAMRY: Your Honor, Mike McGlamry for Plaintiffs. I do not intend to engage in this other than from 8 9 a factual standpoint if anything were to come up about the underlying clawback redactions or PTO 25. Otherwise, Mr. 10 Tropin is going to handle the argument for Plaintiffs. 11 12 THE COURT: Very well. No problem. The parties did notify me of that. 13 On behalf of Sanofi? 14 15 MS. CILIBERTI: Good morning, your Honor, Angelique Ciliberti from Arnold & Porter. 16 17 THE COURT: Good morning, Ms. Ciliberti, good to have 18 you. 19 MR. AGNESHWAR: Your Honor, Anand Agneshwar, Arnold & 20 Porter, on behalf of Sanofi. Pursuant to PTO 32, Ms. Ciliberti 21 is a fourth year associate who is going to handle the argument, 22 but as you have pointed out before, that is acceptable. I am 23 here as a backstop. 2.4 THE COURT: I have ultimate confidence Ms. Ciliberti

is going to be brilliant. Mr. Agneshwar won't need to clean up

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any messes, but if he does, that is my procedure and I welcome him to speak if he needs to.

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All right. With that, Ms. Ciliberti, I am treating this as a motion by Sanofi for leave to file ex parte affidavits and declarations under seal with the Court.

I am going to give you the first and last word, and as everyone has made clear, it is your burden on this one.

I had one kind of procedural question, if I could, to start with.

In looking at PTO 25, it appears that PTO 25 would have required Sanofi to provide a supplemental privilege log to at least log the limited number of documents that we are taking about here. Has that occurred?

MS. CILIBERTI: Yes, your Honor, we have provided a privilege log to Plaintiffs.

THE COURT: For these six or seven documents we're talking about?

MS. CILIBERTI: Right, for the seven clawback documents, they have our privilege log.

THE COURT: I thought that was interesting, they have the documents, so I'm not sure what the privilege log gives them, but I understand that is what the PTO requires, so I wanted to make sure.

With that, I did review the pleadings from both sides, and, Ms. Ciliberti, I will be happy to hear any argument you

would like to make at this time.

MS. CILIBERTI: Thank you, your Honor. May it please the Court. My name is Angelique Ciliberti and I am here arguing on behalf of Sanofi.

Your Honor, what Sanofi is asking is to submit a discrete set of explanatory evidence that is going to provide your Honor with what your Honor needs to determine our privilege claims as to the documents subject to the clawback dispute.

This request is entirely consistent with how Courts handle these kinds of situations where the privilege claim is not apparent from the face of the document, so the weight of authority is on our side and our ask is entirely in keeping with PTO 25.

Now, Plaintiffs have provided no authority, and we are not aware of any, where a Court denied in camera review of evidence that would provide the Court with factual information in order to assess a privilege claim. In fact, your Honor, the case that is the centerpiece to Plaintiffs' brief, the U.S. v Davita case out of the Northern District of Georgia, that case permitted these exact kind of submissions.

While Plaintiffs claim that they will be prejudiced if in camera review is permitted, their claims of prejudice are overblown. They have seen the documents that are subject to the clawback, they have a privilege log that provides our basis

for our privilege claims and, your Honor, they also have personal representations from outside counsel for Sanofi who were involved in the underlying issues that the documents subject to the clawback were created at the request of counsel for purposes of this litigation.

Now, Plaintiffs have told us that this information is not enough, and without additional evidence, if your Honor were to agree with Plaintiffs, Sanofi will not meet its burden, but the only other information that we can provide are the privileged circumstances, including legal strategy, surrounding the creation of these documents, and that is why we are asking the Court for permission to submit a discrete set of evidence that is going to have this information and provide the Court with the tools it needs to make a privilege determination.

Federal Courts throughout the country, including in the Southern District of Florida, have permitted these exact kind of submissions. I won't belabor the point too much, your Honor, we have cited a number of cases in our brief, but I do think there are two cases that are worth talking about today.

The first case is the opinion from the In Re: Denture Cream litigation, and that was an MDL here in the Southern District of Florida.

In that case, there was a dispute over documents that Defendants had withheld as privileged, and Magistrate Judge

Andrea Simonton permitted the Defendants to submit evidence ex

parte, including ex parte affidavits, and the apartment Defendants did this. They submitted a whole binder's worth of affidavits ex parte and this included affidavits from in-house counsel, as well as affidavits from nonlawyer employees, and the Court used these affidavits to provide context and rule on the privilege claims.

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And they are very similar, the types of documents at issue are very similar to the ones we have here, including documents where there are no lawyers on them, but documents that reflect nonlawyer employees carrying out the request of counsel.

The second case I would like to point your Honor to is the case I alluded to moments ago, U.S. v Davita, 301 F.R.D. 676. This is the case that is featured prominently in Plaintiffs' brief.

In that case, the party asserting privilege submitted ex parte affidavits and the other party objected. The Court ended up determining that that was a proper submission. The Court explained exactly why on page 686 of that opinion, your Honor, why Courts generally permit the reliance on these ex parte affidavits.

In certain circumstances there are going to be documents and emails where they are in shorthand or they contain terms or references that the Court might not understand, and in those circumstances, the Court explains that

it is entirely appropriate to submit factual information surrounding the circumstances of those documents.

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And the Court goes on to explain that when that information is itself privileged, that in camera review is a mechanism that Courts use to review the information, get the information that it needs to make a privilege determination, while also protecting that privilege information.

Now, your Honor, Plaintiffs attempt to distinguish these cases by saying, well, there is no PTO 25 in place, but under PTO 25, parties are permitted to submit evidence in support of their privilege claims.

Nothing in PTO, as it states, is intended to change the applicable law governing burdens of proof as to privilege claims, and the PTO even cites a case in the Southern District of Florida, the MapleWood Partners case.

So, it is clear from the PTO, and how the parties have proceeded from other PTOs, when a pretrial order does not account for a particular situation you look to the Federal rules and you look to the governing case law, and the case law is on our side here.

So, now, while our approach is entirely supported, Plaintiffs' lacks support entirely.

The cases that they cite, your Honor, where in camera review was denied by the Court, the Court was denying in camera review of the underlying documents subject to the privilege

dispute. The Court denied the in camera review because the party failed to meet its burden.

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That is a completely different situation than what we have here. Sanofi is trying to meet its burden by submitting evidence that is going to provide the Court with the factual context it needs.

Now, Plaintiffs' approach, while also being unsupported, puts us between a rock and a hard place.

Plaintiffs have asked the Court to order Sanofi to submit all of its evidence up front and permit in camera review only if the Court were to be unable to make the privilege call.

So, under Plaintiff's approach, Sanofi has two options. The first option is that we can remove the privileged information from the declarations in evidence, cross our fingers and hope that we meet our burden. The problem, your Honor, is that your Honor recently held in Diamond Resorts that this kind of watered down declaration with broad conclusory statements is insufficient to support a claim of privilege.

So, that brings me to our second option, option number two, Sanofi can submit the evidence as is, establish our burden, but waive the privileged information within that evidence. Neither of these options are tenable for Sanofi, and none of the cases that Plaintiffs rely on support such a convoluted, drawn out process.

That brings me to my final point, your Honor. The

traditional concerns with ex parte review are simply not present here. Generally, when a Court disfavors ex parte review, it is doing so for one of two reasons.

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The first reason is one that I am sure your Honor can appreciate. Courts do not want to be inundated with hundreds of purportedly privileged documents for it to review. You may recall that you alluded to this concern at a discovery conference back in March when my colleague, Ms. Sharpe, sought your guidance on in camera submissions. You said that you would not want a party to submit 11,000 pages of discovery.

That is not what we are doing here. We are not asking the Court to review thousands or even hundreds of documents.

What we are asking is for the Court to review a discrete set of factual evidence that does not contain legal argument, but is going to provide the Court with the information it needs surrounding the clawback documents and allow the Court to make a privilege determination.

The second concern with ex parte review, your Honor, is one of fairness, the concern that the other party is at a disadvantage because it doesn't have the underlying information.

Here, Plaintiffs have seen the documents, they have seen them in their full unredacted forms. They also have a privilege log that provides that basis for our privilege claims, and they also have personal representations from

counsel who were involved in the underlying issues that the documents were created at their request for purposes of the litigation.

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Plaintiffs are not going to be disadvantaged simply because they do not have privileged communications which they are not entitled to surrounding the creation of the clawback documents.

But Sanofi will be at a disadvantage if it is not permitted to fully defend its privilege claims by submitting all the evidence it has in order to meet its burden, or if it were to have to risk waiver by submitting the evidence as is with the privileged information.

For these reasons, your Honor, Sanofi respectfully asks the Court to permit it to submit the evidence that we identified in our motion for in camera review.

That is the end of my affirmative argument, your Honor. I am happy to answer any questions you may have.

THE COURT: Thank you, Ms. Ciliberti. I do have a couple of questions. Obviously, I haven't seen the proposed submissions that are beyond the documents, the declarations, or whatever else you are going to submit.

Are those limited only to factual declarations by counsel or are they going to also include, for example, an email, say, from Mr. Agneshwar to a nonlawyer saying do this, do that? Are they going to include other documentary evidence

or are they simply going to be declarations by counsel?

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MS. CILIBERTI: Your Honor, in our opening motion we laid out all the evidence that we would potentially submit, and there are, I believe, five declarations that contain factual information, and then there are two additional privilege documents that Plaintiffs have not seen.

THE COURT: Okay. I understand. My other question is, Plaintiffs are requesting -- I think in other cases the Courts have done this -- that whatever is filed, you should at least provide to them redacted versions that are, to the extent possible, shorn of privileged information, but otherwise reflect everything else.

I can foresee a declaration from -- I think you indicated Mr. Agneshwar may be giving a declaration. He will say I am Anand Agneshwar, I am a partner at Arnold & Porter, I am lead counsel in this litigation, I manage all communications with the client.

I would think that wouldn't necessarily need to be redacted, you could provide that, but when you get into this is what I told them, presumably you would want to redact that.

Does Sanofi object to providing -- I know you had a footnote in your pleading, but I want to make it clear on the record. Does Sanofi object to providing that sort of redaction even if I allow you to file the ex parte documents?

MS. CILIBERTI: No, your Honor, Sanofi does not object

to providing redacted versions of the evidence that we would submit in camera.

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THE COURT: Okay. Thank you, Ms. Ciliberti. Let me hear from Mr. Tropin and then I will give you the last word.

Mr. Tropin, let me turn to you. Good to see you.

MR. TROPIN: Good to see you, your Honor. This is Dan Tropin on behalf of Plaintiffs.

Let's be clear, Plaintiffs' issue with Sanofi's position is that ex parte submissions should not be automatic whenever there is a privilege dispute. Judicial proceedings should be adversarial and transparent as a general rule.

Ex parte proceedings of any kind, including on privilege issues, are an exception to that rule, and this exception should not be made lightly, let alone, as Sanofi would have it, automatically. Why? So the opposing party is not forced to litigate blindfolded.

To reiterate, and I think this is important,

Plaintiffs' position is not that there should never be ex parte
submissions, even in this case; instead, ex parte submissions
should only happen when absolutely necessary and
after traditional and transparent steps are taken, and that is
backed up not only in the case law, but also on the record
already in this litigation.

Here, there has been no showing that ex parte submissions are necessary for this dispute. There has been no

showing that Sanofi, for whatever reason, cannot explain what reasons on the surface of the documents are not clear as to privilege with submissions that are not themselves privileged.

So, here the parties can litigate privilege issues without ex parte submissions, especially with the in camera review of documents, and this is reflected in PTO 25 which calls for briefing on privilege issues without calling for exparte submissions of affidavits or other evidence.

If PTO 25 contemplated ex parte submissions, as it did with in camera review of privilege documents, then it would say so.

And then -- so, only if there is some reason that the Court cannot decide the privilege issue without an ex parte submission, for instance, contrary to the idea that there is two options, both of them bad, here Sanofi could provide the evidence it has that is not privileged and then flag for the Court that its support for the privilege claim is hampered by an inability to properly explain itself, and then the Court could -- if it is absolutely necessary, then there could be an ex parte submission.

And to the point about prejudice, that shows, contrary to Sanofi's position, that Plaintiffs' proposal would not in any way prejudice Sanofi. If ex parte submissions are absolutely necessary, then Sanofi will have the opportunity to provide them.

The problem is that Sanofi's proposal puts the cart before the horse, and regardless of any argument that Plaintiffs somehow know what is in the ex parte affidavits, the very submission of ex parte affidavits by definition blindfolds Plaintiffs. That is prejudicial and that is why this is a very rare exception to the rule.

Let me refer back to what this Court said on March 10th on the record, that the parties shouldn't unilaterally just submit something and say we are submitting it in camera because really -- because in camera is an exparte proceeding, it is the exception to that rule, and that is for in camera submissions of documents. In camera submissions of affidavits, other evidence that we don't know what is going to be said in them, is even more prejudicial and more necessary where the documents are going to be submitted in camera.

We could not agree more with this Court's statement at that hearing, and that Court's statement is echoed almost word for word in Diamond Resorts where this Court said, I don't think it is appropriate for me to have in camera ex parte communications with you when I am conducting the in camera review.

So, that again goes explicitly to the context where there is in camera review of documents, that ex parte communications such as ex parte submissions are inappropriate unless they are absolutely necessary.

And I think that this same principle is best expressed in Campero USA, set in our papers where Judge McAliley -- and this was also repeated in MapleWood which, as counsel for Sanofi pointed out a moment ago, is cited in PTO 25, so I think it carries extra importance here -- that "Courts make a principled attempt to try to avoid ex parte proceedings, including in camera review of documents, as it is fundamentally contrary to our adversarial system of dispute resolution.

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"In camera review puts the Court in an undesirable position of attempting to think of arguments that the excluded counsel might make if he or she had access to the documents in question, and the Court can never do the job of counsel as well as counsel can. Thus, it is wise for the Court to not consider an in camera review until the party asserting privilege has done all that it reasonably could to establish privilege."

Let me respond momentarily to Denture Cream that

Sanofi relied on in their papers and a moment ago because In

Re: Denture Cream has been interpreted by Defendants in a way

that is inconsistent with this Court's practice and where we

are now. Sanofi is correct that we view Denture Cream as

inconsistent with PTO 25, and Sanofi is also correct that we

have other reasons to distinguish it that we put in our

opposition.

But more importantly, if you look at the order that was attached as Exhibit A to Sanofi's motion, at page five,

paragraph three, where the procedure for ex parte affidavits is laid out, it explicitly says that these ex parte affidavits should only be submitted, quote unquote, if necessary.

That is exactly Plaintiffs' position here, that it is not that we are calling for a bright line rule that ex parte affidavits should never be submitted in any privilege dispute if there is some occurrence where it is absolutely impossible to explain why a document is privileged based on the document itself in an in camera review, and whatever other context can be provided without privileged communications such as that this document is relaying advice of counsel, who the counsel is, who the individuals on the document are.

In that rare instance it would be necessary to submit ex parte affidavits, but again, here Sanofi has provided nothing of the kind. At most, we have had vague generalities as to what is in these affidavits, and no explanation as to why Sanofi cannot explain itself, and why these documents are privileged without resorting to a rare procedural device that should only be called for where absolutely necessary.

And indeed, that is why we cited to Davita which, even though it did call for ultimately redacted affidavits, Davita was unequivocally clear that ex parte proceedings are an exception to the rule in our judicial system and contrary to its adversarial nature, and that in some cases, in some cases, especially given the complicated nature of the matters

at issues there, the Court might require further context to understand the claim of privilege.

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Thus, again, and this is exactly what we are asking for here, Davita allowed ex parte submissions, quote unquote, where necessary. Let me emphasize that again, where necessary, because that ultimately is Plaintiffs' position, not that ex parte affidavits can never be submitted, but that they can only be submitted where necessary, and that here Sanofi has not illustrated why it cannot support its position that these documents are privileged without resort to ex parte submissions.

So, ultimately, the Court may consider ex parte submissions for in camera review, but that decision should be a last resort and after traditional and more transparent steps are taken, and let us reiterate that the steps would allow Sanofi to flag the fact that it might need to submit a little bit more in camera for the Court's review in the event that they are unable to properly support with on the record under seal, pursuant to PTO 26, submissions.

But on the other hand, following Sanofi's proposal, it will necessarily require that Plaintiffs will be prejudiced by ex parte submissions because they will be left litigating with blinders on.

THE COURT: Thank you, Mr. Tropin. It sounds like the parties are not actually that far apart on some of these

issues. I think everyone agrees there are times when ex parte submissions are appropriate. It is just a question of whether this is one of those, if I am understanding Plaintiffs' argument.

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The Plaintiffs' position is that Sanofi hasn't done enough to get over that threshold. I guess the question to you, Mr. Tropin, is, what else do you think they need to do?

You have a copy of the document, as Ms. Ciliberti points out, you have representations from counsel that counsel was involved, so therefore these are privileged.

So, what else do you think they should have to do before I should let them submit ex parte affidavits?

MR. TROPIN: I think it is actually a pretty simple procedure that can be followed, which is that once the dispute has been crystalized as to whether documents are privileged, as they are here, Sanofi should move to claw them back, submit as agreed upon the documents for in camera review, provide whatever support they can, and then in those papers provide the specific reasons why they are hamstrung, flag them for the Court so the Court doesn't just rule against them, and this erases any chance of prejudice.

The Court can look at Sanofi's papers, our opposition, which is great because then we would not be prejudiced in preparing that opposition, and either decide that the record before it is sufficient to rule on the papers and evidence

before it, or if further evidence is needed, then the Court can simply order further evidence be submitted in the form of ex parte affidavits because it is absolutely necessary.

THE COURT: It sounds to me like where you see the hole is that Sanofi hasn't yet established that they can't meet their burden without these ex parte affidavits, that they should have to explain in a bilateral proceeding why they think they can't get there, allow you to argue why they can, and then the Court would rule.

If the Court agreed with them, I would allow the exparte pleadings; and if I agreed with you, I wouldn't allow the exparte pleadings. Am I understanding your argument correctly?

MR. TROPIN: Correct. The one thing I would add to that is that it should be folded into the argument about the substance itself to avoid unnecessarily taxing the Court with deciding two separate disputes and two rounds of argument, that Sanofi should simply explain why it thinks it is privileged.

If there are reasons that they are unable to articulate properly due to the lack of evidence that would necessarily be privileged itself, then it can flag that for the Court.

THE COURT: I guess my other question is this. There is a general principle and understanding that the Court as -- particularly on preliminary issues, for example, under Rule of

Evidence 104, the Court understands what the Court can consider and what the Court can't consider.

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What would be the harm or the prejudice to the Plaintiffs if I allowed Sanofi to submit the ex parte affidavits along with their briefing on the substantive matter? Presumably in that briefing they are going to explain why I have to look at these other things. Plaintiffs can respond, and then if I need to look at those documents, I will look at them, and I will make clear on the record that I looked at them.

If I determine I don't need to look at them, I won't look at them, and I will make clear on the record I didn't look at them.

What is the Plaintiffs' argument why that isn't a proper procedure that we could follow here?

MR. TROPIN: The problem with that procedure would be that, essentially what is being called for here, which is that Plaintiffs are forced, as the opposing party, to litigate blindfolded where Sanofi's submission will refer to matters that Plaintiffs just simply do not have access to, and the Court shouldn't entertain that unless absolutely necessary.

THE COURT: Your position is, I shouldn't do that in parallel, I should do that sequentially. I should first make them file their motion, establish why they can't meet their burden, and if I accept their argument, after hearing your

opposition, that they can't meet their burden without these ex parte affidavits, can't fairly have a chance to meet their burden without these ex parte affidavits, then I should have a second round and allow them to submit the ex parte affidavits, and then I can rule.

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MR. TROPIN: That is absolutely correct, your Honor.

THE COURT: Thank you. I understand your position, you have made it very clear.

Let me go back to Ms. Ciliberti and give her the final word.

MS. CILIBERTI: Thank you, your Honor. I would like to first address Mr. Tropin's proposed approach.

So, under his proposed approach we would have multiple rounds of briefing, which seems inefficient with judicial resources in mind, and also it is inconsistent with the case law.

Under the case law, as Mr. Tropin pointed out, quoting MapleWood, "a party must do all that it can to reasonably establish privilege before ex parte review." MapleWood is talking about ex parte review of the underlying document. Here we are trying to provide all the evidence that we can up front in order to meet our burden.

I would also like to point out that in U.S. v. Davita, the party there submitted ex parte affidavits right up front.

The procedure there, Plaintiffs had filed a motion to compel,

and in the Defendants' response brief they submitted their ex parte affidavits, and the Court found that this was proper, and to quote the Court, "Courts generally permit the filing and reliance on ex parte affidavits."

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THE COURT: I understand. Again, I think you all are not that far apart.

Do you agree with the Plaintiffs' position that there are essentially two thresholds here? The first threshold is, should you be allowed to submit ex parte affidavits in support of the second threshold, which is meeting your burden of establishing there is actually a privilege here.

First of all, do you agree with that concept, that there really are two thresholds that have to be crossed?

on the case law, we are permitted to submit ex parte affidavits in support of our burden before — in order to meet our burden. It is a single process, and it doesn't — it seems to us that it doesn't make much sense to pare down evidence that this Court has already found to be insufficient to meet a burden of privilege.

THE COURT: Okay, thank you. I understand.

All right. Anything further, Ms. Ciliberti, on behalf of Sanofi?

MS. CILIBERTI: I would just like to address Diamond Resorts where Mr. Tropin talked about how the Court denied ex

parte communication. In that case, the Court was reviewing the underlying documents in camera, and the party asserting privilege asked to submit a memorandum ex parte.

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To be clear, Sanofi is not asking to submit legal argument, our evidence is very narrowly tailored. We tried to include only the facts necessary to give your Honor the information your Honor needs to assess our claims of privilege.

THE COURT: Trust me, I am painfully familiar with the Diamond Resorts case and I remember those proceedings very well. In that case, the parties didn't push the issue as hard as it has been pushed in this case and didn't ask for briefing and didn't really frame it quite the same way.

While I understand what I said there, and I meant it because I said it, I don't know that it is full square on to the issue presented here, but I do think it has some precedential value that I will take into account.

Anything further, Ms. Ciliberti, on behalf of Sanofi?

MS. CILIBERTI: No thank you, your Honor.

THE COURT: Anything else, Mr. Agneshwar?

MR. AGNESHWAR: No, your Honor, I will rest on Ms. Ciliberti's argument.

THE COURT: Very well. Thank you all very much. I will take this matter under advisement. I know this needs to get resolved quickly. This has been extraordinarily helpful, both the written briefing and the argument here today. I will

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get an order out as quickly as I can and we will go forward.
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     Thank you all very much.
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               We will be in recess and I will excuse the parties.
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     Thank you.
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               MR. McGLAMRY: Thank you, your Honor.
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          (Thereupon, the hearing was concluded.)
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               I certify that the foregoing is a correct transcript
     from the record of proceedings in the above matter.
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                      /s/ Pauline A. Stipes, Official Federal Reporter
                                  Signature of Court Reporter
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