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

CASE NO. 20-md-02924-ROSENBERG

IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION.

West Palm Beach, FL
March 2, 2021

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

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THE COURT: Okay. Let me make sure we have Ms. Finken and Mr. Oot, our first people who are going to be talking.

Mr. Oot, good afternoon.

MR. OOT: Good afternoon your Honor.

MR. MADERAL: Your Honor, this is Frank Maderal. Ms. Finken is having a little bit of a technical issue.

THE COURT: No problem, Mr. Maderal. Thank you.

Mr. Oot, if you want to turn off your camera until she gets here, that is fine. If you want to leave it on, that is fine.

MR. OOT: Thank you, your Honor.

MR. MADERAL: Your Honor, this is Frank Maderal again. Ms. Finken has joined.

THE COURT: Wonderful. Thank you. Mr. Oot, if you'd turn on your camera when you are ready, and Ms. Finken, once you get settled.

All right. Good afternoon, everybody. This is In Re: Ranitidine Multi District Litigation, Case Number 20-2924.

We are here this afternoon for two discovery hearings, one relating to some residual issues relating to a GSK deposition scheduled for tomorrow, and the other relating to a number of issues that were raised relating to the 30(b)(6) depositions of the generic Defendants.

With that, let me begin with the residual GSK deposition issues. Let me have counsel make their appearances.

I'll start with counsel for the Plaintiff. Let me remind everyone, as we always do, please state your name before you speak so that the court reporter can make a record for us all.

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

THE COURT: Good afternoon, Ms. Finken.

MR. OOT: Good afternoon, your Honor, Patrick Oot on behalf of GSK.

THE COURT: Good afternoon. Just a preliminary question, counsel, is anything under seal for purposes of this proceeding? I know we were looking through some of the materials and it wasn't clear to us if anything had been filed under seal. Ms. Finken, if you could just educate me.

MS. FINKEN: Your Honor, in relation to the dispute memorandums that were filed on behalf of the generic issues, there were exhibits that were attached to that that would need to be filed under seal due to confidentiality designations.

Because they are not on the docket they were not sent to your Honor under seal, but should they need to be docketed, they would need to be filed under seal based upon some of the confidentiality designations on those documents.

THE COURT: Okay. Well, let's see if we actually utilize those documents during the hearing. If we do, if you and your colleagues alert me that we are delving into that area, then after the hearings are over, I will direct the

parties to file their memoranda on the record and anything that should under seal should be filed under seal.

Mr. Oot, are you aware of anything under seal for purposes of at least the GSK part of the proceeding?

MR. OOT: No, your Honor.

THE COURT: Okay. Thank you both for clarifying that.

I know I got a notice that the deposition is set for tomorrow. I just wanted to make sure that before the deposition occurs were there any residual issues that needed intervention from the Court. I know we had a brief hearing on Friday, I know there has been a lot of back and forth through the special master and with each other, and I want to thank the parties for their efforts to come to agreement on this.

I didn't want the deposition to get started and not have all the loose ends tied up. Ms. Finken, let me turn to you.

MS. FINKEN: Yes, your Honor, we had a lengthy meet and confer yesterday morning where we discussed some of the issues. The Defendants' counsel is going to get back to us with some open questions we have that are relative to the motions that we filed.

For purposes of the deposition tomorrow, I don't think that there is anything in the motions that would hold up moving forward with the depositions. It would be more so the remedy on the back end should we need to take another deposition of

this witness, which is obviously something that I don't think would need to be decided today.

What we wanted to do is try to work through these issues over the next few days with counsel, and at this time seek a continuance and reschedule the PTO 32 hearing should we need to do so after the deposition concludes.

THE COURT: Great. Thank you. Mr. Oot.

MR. OOT: Yes, your Honor, I would agree with Ms. Finken that the parties have come to at least a short-term agreement on our moving forward with the deposition. We look forward to resolving all of the issues without your intervention and we look forward to that.

THE COURT: Very good. I won't be offended if you don't need me.

For now, if you need to -- Ms. Finken, what is your preference, do you want me to just set another date and time for us to get together, or should I just deem the issues temporarily resolved and I'll wait to hear from the parties if you need another date?

MS. FINKEN: I think the way that we left it when I spoke to -- it wasn't Mr. Oot yesterday, it was Mr. Cheffo and Mr. Sachse. We had left it that we would seek another date for after the deposition, towards the end of the week or early next week, so that we could try to work through these issues in the meantime. Then, if we could not, we would come back in front

of your Honor.

I didn't want to necessarily take down the motion because I don't know for sure that we will actually be able to get it resolved. My preference would be that we set another date in the meantime while we continue to try to work through the issues.

THE COURT: Okay. So, I can give you either Friday, I am wide open this Friday, or I could give you Monday other than between 1:00 and 2:30.

MS. FINKEN: Friday is fine with me, your Honor. I don't know Defense counsels' availability, but Friday would be fine with me.

THE COURT: Mr. Oot.

MR. OOT: Your Honor, Friday is a problem for me. Mr. Sachse might also want to be in this upcoming case management conference. I might suggest, at least for my schedule, Monday afternoon might be best if it has to be.

THE COURT: Why don't I do this, I will set it for Monday at 12:30 -- no, I'm sorry, I have a one o'clock.

Monday at 2:00, we'll set it down. That will give you the entire weekend. You can do nothing all weekend but try to resolve your issues and I'll give you extra time to do that. Monday at 2:00 p.m. we will reconvene and if it turns out you don't need it -- let's just plan to get on the phone with you, whether you think you need it or not, and you can give me a

final report. That way we can close the loop on this.

While I have you, let me ask one other question. In going back over the submissions in my materials, I see there is a significant deadline on March 15th for production from GSK, and as I recall at the last -- one of our the last hearings, the indication was that GSK was working valiantly to meet their deadline.

Mr. Oot, does it still look like you are you going to land the plane on time on the 15th?

MR. OOT: We are working on that right now, your Honor. I'd say that there are issues that we are working through with Plaintiffs. That will be a discussion, perhaps, that we could have on Monday. Right now, I couldn't say with certainty that we are going to meet the full completion of everything on the 15th.

THE COURT: Okay. Work it out with each other, obviously. If you don't meet it, as I said before, if somebody misses a deadline and the other party thinks they are entitled to a remedy, you are certainly entitled to ask for that remedy.

Given the relationship here, I will assume that even if you are going to miss the date for some things, you will work with Ms. Finken to try to minimize any prejudice so the case can keep moving. I will leave that alone until I see you on Monday.

Anything else, then, Mr. Oot, that you think we need

to raise on the GSK matter?

MR. OOT: No, thank you, your Honor.

THE COURT: With that, Ms. Finken, anything else on the GSK matters?

MS. FINKEN: No, your Honor. We can talk about the March 15th deadline on Monday. We have been advised that they will not meet the March 15th deadline, but certainly we can discuss that in a more fulsome manner on Monday.

THE COURT: Maybe the world will change between now and Monday. They will get a boost of energy and they'll get it done in time. We'll cross that bridge when we get there.

MS. FINKEN: We can only hope.

THE COURT: Exactly right. Candidly, counsel, that is why I really don't like to try to delve into these things until there is something to delve into because the world does change a lot, particularly in a case like this, seven days is a lifetime. We will see what happens between now and then. I am always happy to talk to you about those sorts of issues, but I try to avoid ruling on them until there is really something to rule on.

With that, I will excuse Mr. Oot. Thank you very much.

Ms. Finken, I think you are staying on for the next matter. We will now transition over to the generic 30(b)(6) issues. The first issue we are going to take up is the

manufacturing issue. My understanding is that Mr. Barnes is going to speak to that for the Defense, and that he has other commitments around 4:15. God forbid we are still on this topic in two hours, but I want to make sure Mr. Barnes had plenty of time to be heard. Good afternoon, Mr. Barnes.

MR. BARNES: Thank you, your Honor, and thanks for accommodating my schedule. Thanks to Ms. Finken as well.

Your Honor, good afternoon, Richard Barnes. I am appearing today in my role as co-liaison counsel for the generic Defendants.

THE COURT: Hold on. Before you go on, Mr. Barnes, let me do a little bit of housekeeping as well.

I guess relating to -- I got an email late last night when I had plenty of other reading to do, so I can't tell you that I read it particularly carefully, even though I know it was not very long, which seemed to indicate there were some other issues that the parties -- related to the generics that needed the Court's involvement, and maybe some of them will be mooted out by what we do today, maybe they won't.

I was going to offer you a hearing on Thursday to address the issues that were raised in that email. I have the whole day wide open.

Ms. Finken, what is your pleasure?

MS. FINKEN: I am perfectly wide open on Thursday as well, your Honor, so happy to appear before you at the Court's

convenience.

THE COURT: Mr. Barnes, are you the right person to ask about this topic or do those go to some of your co-counsel?

MR. BARNES: Let me defer that to Mr. Yoo. I am tied up Thursday and Friday, or Mr. Henry. I will not be representing the generics on Thursday, I am just booked all day, but maybe Mr. Henry can address that.

THE COURT: Mr. Henry, what is your pleasure for Thursday?

MR. HENRY: Your Honor, it's Terry Henry for Apotex Corp. I can make available Thursday if these issues need to go to a PTO 32 hearing.

THE COURT: Ms. Finken, since you sent the email, how much time do you think we will need for the PTO 32 hearing on Thursday?

MS. FINKEN: I don't believe that we will need as much time as we need today to work through the notices of deposition issues, so I would say maybe an hour, hour and a half, your Honor. They are relatively simple issues.

THE COURT: Mr. Henry, any preference, morning or afternoon?

MR. HENRY: Your Honor, early afternoon would be the best. I actually do have something on my calendar at 4:00 o'clock that afternoon, so early afternoon would be best.

THE COURT: We'll schedule that for one o'clock on

this Thursday for a PTO 32 on the issues that were sent by email last night. I will set aside two hours, from 1:00 to 3:00 on Thursday afternoon. We'll enter an order to that effect.

Do I need further briefing from you all or are these the kind of issues that we can talk out in person?

Ms. Finken, what is your sense?

MS. FINKEN: They are relatively simple issues relating to deposition scheduling and timing, and numbers of depositions per day. It might be easier to put together a short memorandum for your Honor just to solidify the issues in advance for your sake. I am happy to do that, I think it might be helpful for you.

THE COURT: I have read PTO 54 and PTO 16, so I am familiar with what they say. I am always happy to get briefing from you, but I also am mindful that every time you are briefing something for me you are not only working on other aspects of this case, and you have a judge and a magistrate judge telling you, get on your horse and ride. So, I don't want to pull you away if you are making good progress on other things.

Mr. Henry, what is your sense about briefing, if any, for Thursday?

MR. HENRY: Your Honor, a little table setting is always helpful.

THE COURT: Okay. How about by five o'clock on Wednesday, then, send me a joint submission. Again, it doesn't have to be formal, just tee up what the issues are.

I know from looking at PTO 54 and PTO 60, I believe the order from Judge Rosenberg was that the generics were supposed to give deposition dates to the Plaintiffs for manufacturing depos, storage and transport depos, and PD depos. So, I am assuming everybody complied and those dates have been given.

I am assuming this is not going to be like law school where everybody votes to be the last person called on in class, and wants their depositions on the last day of the month and we're left with 23 people all of whom want to be deposed on the same day.

I will tell the parties I will not hesitate to play teacher and call on you and unilaterally order the depositions to occur on the days that I think they should occur. So, I encourage you to talk to each other and work it out.

You have 23 Defendants, you have 20 plus days in April, 20 plus days in May. Numerically, you have billions and billions of possible combinations to get everybody done in the timeframe that you have been given. So, I hope you will be able to find one of those billions and billions of combinations that works for you and I don't have to intervene.

We can take that up more fully on Thursday.

MS. FINKEN: Thank you, your Honor. Hopefully, with that sage guidance, we will be able to work it out in advance of the hearing.

THE COURT: I have no doubt you will.

Let's then turn to the specific issues that were noticed for today. I also did want to just clarify one other thing for the parties because I really am trying not to set a precedent here.

As you know, it is generally my practice not to rule on 30(b)(6) topics in advance of a deposition. I really do think the better practice is to have the witness appear, have the questions asked, and then I can rule on a specific record on a specific question. In the normal case, I think that is the advisable way to do it.

However, I recognize this case is anything but normal. I recognize that a number -- all of the issues we are going to address today are really cross-cutting issues that go across lots of depositions, and the rulings on these, on the one hand, are going to affect substantially the burden that may be imposed on the Defendant to prepare a witness and/or the scope of the deposition that the Plaintiff is allowed to take.

I think given the timeframes that we are dealing with, making you, at least initially, go to deposition, ask the questions, get a transcript, because not everybody is as fast and efficient as Mrs. Stipes, wait to get a transcript, file

the transcript with me, have me reconvene the hearing, have me rule, and then potentially have to reconvene the deposition, is simply not in the best interest of moving this case forward at this stage.

That is why I am having this hearing today, because I think, under my duties under Rule 1 to efficiently and cost effectively move the case along, I am making an exception to my usual rule, but I don't want everyone in this case to think that every 30(b)(6) deposition you get to have a PTO 32 hearing in advance.

That is my goal for today, and there may be specific topics that I do defer to you and say, go ask the specific question, but I will try to at least address all the cross-cutting issues.

Thank you for indulging me to make those opening remarks and set the table. Let's turn to the manufacturing issues.

I have the motion that was submitted, I have the Plaintiffs' response. I am going to kind of use the Defense's motion as a road map. Let me see what the topics are. Global issues. Okay.

So, the first issue seems to relate -- is the argument that because the manufacturing defect claims have been not repled in the new complaints, that certain discovery topics should not be permitted.

Mr. Barnes, thank you for being patient. Let me ask you to tee that up or frame that however you want to best frame it.

MR. BARNES: Thank you, your Honor. Richard Barnes, counsel for Perrigo, and appearing today as co-liaison counsel. There are three motions today, and we appreciate your Honor taking these on to give the parties some guidance.

I think we did make some progress in the meet and confers, we did get some things resolved, but as to these overarching issues which the generics tried to put forward in the three motions to give your Honor a sense of these cross-cutting issues that need to be resolved on the front end, let me go right to the manufacturing issues that we have here.

To set the stage on how we looked at it, last night, Special Master Dodge sent an email to Mr. Yoo and basically advised that perhaps we should advise you up front of the one thing that we would most like you to resolve at today's hearing to move this process forward.

I looked at it and I thought about it. I didn't really confer with my colleagues who were a bit busy this morning, as you might expect, but from my perspective, it simply is this, that the Plaintiffs have not adjusted the scope of any of these notices to match their now much more narrow claims against the generic Defendants.

So, let's -- to set the stage, as you know, Judge

Rosenberg's preemption order dismissed with prejudice all design claims about the molecule itself, as well as all claims for labeling other than permitting them to attempt to replead on expiration dates.

She held that the manufacturing defect claims were dismissed, but permitted the repleading of a cause of action to see if they could state a cause of action under state law for a manufacturing defect that wasn't preempted or otherwise barred.

So, the point of the matter is this: After a lot of meet and conferring in January, when we were trying to figure out what the claims would be and trying to negotiate some of these issues on these deposition notices, the generics were not apprised of what the claims would be, except that we understood from the meet and confers that the Plaintiffs would plead everything to the maximum extent provided under Judge Rosenberg's order.

When the pleadings were filed earlier this month that was not the case, and specifically and of special relevance to this discussion is that the Plaintiffs elected not to pursue a manufacturing defect claim.

It is our position that for the purposes of determining the scope of discovery, as there is no claim that the manner in which the Ranitidine molecule was manufactured to make it defective or in some way unreasonably dangerous, the issues as to manufacturing have got to be very limited to the

claims that have been asserted.

So, the Court's preemption ruling, combined with the Plaintiffs' choice not to replead this cause of action, has served to drastically narrow the claims at issue against the generics.

So, what I think we are asking for today, a cross-cutting issue, is that the Court enter a protective order that reflects the issues that have been pled, the claims that have been made, and to keep it focused on a proportionate amount of information directed to these claims that remain against the generics.

So, that is kind of -- as I summarize where we are, we think that the notices are simply at high tide and not related to the narrow substance of the claims as pled.

Specifically as to manufacturing of finished Ranitidine products, we agree that the Plaintiffs, under the instructions from the Judge and how we understand them and from your Honor, that the Plaintiffs should be entitled to question generic witnesses about the stability testing that was done on products over time and the methods that the generic companies used to assess the rate of degradation of the Ranitidine molecule over time in an effort to set the expiration date and the conditions of storage.

Those are the two claims that are in the case. So, that is what we think the focus must be on, and in that they

would understand the issue of how -- the care that was taken to set the expiration dates, as well as why, or why not, to give them their due, that the storage conditions or the transfer conditions were not satisfied by the generic Defendants.

So, as you read their amended complaint and you read the preemption briefing, there is absolutely no dispute that the way the generic companies, or any pharmaceutical company sets these parameters, is through stability testing, and it is the stability testing that establish what the expiration date should be, and also what storage conditions would be an unacceptable or acceptable temperature or humidity.

So, the policies and procedures directed to this question are relevant and we have produced them. They have had them against many of the generic Defendants since July. They have had the results of the stability testing since July. They know the parameters that were set. They know the post recall testing that was done on the molecule itself. Ms. Finken has attached some of the work to her motion.

So, the primary area of disagreement can be summarized as this, it is because there is no pending claim as to manufacturing, this deposition notice is disproportionate in asking manufacturers to prepare a witness to walk through every aspect of the manufacturing process for Ranitidine, the quality issues relating to that, the quality management issues, and it is simply beyond the scope.

It is especially disproportionate and unreasonable to ask the generic Defendants about aspects of the manufacturing process that have absolutely no bearing on the remaining claims as to expiration date, and storage and transportation conditions.

So, as we understand what the Plaintiffs are asking for, we believe that we do not want our witnesses to be prepped and sit for a deposition on issues that are entirely outside the scope and collateral.

There are 43 or so topics on the manufacturing notice. I don't know why I agreed to take that on, but the first topic is emblematic of our issue. I will read it to your Honor.

We are to produce a witness to be prepared to explain the specific process or processes used to manufacture Ranitidine freebase, Ranitidine active drug substance (API) and Ranitidine finished product of your RCPs, which is Ranitidine containing products, including, but not limited to, the drug substance, synthesis, purification, crystallization or recrystallization process, testing of the pH values of the drug substance, the grade of the drug substance, solvent composition, the solvent volume, water concentration, and crystal morphology.

Given that it is not alleged that the physical properties of the Ranitidine molecule is defective in manufacture, all this detail is besides the point and it is

directed to issues that are not in the complaint.

Because the Court has held the questions about the design of the Ranitidine molecule as preempted, and there is no remaining manufacturing claim, Plaintiffs simply can no longer allege that somehow these physical properties of the Ranitidine molecule produced in this manufacturing process makes the molecule defective.

What is relevant is how we set our expiration dates and our storage conditions and the work and testing that went into that process. That is what is at issue, and that is what we should be held to testify about.

THE COURT: Okay. Let me -- I didn't mean to cut you off. Go ahead.

MR. BARNES: I just wanted to say, I am not saying there are no manufacturing witnesses -- you know, that there is no possible question. I guess what we are saying is, they can ask the manufacturing witnesses about whether -- the Ranitidine API, to the extent that a manufacturer would know that because many manufacturers don't manufacture API, or the Ranitidine finished products that are manufactured in the United States and emerge from this manufacturing process.

The question is whether they demonstrate a rate of degradation that should have yielded a different -- a shorter expiration date, or a different transport condition or storage condition, because that goes to their remaining claims, and

that is fair game.

To summarize, we should not be forced to answer questions about a theory or a cause of action that is not alleged in the case and would require hours and hours of work.

THE COURT: Okay. Thank you. I will give you a chance to be heard in a second. I will come back to you.

I was looking at your chart here, and you objected, I think, 32 times that the topic does not apply to a generic Defendant that did not manufacture API or Ranitidine containing products. First of all, that is not a legal objection.

And second of all, then there is no burden to prep a witness to simply say, we didn't do it. I don't see what the burden is to simply have the witness say, that is not what we did. So, I hear you, I see that. To the extent that is your objection, I overrule that objection.

Ms. Finken, let me hear you in response. The argument that they are making is, if this evidence is relevant to your currently existing claims, then it is relevant to your currently existing claims, and that is all that I am focused on, are currently existing claims.

From reading your materials, if you want to address this, this seemed to me to be the issue that I was having some confusion about, is whether -- is the Plaintiff's theory that a Ranitidine molecule is inherently unstable and will degrade regardless of how you make it, or just by the nature of what

the chemical makeup is? If you put these -- I am not a chemist -- but if you put these molecules together, it is eventually unstable no matter where you get your carbon from, or your nitrogen from, or whatever else; or is it the Plaintiffs' theory that different formulations of the molecule will degrade at different rates, et cetera?

If you could address that in your remarks, that would be helpful to me.

MS. FINKEN: Sure, your Honor. Just to address that up front, your question, and specific to what Mr. Barnes just said -- I apologize, Ms. Stipes, it is Tracy Finken for Plaintiffs. Please, if I am going too fast or you can't hear me, I will be happy to repeat it.

To address your question and to address what Mr. Barnes just admitted, he admitted that the rate of degradation of the product is relevant to the claims that we have brought in this case, and he admitted that that is relevant to the expiration dates and the storage and conditions of the product.

The Defendants' own documents identify that different manufacturing processes affect the rate of degradation of the product and they affect the variability of NDMA formation in the product, and they affect how the expiration dates are set, and the requisite storage and transportation conditions, which are all directly tied into the claims that we have brought against the generic manufacturers in this case. That is one

point.

The second point, your Honor, as far as the inherent instability of the product, there are counts within our complaint that allege that the molecule itself is inherently unstable and degrades to form Ranitidine -- to form NDMA, I am sorry. However, with that being said, there are different manufacturing processes and different conditions that affect the variability of the formation of NDMA within the product. They affect the degradation rates and they affect the variability of NDMA within the different products.

This is information that was admitted to by all the Defendants in their root cause analyses that they submitted to regulatory agencies here in the U.S. as well as foreign regulatory agencies. That goes through all generic Defendants and the brand Defendants.

Another issue that I just -- I want to point out on that is that the generic manufacturer Defendants also manufacture product for the brand Defendants. So, to the extent that the manufacturing processes are relevant to other products within this litigation, I just wanted your Honor to be aware of that.

For example, Dr. Reddy's manufactured product for GSK, Apotex manufactured product for the retailer Defendant store brand products. So there is a lot of, for lack of a better word, incestuous relationships across Defendants as far as the

manufacturing processes and the Ranitidine that was ultimately put on the market.

THE COURT: They would call it intra-industry efficiencies.

MS. FINKEN: Yes, that is a much better way of phrasing it, your Honor.

Just going back, though, to your Honor's point, I just wanted to point this out, that you may have noticed in the submissions to your Honor that the Defendants did not, as required by PTO 32, certify that the dispute resolution motions were ripe, that there was a meet and confer process with Plaintiffs and a good faith effort to resolve the disputes, and there is a reason for that, your Honor.

It is that Defendants cannot certify this in relation to the disputes they raised in their motions because they served almost 50 pages of objections and charts that we heard about for the very first time on Sunday.

These objections were never raised as part of the meet and confer process, they were not discussed, so Defendants cannot certify truthfully to the Court that such had taken place as required to do under PTO 32.

THE COURT: I saw that loud and clear in your response, you said it a lot, and you said it loudly, and I ceded that and I considered that, but in looking at what the specific objections were, the line by line, I went through the

whole chart, it seemed to me that if I simply resolve the issues that are raised in the memo that clearly were fully vetted, my impression was that would resolve 80 to 90 percent of the specific objections that were raised.

Maybe they weren't raised in a manner that you had a specific meet and confer about topic 17, but my impression was that if I rule on the issues that are fully vetted in the motion I will resolve most of those issues.

I heard that argument and I considered whether I should address a waiver question, but I am not going to do that because I really do think the issues that were properly vetted will resolve those issues.

MS. FINKEN: Thank you, your Honor, and I hope that is the case because the express agreement between the parties that was memorialized in PTO 60 contemplated that the parties would have this meet and confer process over the course of the month of February and that we would resolve all disputes today at this PTO 32 hearing.

That was the process that was contemplated, it was the process that was agreed upon and sent to the Court in the February 4th letter of Mr. Henry, and it was ultimately memorialized in PTO 60.

I can personally state, I have gone back and looked, I have spent almost 30 hours over the month of February engaging in meet and confers with the Defendants, specifically the

generic Defendants, on these 30(b)(6) notices and on PTO 60.

So, to the extent that items were not raised during those discussions, it is a little disturbing to me that they are being raised at the last minute today, but I will move on from that, your Honor.

THE COURT: All right. Great. Let me just circle back, though, to make sure I understand your answer to my question, which you answered, but I want to make sure I understand your answer.

Your position is that, first, as a factual matter, different -- this my phrase -- different formulations, but Ranitidine which is manufactured from different ingredients are using different manufacturing processes. Two different Ranitidine tablets, or Ranitidine -- I guess it's a tablet, I never took it -- that are manufactured in two different manufacturing processes using different APIs and different processes can have different degradation rates. That is pled and that is your theory pled.

Again, I didn't read all five thousand pages, but that is pled in your complaints?

MS. FINKEN: Your Honor, that is a factual matter that is pled in the complaints, and I can also tell you that for purposes of this dispute and what we are here to determine today, is whether or not our side, the Plaintiffs, can question the generic manufacturer Defendant witnesses in relation to

documents that they already have produced, that they have produced to the regulatory agencies, they have produced already in large part to us. So, there is no burden on them to go and seek out these documents for production.

We are seeking testimony relating to the manufacturing processes and the use of such things as solvents in the manufacturing process.

Defendants' position is that Plaintiffs should not be permitted to question their corporate witnesses regarding these documents that have already been produced and which were submitted in relation to the root cause analyses of how NDMA came to be in their Ranitidine products. This issue goes to the very heart of Plaintiffs' entire case, it is a cross-cutting issue that cuts across all theories of liability, across all Defendants.

Each Defendant was required by the FDA to submit a detailed root cause analysis to the FDA and other regulatory bodies answering certain questions related to the mechanism of action as to how NDMA was forming in Ranitidine. Many of the generics did that. Aurobindo, Dr. Reddy's, Apotex, and others have done that.

Some of these documents were submitted to the Court as exhibits to our memo for the Court to see firsthand the level of detailed analyses of their manufacturing processes that the generics submitted to the regulatory agencies on these very

specific issues, and how they detail with great specificity these manufacturing processes, the use of solvents, the use of excipients, et cetera, that may have played a part in the formation of NDMA, the rate of formation of NDMA, the rate of degradation of Ranitidine that forms NDMA, and the levels of NDMA in the products themselves.

This questioning of a witness is not about a manufacturing defect, it is not a manufacturing defect claim. Mr. Barnes was right about that. However, it is about mechanism of action, how the Defendants themselves concluded that NDMA was forming or not forming. It goes directly to the defenses that will be propounded in this case. It is about a notice issue and how that notice may or may not affect the underlying claims of negligence and design defect.

It is about causation, and I can only assume, your Honor, that the Defendants are going to rely upon their own scientific analyses of their processes that they reviewed for purposes of their investigation into how this was occurring and how much NDMA was being formed and how quickly.

I can imagine that the generic Defendants are not willing to stipulate to the mechanism of action and the amount of NDMA in each pill and how it forms over time and is subject to different degradation and formation of NDMA invariability.

Just to be clear, perfectly clear, when I speak about the root cause analysis that the generics prepared for the FDA,

I am referring to a set of documents that were prepared as a culmination of their entire investigation into the manufacturing processes, the use of solvents, the use of excipients, any potential contamination, the molecule itself, the degradation of the product, the stability of the product, et cetera.

Defendants have been stating repeatedly that it is too big of a burden or disproportional to gather documents and prepare a witness to testify about manufacturing process; however, these documents been gathered, many of them have already been produced. The generic manufacturers must submit detailed specifications of the manufacturing processes used for their products.

The generic manufacturers have to do this whether they physically manufactured the product in the U.S., whether it is their foreign affiliate who manufactured the products for them in India, whether it is a third party manufacturing for them on Mars, it does not matter. The generic Defendants have a responsibility to provide that information to the FDA, and they have done so, and they have provided that information to us as well.

They have done their own scientific investigation of those processes. They have come up with conclusions on NDMA formation and how and why that is happening, and how much in terms of the degradation of the product. And for Plaintiffs

not to be able to question their witnesses about those conclusions that they are going to rely upon for purposes of their defenses in this case would be unfairly prejudicial to us.

So, for that, your Honor, we would request that you -- respectfully, we would request that you deny their motion for protective order in relation to the manufacturing notice.

THE COURT: Let me turn back to Mr. Barnes.

Mr. Barnes, so much of the protective order can be predicated upon annoyance, harassment, undue burden. Are you also arguing relevance and disproportionality or are you just relying on Rule 26(c), the grounds for protective order?

MR. BARNES: Relevance, proportionality, and burdensomeness, your Honor.

THE COURT: Okay. Let me let you have the last word on the merits in response to Ms. Finken's arguments.

MR. BARNES: I will not respond to the meet and confer process. I am not waiving anything, though.

THE COURT: Understood.

MR. BARNES: I want to go back to first principles, your Honor. They have had these documents since July from, let's say, Apotex. Apotex produced all this stuff in the start of July. They had specific allegations in the original complaint as to solvents, as to manufacturing defect. It was in the original complaint. They abandoned the manufacturing

case.

What we have now is the manufacturing process yielded a Ranitidine molecule. You asked a question, which is a good one: Does the formulation matter? The formulation is a design issue, it is Ranitidine. The question that remains to be litigated is, given the molecule that came out of this manufacturing process, which is not alleged to be wrong in any way, should you have set a shorter expiration date which, according to their theory, would have had less NDMA in the molecule?

Their fundamental issue in this case is at figure 1, is that Ranitidine is inherently unstable and has constituent parts A and B that, through no exogenous force, plays off a molecule called NDMA, and that is their case. Their point is, you should have done a shorter expiration date and you should keep the truck away from the Mojave Desert. That is basically what they are left with.

So, they have the physical product itself, they have the Ranitidine tablet from GSK, let's say. Let's keep Mr. Oot out of this as best I can. But still, they look at that and they can measure the NDMA in that tablet, they can measure the original specks of it, and they can basically tell what the amount of NDMA is, and then their experts can say, based on the physical thing itself, that a shorter expiration date would have provided less NDMA.

That is their case. It is not that we have had solvents or we have any specific process, it is that you should have had a shorter expiration date or you should have used a different storage condition. They want to boil the ocean and go through the entire manufacturing process.

We produced those documents pursuant to a court order while we were litigating the Motions to Dismiss. We all complied and they have had it and they have chosen for tactical reasons not to pursue it.

What we are asking is to cabin this to the issues they have pled. If their experts want to look at the reports that were filed pursuant to FDA directives, we can talk about that. Right now it is about what should the company produce on its manufacturing and manufacturing witness. It is not in the case.

The formulation is the design, and to the extent that one design yields a morphology that is slightly different from the other, you look at the pill itself, the tablet itself, and you will see the morphology. Then she can have an expert say morphology A is more prone to degradation than morphology B. It's not known as to how you got morphology A or B.

Neither is it the product of a manufacturing defect. After the process, you have the physical inanimate object, the physical properties can be measured, and that is expert discovery, and that will happen later in the case. They have

the scientific work produced line after line by many Defendants. They have a published work by GSK in its scientific literature which goes through the process chapter and verse.

We are concerned that they are making this through the back door, again, a manufacturing defect case without pleading it. They are making it about the formulation, which is your Honor's question, that is preempted.

To the extent this one pill is different than the other, then you measure it and you have the difference, but as to how it got to that point is irrelevant.

We are happy to have her basically look at the stability tests and see what we should have been on notice of in terms of setting the expiration date and the conditions of storage. That is their case, that is what we are here to talk about.

THE COURT: Thank you very much.

MS. FINKEN: Your Honor, can I respond just briefly?

THE COURT: Sure.

MS. FINKEN: I just want to point out again that the manufacturing process and the testing that is done as part of the manufacturing process is relevant to how the Defendant -- how the Defendants set the expiration dates because the degradation issues and stability of the product changes based upon how the manufacturing process is. This is true.

I would challenge Mr. Barnes, if he is going to continue with this line of argument, that he then should stipulate to the Court on behalf of all of the generic manufacturers that no generic manufacturer will rely on manufacturing processes, API manufacturers, contaminants, solvents, foreign affiliate manufacturers, component part manufacturers, any documents related to the manufacturing processes or root cause analyses, or anything else that they are seeking limitations on scope in terms of defending their claims.

So, if Mr. Barnes is willing to stipulate that to the Court, that they are not going to rely on their own internal documents, their own investigations, their own processes that they have evaluated for purposes of this claim, then maybe we don't have a dispute. But I don't think Mr. Barnes is prepared to do that today.

THE COURT: Again, that is not an issue before me. Based on my ruling, if you all want to have further discussions, you all can discuss away.

MR. BARNES: Thank you, your Honor.

THE COURT: Okay. I start, as I always do in these situations, with Rule 26(b)(1), which says that parties may obtain discovery regarding any non-privileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues

at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the resolving the issues, whether the burden or expense of the proposed discovery outweighs its likely benefit.

I also have to look at Rule 26(c), which is the protective order rule, which says, a party may obtain a protective order based upon to avoid -- based upon good cause to avoid annoyance, embarrassment, oppression, an undue burden or expense. They sort of bump up against each other.

Let me start with 26(b)(1). First of all, I find this evidence is relevant regardless of what the claims are. I agree with Mr. Barnes that there is no manufacturing defect claim. Just because there is no manufacturing defect claim does not lead to the conclusion that the manufacturing processes are irrelevant.

They may be relevant to other aspects of the case, and Ms. Finken has articulated a theory of relevance as to why they are relevant to other aspects of the case. So, I do find this evidence to be relevant to the existing claims and defenses in the case, particularly relating to the expiration dates and the storage and transport issues. So I find it is relevant.

The question is, is it proportional? I'll start with considering the importance of the issues at stake in the action. As I've said previously, the core of this case, the

most important question in this case is, does Ranitidine cause cancer, and under what circumstances does it cause cancer, and did these manufacturers and distributors know that?

I think the evidence that is being sought here, and the theory under which it is being sought is central to this case. It is extremely important to the issues at stake in the action.

The next issue is the amount in controversy, which has more zeros in it than I can count, so I will concede that there is a lot in controversy in this case.

The parties' access to relevant information. Clearly the evidence as to how the generics manufacture their Ranitidine is exclusively within the possession of the generics. I can't expect the Plaintiffs to go get it from somebody else.

The parties' resources, I don't know, I don't have a record in front of me. I could speculate that the generic manufacturers probably have more money than the Plaintiffs, but some of these Plaintiffs' lawyers have a lot of money, so I don't know. That one is sort of a wash for me.

The importance of discovery resolving the issues is -- given that expiration dates and storage conditions are important, how important is this evidence to try to prove that? And I do think it is important.

As Ms. Finken has articulated, if the rate at which

the product degrades is a function of the ingredients and the process that go into the product -- I am taking her at her representation that that is properly pled.

I accept that representation that it is properly pled that the rate of degradation is at some level a function of the ingredients and the manufacturing process, and that the rate of degradation is therefore a factor that goes into how one should set the expiration date, which is a specific claim in this case, that the expiration dates were not set correctly. I find that this evidence that is being requested here is important to resolving that issue.

Finally, whether the burden or expense of the proposed discovery outweighs its likely benefit. I hear Mr. Barnes telling me it will be burdensome to prep somebody. I also hear Ms. Finken saying, maybe inferentially, but that really at the deposition as a practical matter the questions are going to be pretty much tied to the documents that have already been produced.

If that is going to be the case, perhaps between now and then Ms. Finken can give Mr. Barnes a little more guidance about the specific area she is going to cover and specific documents she is going to ask about.

I think to the extent there is an extended burden here, that can be mitigated.

So I find, under Rule 26(b)(1), this evidence is

relevant and proportional, and under Rule 26(c), I do not find that the Plaintiffs -- that the generic manufacturers have met their burden of establishing undue burden or expense, annoyance, embarrassment, oppression, so I will overrule the request for a protective order on that issue relating to the manufacturing processes and I will allow -- I will just overrule that objection.

Let's move to the next one here on the manufacturing, which is the relevant testing should be limited to testing which can detect NDMA as opposed to nitrosamine.

Someone is going to have to educate me on this one. Ms. Finken, why don't you tell me what are you asking for. Then I can understand what it is that Mr. Barnes is objecting to.

MS. FINKEN: That is an excellent question, your Honor. So, what we are asking for in terms of this particular deposition notice, we have very specific definitions of testing that sets forth a list of very specific types of testing, and that testing is all relevant to detecting MDMA, nitrosamines, impurities, and carcinogens within the products themselves. It is testing that the Defendants have used in their root cause analyses, the Defendants have used over time in looking at impurities in the drug product, and we have met and conferred on this issue quite a bit.

During that process, I have requested from Defendants

multiple times for them to point to specific tests that they do not believe are relevant to this case. They have refused and declined to do so. They continue to make boilerplate objections to the list of testing, and they wanted us to make it more vague, ambiguous, and less specific in terms of the definition of testing, which we did not want to do.

We made it very specific for a reason after consultation with our science committee and also looking at their own internal documents.

THE COURT: If I could stop you. You know a lot more about this than I do, so I am going to have to slow you down just one second.

What is a nitrosamine -- what is it you are looking for? What are you trying to get to at the core?

MS. FINKEN: Nitrosamines is a class of carcinogens which NDMA falls within. So, when we use these terms -- and this is a great point, your Honor, because it is something that we have also discussed with Defendants because they wanted us to limit the term to NDMA.

However, when you look at the Defendants' documents themselves, when they reference NDMA, they reference it as a nitrosamine. They reference it as an impurity. They admit that it is a genotoxic impurity and a carcinogen. They use all of these terms as synonyms for NDMA in their own documents, and that is why we have crafted this deposition notice specifically

the way that it is.

It is based upon the use of the verbiage that they use when they are referring to NDMA in their own documents, when they are and looking at evaluating the product itself, and we have had this discussion.

We have also tried to limit the burden for Defendants. They have indicated that it would be burdensome and disproportional to prepare a witness to testify about all of the testing that they did in relation to our list over a long period of time.

We have offered to them to produce in advance of the deposition specific Bates numbers for specific testing that we might want to question them about so that they can adequately prepare their witness in advance of the deposition.

They have indicated that their witnesses could testify to the testing that has been done generally, but they have concerns about the burden and disproportionality of having them testify to specific testing that might have been done ten years ago, 15 years ago, 30 years ago. That is why we offered to help alleviate their burden by identifying the actual testing that we might question in advance of the deposition, and they refused this offer, your Honor.

Obviously, the testing that is done -- we have a negligent failure to test claim that has been pled in the complaint, it's in Count 8 for your Honor's convenience, and I

know you may not have been able to read the full extent of all of the complaints that have been filed at this point. I know it is the trilogy of Moby Dick, so to speak. So, I understand that, your Honor.

In Count 8 we have a negligent failure to test claim against the Defendants, the generic manufacturer Defendants. Within that negligent failure to test claim we have paragraphs that relate directly to specific types of testing that is in this list, the definition, chromatography testing. We also refer to stability testing. All of this is outlined generally within the claims of the negligent failure to test claims, as well as in the stability and degradation and expiration claims.

So, we have asked them repeatedly if there was a specific type of testing that they believed was not relevant, to identify it for us so we could have a discussion and they have not been able to do that, your Honor.

THE COURT: So, let me circle back one second, Ms. Finken. As I understand it, what you are trying to find is, over the course of however many years -- and I realize we are lumping 23 different Defendants into one bucket here and I am going to assume some of these manufacturers have only manufactured the product for a few years, some of them have maybe not manufactured it in the last decade. I recognize there is differentiation within the category here.

Essentially, it is my understanding that your theory

is they have done testing over time, whichever test it is, which has indicated that Ranitidine can devolve into a carcinogen, a carcinogen can arise from a degradation of the Ranitidine molecule. Am I with you so far?

MS. FINKEN: Yes.

THE COURT: That is your theory, that it causes cancer.

MS. FINKEN: Correct.

THE COURT: And that they knew it because they were doing testing over time and that testing either did or should have shown them. Okay.

So, the testing did show them is your direct evidence of actual knowledge, and now you have a separate failure to test, which is, I guess, they could have and should have done other testing, which they didn't do.

MS. FINKEN: Correct.

THE COURT: So, I am assuming the request here is you only want to know what they did do, so then you can compare it and say, well, you didn't do everything else and, therefore, that was your negligent failure to test.

Am I with you?

MS. FINKEN: Your Honor, you are actually making a great point of another concession that we offered to the Defendants, which is, to the extent that they did not do any of the specific types of testing over the course of the time that

they had product, they could answer that in an interrogatory answer to expedite the process and alleviate the burden of preparing their witness.

This is not necessarily a cross-cutting issue. There are Defendants here that may not have done 50 percent of the types of testing that are on this list, there are Defendants that may not have done any of them, and there are Defendants that may have done all of them.

It is variable to each Defendant, which is why we were very specific, it is why we offered up the interrogatory response offers to expedite testimony and burden. We have offered up identifying specific testing ahead of time so that we could have a discussion about it, and we have worked very diligently to try to alleviate the burden, but still get the information that we need from Defendants.

THE COURT: Putting aside burden for a second, I am going to turn to Mr. Barnes in a second, I want to understand relevance here.

The relevance is, it goes to negligent failure to test, to the extent that tests didn't happen, and to the extent tests did happen, the results may have put them on notice that they should have warned the FDA or taken other action with regard to expiration dates or other things that you have alleged.

As I recall, you have a negligent failure -- yes,

Count 5, failure to warn through the FDA. So you have that, too, right?

MS. FINKEN: Yes, your Honor, and one of the other items that I want to point out about this testing is, some of this is designed to detect impurities in the product, and the way that the testing was done, that they did over time when the impurities showed up in the chromatograms of the product, there is an argument that they should look into what the impurities were, identifying those impurities as to what type of impurity it was, because NDMA shows up as an impurity on these chromatograms.

To the extent that they ignored spikes in the chromatograms because impurities were showing up and never went and did the next step to see what those were, that is obviously something that we would want to ask their witnesses about.

I just wanted to make sure that that was clear for your Honor.

THE COURT: It is. Thank you very much.

Mr. Barnes, let me let you respond.

MR. BARNES: Thank you, your Honor. Thank you, Ms. Finken, for -- just so your Honor is aware, I was not specifically involved with Ms. Finken during the meet and confers. As liaison counsel, I was receiving reports from Ms. Thompson and Mr. Henry.

I think we can make some progress perhaps here.

If your Honor would hold the Plaintiffs to the representations they have made here today and in their brief, we may not have the issues.

Our fundamental concern was that the scope of these questions were impurities. Well, an impurity is anything in a pharmaceutical product that isn't the drug substance. It is a very broad concept. We were trying to get the limitation that the impurities and degradation be limited to the scope of the impurity at issue in this case, which is NDMA. Okay.

As I read last night in their opposition, on page two they argue that NDMA is a nitrosamine, a carcinogen, an impurity, a mutagen, and a genotoxin.

So, if a document describes NDMA in those terms, obviously that is about NDMA. We will have testimony as to how that -- those terms are analyzed by the industry generally and our clients, but if that -- as long as it is so limited to NDMA and that we get the relevant documents for the deposition and -- you know, then perhaps we don't have the dispute.

Asking witnesses about NDMA as a nitrosamine is the issue in the case. It is not like, though, what did you do to look for impurities, or what did you do about nitrosamines generally. To the extent NDMA is a nitrosamine, have at it.

We just want the case to be focused on the NDMA issues that are the focus of this MDL. But if it expands to general impurities or the class of chemicals known as nitrosamines and

all possible carcinogens, that is way beyond the scope. If it relates to the NDMA that is in this case, then I think we can come to some sort of agreement, I think, amongst the parties.

So, I think that is really all I can say. This type of inquiry on testing can get very broad and require us -- some generic may have had a batch that had maybe an impurity, arsenic. We are not chasing shadows here.

So, if it is limited to the nitrosamines and genotoxicity, or whatever it is, that intersect with the impurity at issue in this case, which appears to be what they want, then I think we can work through those issues with Ms. Finken.

THE COURT: Okay. Ms. Finken.

MS. FINKEN: Your Honor, may I respond?

I think the problem here, and we have had these discussions, is that the way that the Defendant asks for these types of impurities cuts across multiple impurities, and it is not like there is just one test for NDMA and one test for another impurity. It cuts across all impurities, and that is the way that they do it.

What we have struggled with here is that over a long period of time they have been testing these products for impurities, and impurities were showing up where there was not necessarily a followup being done in terms of identifying what those impurities were. It's our position that over a period of

time there were impurities in there that were NDMA and they should have been followed up on, and that was not done.

This is why we struggle because it is a little bit of gamesmanship with the wording. We have tried very hard to work with the Defendants to limit the burden of testimony to the span of time that they were testing the products and what specific tests we would want to question them about.

But my concern is, by limiting it the way that Mr. Barnes is suggesting, that it is gamesmanship, and it is going to preclude testimony about testing that has been done over time that should have, could have, would have, detected NDMA if they had done the proper followup or the appropriate testing. It may have detected something that they labeled as an unknown impurity, which may have been NDMA.

I am talking generally because, obviously, there are 23 Defendants, and I haven't looked at all of their testing, nor has all of it been produced at this point. We have been trying to work with the Defendants in terms of burden, in terms of scope; they have been unwilling to work with us.

We are not willing to limit the terminology to testing or questioning just specifically about NDMA because, as a practical matter, that is not how they test these products. They don't test it that way.

THE COURT: Okay, I hear you.

MR. HENRY: Your Honor, Terry Henry for Apotex. Could

I have one brief moment to respond to Ms. Finken?

THE COURT: Sure.

MR. HENRY: Your Honor, I wanted to address a couple of issues. The first is the proposal by the Plaintiffs that they identify documents five days in advance of a deposition in order for us to answer questions and reduce the burden on our witness. We actually thought that that was a workable solution. The problem was, on the back end the Plaintiffs did not agree to not ask questions about the other 28 odd tests that were in the list.

Similarly, we had thought we had worked out an agreement on the interrogatory, so the Plaintiffs list the tests, we answer that with an interrogatory saying which tests we did on Ranitidine. But the Plaintiffs did not agree that that would relieve us of the obligation of preparing a witness to testify about the other 26 or 27 tests that we didn't do.

So, for us on our side, even though we had some of these proposals on the table, it did not reduce the burden on preparing witnesses to present testimony at the 30(b)(6) deposition when they are speaking on behalf of the entire corporation.

Now, we do understand the Plaintiffs' concern that if they show a witness a chromatograph that has a stray peak as unidentified, Plaintiffs' concern is that a Defendant is going to object and say that is not NDMA and I don't have to answer

any questions about it. I think -- I understand that concern.

I think it is a stretch to say we'd have Defendants playing those games at a deposition because there is a PTO 32 process that the Plaintiff can seek a remedy for that. I also think that there is a way that we can resolve those issues up front, particularly if the Plaintiff is presenting the documents before the deposition so that there could be a meet and confer process.

That is all I have to say on that, your Honor.

THE COURT: Thank you. Let me start with this. As far as I am concerned, you all can negotiate any time you want to, before or after, but when you come to me, I am not here to negotiate with you. I am here to rule on the issue that you have framed for me.

You all can talk all you want. I am going to rule on the legal issue you present me, and your time to negotiate on that issue is over. I am going to rule. First thing.

Second thing, I hear you, Mr. Henry, but I continue to be baffled by the argument that there is some burden to prepare a witness to say, we never did that test. What is the burden to prepare a witness to say, we never did that test?

MR. HENRY: Your Honor, from my perspective, there is going to be more than one of those questions. There is going to be a series of questions in which the Plaintiff will attempt to establish that because the Defendant did not adequately

evaluate, or purchase the equipment, or properly calibrate some other piece of equipment, that there is some form of negligence there. Right?

So, rather than testifying about the process of selecting the test that they did do, there will be questions about the 26, 27 tests that the Defendant didn't do, and I have a burden to prepare my witness to understand what those tests are, and what, if anything, the company did in order to select between those tests. That is the burden, your Honor.

THE COURT: Okay. Again, I think if the question is simply, did you do this test, there is no burden to answer that. If the question is, why didn't you do those tests, that may be a different issue, but that is not the issue before me.

I am going to overrule the objection and the request for protective order. I find the requested evidence, for the reasons Ms. Finken has articulated, is relevant to the claim, it is proportional to the needs of the case.

I think the -- my sense of it is that the Defendants are giving this a hyper technical reading, that in the real world, I don't think Ms. Finken or Mr. McGlamry or Ms. Luhana, or whoever is going to take this deposition, is really going to waste their seven hours, that they -- one time only seven hour deposition probing all these aspects of did you have an impurity caused by somebody dropping their Dippin' Dots into the vat.

I just don't see it, I don't see the undue burden here, so I will overrule the request for a protective order on that issue.

Does that also subsume within it, Mr. Barnes, the next issue in your memo here, which is that the notice should be limited to NDMA, not all nitrosamines or impurities, that I just merge B and C?

MR. BARNES: Let me make sure I understand, your Honor. As I am hearing your ruling, that we would -- the testing that we did, whatever it is, the testing that was done would be limited to those tests that were done to assess the degradation of the Ranitidine and the products of the degradation, and we want to limit it to NDMA and the products of, you know, the degradation process, and not just generally nitrosamines and other impurities. We want to focus the case on the tests that were designed to look at the degradation and then the formation of Ranitidine, I mean NDMA.

As long as it is confined to the questions of the testing that was performed on the Ranitidine molecule to see, you know, how stable it was, and they -- Ms. Finken will ask, well, you didn't go far enough once you did this test. I think the generics need to respond, we went as far as USP requires and the evidence required us to, and that would be a question for experts.

As long as it is not a wide-ranging discussion of

impurities generally, I think we can get through the deposition without a fight.

THE COURT: Ms. Finken, is that different from what I have already ruled on?

MS. FINKEN: No, your Honor, it is not different and the reason why it is not different is that the terminology NDMA, nitrosamine, impurity, carcinogen is used in conjunction with the definition of testing in the definition. That is where the terminology comes up within the definition of testing, and it all overlaps.

So, I do not believe that it is a separate issue as it is all used in conjunction with the testing that we just discussed.

THE COURT: If I understand your argument from before, where those words come from is from tests -- discovery you have received where one or more of these generic manufacturers has used that terminology to describe a degraded NDMA molecule. Is that correct?

MS. FINKEN: Correct. Your Honor, we have attached some of them as exhibits to the motion. They refer to NDMA as a nitrosamine. They refer to it as an impurity, a genotoxic impurity, and a carcinogen in their own documents.

THE COURT: I just --

MR. BARNES: Let me make it clear, as long as it is in the context of NDMA -- I am sorry.

THE COURT: Go ahead, Mr. Barnes.

MR. BARNES: I apologize. As long as the -- if there is a paragraph where they talk about the nitrosamine, NDMA, and its carcinogenic potential, that is NDMA and it can be described in that way, then we would not have a problem. But if it is all nitrosamines, well, the pathway for all nitrosamines is not this case. There are all sorts of ways nitrosamines can be formed. It is a different kettle of fish.

THE COURT: Understood. This is exactly why I don't like to rule on these things in advance.

The specific question that Ms. Finken asks to the manufacturer who has used the phrase "impurity" in their prior testing will be very different, or may be in a different context, or may require a different ruling than if she asks the same question to a manufacturer who has never used that term in their own documentation.

So, as to this, I am going to not at this time grant a protective order. I have given you the guidance I believe I need to give you. I think there is sufficient room here for the deposition to go forward, and if a Defendant believes either that they don't need to or don't want to prep a witness because they think this is an improper area of questioning, Ms. Finken will ask the questions, you will instruct the witness not to answer the questions, and then on a full record I will rule on that.

This is getting too granular for anything I am comfortable dealing with in advance. I will let you ask the questions, and lodge whatever objections you want to lodge, and we will go from there.

I will make very clear to the responding parties, if your intention is to instruct your witness not to answer areas of questioning you can choose not to prep your witness to answer those questions. You proceed at your own risk, because if I determine that they should have been prepared to answer the question, there will be a second deposition, you will pay for it, and we will go from there. That's just how this has to work.

Let's go to the last issue because I want to get Mr. Barnes out of here by four o'clock.

MS. THOMPSON: Your Honor, Sara Thompson for Defendant Teva.

I just wanted to point out two things. Number one, this is not limited to testing, the manufacturing notice. This definition related to impurities, carcinogens, expanding beyond NDMA is in two other sections of the manufacturing notice. So, I just want to make sure that we are being clear because it is different in the context of testing than the two other contexts where it is brought up, which is quality assurance and quality control activities. It is in multiple subparts there.

It is also in multiple subparts related to compliance

with current good manufacturing practices, or CGMPs. We haven't talked about that yet, we have only talked about it in the context of testing.

Before your Honor makes a ruling that may be held by Plaintiffs or by the Court as to other categories, I wanted to make sure we talked about it in that context because it is a little bit different.

THE COURT: Is there anything substantively you want to be heard on on that?

MS. THOMPSON: Yes, your Honor. I think the main issue here is that NDMA or nitrosamines are the focus here as opposed to all other types of carcinogens, impurities, genotoxic impurities, et cetera. That is the scope of this MDL, that is what the JPML assigned to this Court.

If we are talking about quality control activities designed to detect any impurity, that will dramatically increase the scope of the depositions, potentially increase the number of witnesses who have to cover those topics. Things that could be counted as impurities include irrelevant things like microbial contamination that have no place here in this MDL.

I just wanted to make sure we didn't move off of that topic, understanding that it is not limited to testing in this notice and we didn't limit it to testing.

THE COURT: Understood. I am going to adhere to my

ruling because my ruling is not necessarily that they are allowed to ask you about those things. My ruling is simply I cannot judge that today. You, as the party deponent, can deal with it accordingly.

I will rule on it when I have a clear record and I can see it in context. So, that is my ruling to that as well, which is essentially a nonruling. My ruling is you don't get a protective order today, and we will move forward from there.

The last issue, then, on the manufacturers, I want to finish this up and then we will take a ten minute break, is time limitations and not limited to activities directed at the U.S. market.

Mr. Yoo, I noticed you turned on your camera. Is there something you want to be heard on before I move on?

MR. YOO: I will wait, your Honor. I thought I could be helpful, but based on your last comment, I will just wait until you get to the next motion, your Honor.

THE COURT: Very well. Thank you, Mr. Yoo.

MR. BARNES: To the extent we are talking about --

THE COURT: You have to identify yourself, Mr. Barnes.

MR. BARNES: I'm sorry. Richard Barnes.

What is the next topic you wanted to address?

THE COURT: I'm going down your memo here. It's topic D on page three of your memo.

MR. BARNES: Time limitations, is that Ms. Thompson's

subject? That cuts across several notices so perhaps Ms. Thompson can handle that. Mr. Yoo is handling foreign -- non U.S. issues. I think those are the two points you made. They cut across several notices and I think Ms. Thompson handles the timing, and Mr. Yoo will cover the foreign regulatory issues.

MS. FINKEN: Your Honor, may I address the timing for just a moment?

THE COURT: Hold on, stop, stop. Who are you?

MS. FINKEN: Tracy Finken on behalf of Plaintiffs. Sorry, Ms. Stipes.

May I address the timing part of this for a second?

THE COURT: Yes. Go ahead.

MS. FINKEN: I just wanted to bring this up because we discussed this over the weekend, and we discussed the fact that the timing aspect is very variable as it relates to each generic manufacturer. They all had these products at very different times and this is not really a cross-cutting issue that should apply to all generic manufacturers.

It is something that we should address as it pertains to each individual generic manufacturer when we do our meet and confers with each in relation to the deposition, and is not appropriate to do as a cross-cutting issue, your Honor.

THE COURT: I understand your position. Let me hear from Ms. Thompson.

MS. THOMPSON: Thank you, your Honor, Sara Thompson for the Teva Defendants.

While Ms. Finken is correct that she did propose that we could deal with this on an individual Defendant basis, there is one cross-cutting issue, and that is that none of the notices have any time limitation or relevant date range at all specified within them.

As your Honor may remember, I am sure it feels like a lifetime ago, at the personal jurisdiction discovery hearing your Honor asked questions about this, what should be the relevant time period, and ultimately made a ruling based on the length of involvement of each of the Defendants who are going to have to answer that discovery of how far back it would go.

Even though some of those Defendants went back as far as 1997, which was the first date that Ranitidine was approved for sale in the U.S., your Honor ruled that four years was the appropriate time range, in part based on the average length of Statute of Limitations state by state was shorter than four years in most instances, and four years was kind of the outer limit.

We actually had proposed to your Honor a ten-year look back, which is broader than the four years that your Honor ruled in the personal jurisdiction context. The reason was because we recognize that some Defendants, my clients included, stopped selling Ranitidine years before this litigation was

filed and years before the events that occurred in 2019 that led to this litigation.

So as a result of that, we proposed going back ten years for two reasons. Number one, to ensure that we were actually encompassing more of the relevant time period; and number two, because most of these Defendants are going to have to educate a witness through documents.

A lot of us have a really long history. My clients go back as far as 1997. A lot of the generics acquired companies that had previously made Ranitidine, so there is no one left who knows that history personally. A lot of these companies are off the market now, including my client.

In each of those instances, you don't have necessarily someone with personal knowledge, so you have to inform it through documents, and document retention, unfortunately, only goes back a certain amount of time. So, that was intended to target it to when we would actually potentially have documents that could inform the testimony.

Setting aside what your Honor raised at the in-chambers conference, which was the somewhat dubious value of having a witness read from very old documents who doesn't have any additional knowledge to add.

That is why we proposed the ten years. The Plaintiffs have rejected that. This proposal to do it on a Defendant-by-Defendant basis was incorporated into our briefing

as something that we would find acceptable, but we would like the Court's guidance on whether or not that is going to go back to the very beginning of when a Defendant ever had involvement, particularly if they may not have witnesses available with knowledge, documents to inform the testimony, because that impacts the burden and the proportionality analysis.

THE COURT: Can I ask you, your ten-year proposal -- again, I am not going to negotiate this with you, I just want to understand it.

Was it ten years from today or ten years from the last manufacture? If your client stopped manufacturing this in 2005, are you offering '95 to 2005, or are you offering 2011 to 2021, in which case you have nothing?

MS. THOMPSON: Sara Thompson again, your Honor. We proposed January 1st, 2010, until the filing date of this MDL, which was February 2020. We thought that was a reasonable time period, that we go back ten years from when the MDL was formed.

THE COURT: I understand that proposal.

What is the legal objection that you are making to the notice that I need to rule on today?

MS. THOMPSON: There are two issues, your Honor. Number one is that there is just a lack of a relevant time period at all. There is no time limitation at all as the notices are presently drafted. We raised this issue previously, this didn't come up recently. This was included in

objections that were served to a prior iteration of this notice.

There are numerous cases cited in our briefing where Courts have granted protective orders where there was no date range specified at all, or where the date range would have potentially implicated decades of history that was unlikely to be proportional to the needs of the case.

Issue number one is just that there is no date range. Issue number two is that if there is going to be a Defendant-by-Defendant date range, we would like some thought to how we balance the burdens and the proportionality, particularly for those Defendants who have long history, who acquired other entities who had ceased manufacture, and those Defendants who may not still have documents from the older time period.

THE COURT: I understand your position. Let me ask Ms. Finken.

I assume your position is that the date range is whatever period of time you manufactured the stuff.

MS. FINKEN: Correct, your Honor. I would just like to point out that all of the Defendants' products are off the market right now because it is a globally recalled product that Defendants admit contain a carcinogen.

We have thousands of people that have registered claims in the registry who allege that they have taken generic

manufactured products that date back to the time that they began manufacturing it, and we should be able to take discovery as it relates to that timeframe.

We have individuals with cancer that used the products when Teva marketed it, we have it when Perrigo marketed it, we have it when Dr. Reddy's marketed it. They bought it, they consumed it, they have cancer, and it is a globally recalled product that contains, admittedly by Defendants, a known carcinogen.

So, we would suggest that the timeframe should be the relevant timeframe that they had the product, they manufactured it, and they marketed it in the U.S.

THE COURT: What about a response to their burden argument? Ms. Thompson said she represents Teva, and Teva started making this drug -- when, Ms. Thompson, in 1995?

MS. THOMPSON: Yes, your Honor, that either we made or an acquired entity made, and it goes back as far as 1997.

MS. FINKEN: In terms of burden, your Honor, this is something that we have discussed at length with the Defendants, which is why, if you notice -- I don't know if you can tell from the notices that Defendants attached to their motions because they are not the operative notices that have been through the meet and confer process, the ones that we provided are that have been through several iterations of redlines over the 30 hours I spent meeting and conferring over these.

But with that being said, if you notice, in our notice we provided the opportunity for certain areas of the notice of deposition that the Defendants can answer by interrogatory responses so that we can expedite and alleviate the burden and the testimony in this case. The witness could rely on the interrogatory responses for purposes of certain questions, for foundational purposes and whatnot, and we have worked very diligently with them to try to help assist with this timeframe.

This is not something that we have run into an objection with other brand Defendants who have had the product as long, if not longer, than these generic Defendants on the market.

From our perspective, we have worked diligently to try to alleviate the burden. It is all relevant to our clients' claims who took the product over the life span that they marketed and manufactured it, and we think it is critical and highly relevant to the case.

THE COURT: I have your the notice that you submitted to me. Where is the part about they can opt to respond by interrogatory?

MS. FINKEN: Your Honor, at the top, I believe it's at the top of the -- I might have to phone a friend.

MS. THOMPSON: Your Honor, it is in the instructions. Sara Thompson.

MS. FINKEN: It is in the instructions and it provides

certain questions that are acceptable for us to be answered by interrogatory.

THE COURT: I see that.

MS. FINKEN: This was agreed to by the parties. It is in PTO 60, we have addressed it.

THE COURT: Okay. I see that. All right.

At this point, again, I am not going to rule -- I am not going to unilaterally impose any time limits because I have no evidentiary basis from the Defendants to impose any sort of time limit. I don't know whether it is really hard or really easy for Dr. Reddy or Teva or Strides, or whoever it is, to retrieve documents or not. I don't know.

I have no record on which to rule, so I am going to deny the motion for protective order, again, without prejudice if you all want to continue to talk.

It seems like the Plaintiffs have made a reasonable proposal to try to limit the burden. If on an individualized basis a particular manufacturer feels that they have an evidentiary basis to object, you can invoke PTO 32 on behalf of that individual Defendant, but I don't think I can make a blanket -- and I will decline to make a blanket ruling on a time limit or anything like that.

I do agree that it is very individualized. If I say ten years back and Teva did a lot of testing in the '90's and early 2000's, and then they just stopped testing, then the

Plaintiffs don't get evidence that Plaintiffs need. On the other hand, the Plaintiffs may get a whole lot of cumulative testing that they don't need, but I can't rule on that as I sit here today.

I am denying the motion for protective order, but without prejudice to an individual Defendant raising a PTO 32 objection, and you can submit your evidence and I will rule based on the evidence.

I think those are all the issues --

MS. THOMPSON: Sara Thompson for Teva. While Mr. Barnes said Mr. Yoo is going to address one aspect of the U.S. versus global, we also raised an issue here specifically with respect to the storage and transportation and manufacturing notice that is a little bit different than just the regulatory aspect. I don't know if you want to do that now or if you want to wait.

THE COURT: Sure, go ahead.

MS. THOMPSON: One of the things that we raised, your Honor, in our objection specifically to the storage and transportation notice which, as I mentioned earlier, was the first notice that was served by Plaintiffs and where we have done the most meeting and conferring. Ms. Finken mentioned 30 hours. I haven't added it up for my bills, but having entered all of my time for February last night, I know it was a lot. Mr. Henry and I were on a lot of calls about this notice and

the other three notices.

This was an issue that, at the risk of confusing things, we called a global issue because it applied to all three notices, but it is the question of whether or not we are focused on products made for the U.S. market or if we are focused on Ranitidine made for any market.

This is particularly important in the generics space because we have a lot of generics here who made product not only for the U.S., but for other countries or other regions.

THE COURT: I'm sorry, Ms. Thompson, let me stop you. I recall this issue. Let's just put this aside. I want to deal with this when we deal with the storage and transport issues just because in my thought processes that is where I had pigeonholed it.

MS. THOMPSON: That's fine, your Honor. I just wanted to make sure because you asked were there any other issues for the manufacturing and this does apply there, too.

THE COURT: No, I appreciate that. Mr. Yoo, I think you had an issue with regard to the manufacturing aspect. Is that now or is that a later issue?

MR. YOO: Your Honor, I am supposed to argue the motion as it relates to pharmacovigilance, but I think these cross-cutting issues affect all three of the motions. Some of these issues have already been covered by your Honor's ruling.

THE COURT: I am using your three memos or your three

motions as my agenda, so if the topic that you plan to argue, Mr. Yoo, is in the pharmacovigilance memo, we will get to that when I get to the pharmacovigilance memo.

Right now, I am just working off of the Defendants' motion regarding manufacturers. There were four topics, A, B, C, D. I just want to make sure, not waiving any objections you have to the rulings I have made, I will turn to Mr. Barnes.

Have I at least ruled on the issues that you believe you raised in A, B, C, D of your motion?

MR. BARNES: Your Honor, I believe that we raised issues about the solvents. In the interest of time, my sense is that you would have the same ruling on the same rationales that you have used to dispose of the other issues, so we don't need to talk about solvents.

I believe the rationale you applied would suggest that they would be allowed to inquire as to that on the same rationale as you came down on testing.

THE COURT: That is correct.

MR. BARNES: So, I think, then, if that -- I think we are in agreement that that would be the outcome. I would say the manufacturing issues that we raised in our motion have been dealt with, sir.

THE COURT: Okay. Again, you are not waiving any objections you have, and you are preserving all objections to my rulings if you want to raise those issues with Judge

Rosenberg. I just want to make sure I have ruled on everything you wanted ruled on.

Here is what I'd like to do. It is 3:40. Let's take a recess until 3:50. When we come back I would like to take up the storage and transport issues. Are you arguing those, Ms. Finken? I know Ms. Goldenberg is arguing something.

MS. FINKEN: Yes, your Honor, that's me.

THE COURT: That one seems to me, at least from the memo I have read, compared to what we just did, shorter. I would like to get through that quickly and then we'll go to the pharmacovigilance immediately after that.

Let's take a ten-minute recess and come back at 3:50. We will be in recess for ten minutes.

MS. FINKEN: Thank you.

(Thereupon, a short recess was taken.)

THE COURT: Let's go back on the record. Good afternoon, everyone. Before we took the break, I said we would take up when we came back the storage and transportation motion.

Ms. Thompson, I understand we were going to use this as the vehicle to talk about the foreign manufacturer, domestic manufacturer issue. Are you going to address that or is Mr. Yoo going to address that?

MS. THOMPSON: Sara Thompson for Teva. I am going to address it more on the product, where it was intended to be or

where it actually was sold. I believe Mr. Yoo is going to address it in the context of regulatory agencies.

THE COURT: All right. Very good. We will do that. I am going to use, so everyone understands, the Defense's motion as my agenda item.

I reviewed the motion, I reviewed the response, and I reviewed the chart, and it wasn't clear to me that there was anything left at issue. At least Ms. Finken's response seemed to be that we have resolved everything.

Ms. Thompson, let me turn to you. What do you believe to still be at issue as it relates to the issues framed in the storage and transport memo and the chart that was attached to it?

MS. THOMPSON: Thank you, your Honor. Sara Thompson again for Teva. I think the only issue remaining is this ex U.S. versus U.S. product issue. We noted here that we incorporated the arguments that we had made so I think this is the only one left as to this notice that we haven't already discussed.

There were also individual objections, but we did not brief all of those, as your Honor noted, we are focusing on what is actually in the submission itself.

THE COURT: Very good. Although I will tell you, my reading of even the ones you didn't fully brief, Ms. Finken's responses were either it is moot or it is no longer in the

notice.

I will let you all work that out between yourselves. It seemed to me there may not be as much to fight about as it might have looked like in the first instance.

Let's talk about the foreign versus domestic issue. Ms. Thompson, let me let you frame the issue from your perspective.

MS. THOMPSON: Sure. I think that the most important thing here to keep in mind is what the claims in the amended master personal injury complaint are directed to.

There are storage and transport condition claims, it starts with Count 10, and they go through 50 states, but they are all focused on product that was sold and used in the U.S., and they are focused on how that product at every step of the way arrived, was stored here, was distributed here.

From the API sourcing, the active pharmaceutical ingredient, how that got here, where it was stored when it arrived here before it was used to manufacture the product, where the manufactured product was stored either here or manufactured overseas and then shipped here, and then where finished drug product was distributed. That is the focus for all of these claims, it is on product that ultimately was distributed and used in the United States.

So, we have asked for the limitation that the Ranitidine containing products be limited to those that were

sold and distributed in the U.S. market, that were imported or manufactured for the U.S. market as opposed to globally. This is important because many of the manufacturers, including Teva -- we are by far and away not the only one -- made product for the U.S. and for other markets. We may have made it at different places, that is definitely true for Teva.

There is no overlap whatsoever between our suppliers and our manufacturing facilities for non U.S. markets and for U.S. markets. We sourced our API from different entities for the most part. There is one exception.

So, we don't have commonality of issues that are focused on in this notice if we expand it beyond the U.S., so it literally doubles, or even triples, or quadruples the burden. It potentially requires a different witness as part of preparing to disclose deposition dates.

One of the things that we looked into was who would be the right person to speak about API sourcing Ranitidine containing products. We learned it is a different person for the U.S. versus the rest of the world. If we have to speak to the entire world, that is multiple witnesses, and it's different people using different documents, using different systems, meeting different standards.

So, this is a really important limitation that we thought would be noncontroversial, but whenever we have tried to raise this we have been told that because this was a product

that was sold globally, that Plaintiffs will refuse to limit it to manufactured for the U.S. market.

However, their submission does seem to suggest that that is Plaintiffs' position with respect to this notice because there is a statement in there about some of this product is made outside the U.S. but then is imported into the U.S.

We are not suggesting that if it is merely made outside the U.S. that it is somehow not relevant or that it should be not relevant. We are saying if it is not made for the U.S., if we are talking about product that never came to the United States, that should be outside the scope of the notice.

All along when we have been negotiating this we have been focusing on who did we supply -- or who did we source our API from, who were our third-party manufacturers, where was it stored when it came into the United States.

There was never an understanding, I think, among either side until very recently that this was intended to be a global scope of storage and transport. That is why we are raising it here, but we raise it with respect to the other notices as well because it is also an issue for manufacturing.

The products are made at a different place if they are for non U.S. markets. The products are likely also stored then at a different place if they are made for non U.S. markets. If

they are made elsewhere, they are probably stored elsewhere.

They are sourced from different suppliers. The policies and procedures are likely not the same, then, when you are dealing with product that is made at one plant versus another or in one country for that country's standards.

So, these are the reasons why this really has the potential, if we do not limit it to product sold in the United States, which is the focus of the amended master personal injury complaint, it is the focus of this MDL, products sold in the United States.

THE COURT: Let me, again, make sure I understand your point.

There is an evolutionary life cycle to each of these pharmaceuticals, right? Let's take it backwards. It is sold and consumed by somebody in the United States who the Plaintiffs allege got cancer. If we trace it backwards, it had to get to that person, it had to be sold to that person, it had to be manufactured somewhere, the manufacturer had to get its basic ingredients, its API somewhere, et cetera.

If I understand you, you are not objecting to the Plaintiffs getting discovery of that life cycle. As long as the product ended up in the body of a human being in the United States, you are okay tracing it all the way back to the source.

Your objection is the opposite, which is if it ended up in the body of somebody outside the United States the supply

chain and the manufacturing chain and everything else should not be. Am I understanding you correctly?

MS. THOMPSON: Yes, your Honor. I think one thing that is important is some of these may have been made at a facility that made it both for the U.S. and for other countries. We are not talking about eliminating that as a relevant issue. We just want to focus on what actually happened with product that ended up in the United States.

If we can just carve out product that never touched the United States, that was never intended for here, that never traveled through here, this will dramatically decrease the burden of putting up witnesses.

And if we have to put up witnesses on those other topics it is going to expand the number of depositions, the burden to get ready, the time that is going to be required, and it will be of no benefit to the actual claims in this case that are related to storage and transportation of product within the United States according to the Plaintiffs' own pleading for all 50 states, storage and transport claims.

THE COURT: Got it. I understand. Let me turn to Ms. Finken and let her respond to that.

MS. FINKEN: Yes, your Honor. I think you sensed my confusion in our response to the motion because I thought we had an agreement on this storage and transport notice of deposition. I don't think that there is a dispute, to be

honest with you.

Our storage and transport notice, while -- if what Ms. Thompson is saying is correct, that they are not going to dispute providing witness testimony and documents in relation to foreign manufacturing of U.S. product, and storage and transport of U.S. product that is made overseas and how it gets over here and where it is stored over there, it does not sound like we have a dispute. That is what we are seeking.

THE COURT: My question to you was going to be: Do we have any Plaintiff in this case who didn't consume their Ranitidine in the United States?

MS. FINKEN: To be honest with you, your Honor, I do not know. If we do, it would probably be minimal. That is not what we are seeking right now.

We are seeking storage and transport, whether it is overseas or whether it is in the U.S., based upon the U.S. products that come here, because the bulk of it is manufactured overseas. I think Ms. Thompson will admit to that and that is something that is highly relevant in terms of the storage and transport claim.

As long as that is their position, that they are not going to limit that, I think that we probably don't have a dispute.

THE COURT: Ms. Thompson, do we have an agreement?

MS. THOMPSON: Sara Thompson again for Teva.

Your Honor, I think the thing that we propose, that I think makes sense, is to define in each of the notices "your RCPs" as your products that were made or sold in the United States. That is what we were taking about, and we have that definition that we had previously proposed to Plaintiffs, but we had not reached agreement on it. That would focus it appropriately on the products that were actually used in the United States by these Plaintiffs.

THE COURT: Okay. Here is what I am going to do. I will leave it to you two to wordsmith how you want to deal with this.

My ruling would be that, to the extent the 30(b)(6) notice could be interpreted to require testimony relating to the manufacture, distribution, storage, transport, et cetera, the life cycle of pharmaceuticals that were not consumed in the United States, I would exclude that from the 30(b)(6) notice.

You two can redraft it however you want to. I think those are the meeting of the minds that you two have reached and I will leave it to you to write it up, but that's my ruling.

The generic Defendants do not have to produce a witness who can testify about the life cycle of drugs that were sold in Japan, in Israel, in Great Britain, and everywhere else, only in the U.S.

Does that resolve transport and storage? Have we set

a world record in resolving that?

MS. THOMPSON: I believe so, your Honor. Those were the main issues that we had briefed.

THE COURT: Okay. Ms. Thompson is going to retire undefeated. Then I think we move to PV, to pharmacovigilance. I practiced saying that so I would not fall behind Judge Rosenberg.

Mr. Yoo and Ms. Goldenberg, good afternoon.

MR. YOO: Good afternoon, your Honor. Thomas Yoo for the generic Defendants.

THE COURT: Good afternoon.

MR. YOO: We are on a roll, I will try not to mess it up, your Honor.

I didn't want to jump in earlier because Ms. Finken was a little bit out numbered, but she actually did pretty well. Maybe we should have brought more people on our side.

You made a comment that I thought was an important comment. You said that you felt as if the Defendants were doing a hyper technical reading of the deposition notice. If that is the case, your Honor, I think it is because the way the 30(b)(6) notices were written by the Plaintiffs, it was our concern that there were too many definitions and statements that were just out there untethered to a context for this case.

If I am hearing your Honor's comments and Ms. Finken's comments today, if I am understanding them correctly, I think

we've got the necessary context to allay a lot of those concerns.

For example, I think, from our perspective, it would have been much easier for us to understand what the Plaintiffs wanted if they had asked for a witness regarding, for example, the testing that we did. We don't disagree that they get a witness to talk about the testing that each of us did do, but they didn't ask it that way. They said, give us a witness on this type of chromatography and this type of analysis and that type of analysis in a vacuum.

It was almost like we got a list of a hundred expert topics and we had to go find witnesses to cover those topics whether they had anything to do with what we did with regard to Ranitidine.

So, if the context is it relates to what we did with our product that was used by someone in the United States that makes eminent sense.

So, I say that because I think it is going to take care of some of the issues that I came armed with. We probably don't need to get into those in as much detail, but one of the things that we put in our motion, as your Honor can see, is, the Plaintiffs ask for pharmacovigilance witnesses to talk about a variety of topics, again, as written in a vacuum, carcinogens, toxic impurities, nitrosamines.

Our feeling was this MDL expressly is about NDMA and

Ranitidine and allegations that we withheld safety information or risk information about NDMA in Ranitidine in the United States. If that is the understanding of the context, then we are fine.

If I am understanding Ms. Finken's comments earlier, they saw some documents from the Defendants where some of the Defendants used NDMA interchangeably with nitrosamine or carcinogen or impurity. I get that.

If we are still talking about NDMA, then certainly they can ask about our use of the term nitrosamine as opposed to NDMA.

If, on the other hand, if they want a witness to give expert testimony about carcinogens, the hundreds of carcinogens listed by EPA and other agencies, then that's a problem, but I don't think, from what I am hearing today, that we are going to actually run into that when the depositions occur.

I think the only remaining issue as far as pharmacovigilance is concerned, your Honor --

THE COURT: Hold on. Okay.

Mr. Yoo, what is the issue that you think we do need to address?

Before we get to that, let me just say, my hope had been -- my assumption had been that those sorts of clarifications had been worked out during the meet and conferral process, because we have all been there. When you

draft a document request and deposition notice you only have the words that you have, and those words sometimes have gaps, or they are subject to ambiguity or hyper technical reading. Good lawyers defending their clients and representing their clients have to be cautious not to overcommit. I understand that need.

That is what I assumed was worked out in the meet and conferral process, it says that, but what we really want is this. We don't need to rewrite it. We agree. The special master is sitting here, we all agree. I assumed that was part of that process, and maybe it was and maybe there is still a misunderstanding.

I appreciate your comment, and I will tell you, and I have said this before, I spent a lot of my career doing white collar defense and we would get subpoenas from the Government. Anybody who has ever gotten a subpoena or a request for documents from the Government knows it's essentially every document your company has ever generated from the beginning of time to the present relating to all topics that conceivably might have committed a crime. That's the scope of the subpoena.

I would always pick up the phone and call the prosecutor and the first question was, okay, what do you really want and what are you looking for? I assume that is how the meet and conferral process is, okay, we got this, we

understand. You have marked your territory, but what do you really want and how do we get there? It sounds like that is the process that is at work here and I appreciate that.

Mr. Yoo, what are the PV issues that you think are still ripe for ruling this afternoon?

MS. GOLDENBERG: Your Honor, I apologize, I don't mean to cut Mr. Yoo off. This is Marlene Goldenberg for the Plaintiffs.

I wanted to just note at this point that I disagree with some of the ways that Mr. Yoo has characterized what we now have rulings and agreement on. I am happy to address the issue that he was about to bring up and circle back to the rest, but I just didn't want to let this pass --

THE COURT: That is fine.

MS. GOLDENBERG: -- without putting that out there.

THE COURT: That is fine. I know what my rulings were. You all can disagree about what they were, but I know what I ruled. If there is ambiguity about that I am sure we will find a way to sort that out. No one is waiving anything by sitting patiently and letting the other person talk.

Let Mr. Yoo finish up and then, Ms. Goldenberg, I will give you as much time as you need.

MR. YOO: Thank you, your Honor. Thomas Yoo again for the generic Defendants.

I believe the only remaining issue on

pharmacovigilance is that the deposition notice defines "regulatory agency" as any regulatory agency globally. It is not what we communicated to the FDA, or what was in our FDA regulatory documents, it is FDA and any other agency anywhere in the world, and we think that is overly broad.

And we think that if we literally had to comply with that we would have to go, depending on the Defendant and in how many countries Ranitidine is sold by that Defendant, we have to talk to the regulatory people across the world. I don't think that that is what the Plaintiffs really want. I certainly don't think it is what they need.

So, we would request that the regulatory and pharmacovigilance issues be limited to our reports to the FDA, our communications to the FDA.

If I am understanding the Plaintiffs' papers correctly, they do have this concern that when they look at our FDA communication documents, at least for some of the Defendants, sometimes they see a reference to things that occurred outside of the U.S.A.

Well, to the extent a Defendant reported X U.S. data to the FDA and it is therefore part of the FDA communications, then I think it is fair game. What we don't want to have to do is go talk to our regulatory head in Japan, or the Middle East, or Brazil and find out what is in those documents, because obviously it has nothing to do with our dealings with the FDA.

THE COURT: Okay. Let me hear from Ms. Goldenberg.

MS. GOLDENBERG: Sure, your Honor.

THE COURT: I'm sorry, Ms. Goldenberg, I apologize.

Mr. Yoo, your objection there is undue burden and relevance and disproportionality. Am I correct?

MR. YOO: That is correct, your Honor.

THE COURT: I apologize, Ms. Goldenberg, for cutting you off. Please.

MS. GOLDENBERG: No problem, your Honor. This is Marlene Goldenberg for the Plaintiffs.

Let me start out by tweaking one thing that Mr. Yoo said. I wanted to point out that our definition of regulatory authority is not what he said it was. What we have asked for is in the chart, but just to paraphrase, we are looking for information that was submitted to the United States FDA and then limited and targeted other agencies.

So, we have asked for information from the European Medicines Agency, Health Canada, and then any facility that makes product, or distributes product, or sells product that goes to the U.S.

Understanding what we just talked about in the context of storage and shipping, we know, for example, that many of these facilities are located overseas, as you said, in Israel, in India, and other places, and this is a Defendant specific inquiry and we have left it that way in the definition.

The reason that we need information from around the world is because pharmacovigilance is different from manufacturing and it is different from storage and handling. The difference is pharmacovigilance involves the study of understanding from a post-market standpoint how the product fares in the real world.

Ranitidine, the molecule, is largely the same wherever they send it, whether they send it to Israel or Japan, and people, who are largely the same, live in all of these countries. So, if a person in Israel has an adverse event or they develop cancer because of Ranitidine, it is no less relevant to this case because they live in Israel than if they lived in the United States, and the Defendants agree with that.

We cited Teva USA's website in our papers where they talk about their global pharmacovigilance database, and in fact, the Defendants are required to report these global adverse events to the FDA in their filings, and we attached one of those as an example so that you could see that.

So, while manufacturing does make sense to confine to the U.S., pharmacovigilance is something that our experts need to be able to look at to make determinations about general and specific causation in this case, and we assume the Defendants' experts are going to be analyzing that very same data.

So, prohibiting us from questioning witnesses about this information handicaps Plaintiffs' ability to prove their

case, and unless Defendants are going to say they are not looking at any information from other countries, I think that Rule 26 is clear that we are entitled to any information about the defenses they would raise, too.

THE COURT: Let me clarify again and make sure I understand you, Ms. Goldenberg.

Your ask is the U.S., Canada, the EMA, and then any country's regulatory authority where Ranitidine is manufactured which is ultimately sold in the United States. Am I understanding that is the scope?

MS. GOLDENBERG: Correct, because those countries have authority to inspect those agencies, and so we assume there are documents there that would be relevant.

THE COURT: Let's assume generic manufacturer -- Mr. Yoo, who is your client? I will pick on your client for a second.

MR. YOO: Thomas Yoo. My client is Glenmark.

THE COURT: Let's say Glenmark has a manufacturing facility in Romania and they sell into the E.U. and somebody in Liechtenstein gets cancer from their Romanian produced Ranitidine. Who do they report that to? Do they report that to the regulatory authority in Romania or the regulatory authority in Liechtenstein? Who gets that report? Is it where the adverse event occurred or is it where the drug was manufactured which led to the adverse event, if you know?

MS. GOLDENBERG: Is that question for me, your Honor?

THE COURT: Yes, for you, Ms. Goldenberg.

MS. GOLDENBERG: So, adverse events is an area where I think that information does make its way to the U.S. FDA because the manufacturers have to report that information.

What isn't going to make it to the FDA necessarily are the documents that we cited to in our submission. For example, when this whole thing broke and everyone found out that there was NDMA in these pills various regulatory agencies sent out inquiries to the manufacturers asking them to answer some targeted questions, which is what you saw in the document that we submitted.

There is an issue there about what happened from a timing sequence. For example, if the European Medicines Agency got to this before the FDA, and the Defendants in those documents concede we have Ranitidine tablets that are contaminated with NDMA, but then we find out that they waited six months to recall that product in the United States, that is an issue that goes to notice.

I will tell you I was just involved in a different case where the manufacturer of a pharmaceutical drug warned the EMA and Health Canada five years before they decided to warn the United States. So this is a real thing that actually happens.

The other information that doesn't necessarily get

there is, again, inspections of these facilities that go to manufacturing issues, and we have seen 483 -- those are what the FDA calls the letters when they inspect them, but other agencies have comparable letters -- saying things to the effect of, this company isn't doing adequate stability testing, which goes directly to the expiration date claims. That is why these facility inspections are also important.

One could argue about whether or not they belong in manufacturing topics or PV. I think we have topics that cover both, but we are willing to confine this to the PV notice so that we get this information that is relevant to more than what the Defendants say in their motion.

It's not just failure to warn the FDA, this all goes to how the product acts in the real world and whether or not their expiration dates are set properly, whether or not their products are degrading on the market and on shelves and in shipping, and whether or not their storage conditions are adequate.

THE COURT: Thank you. Let me go back to Mr. Yoo and have him respond.

Mr. Yoo, with that clarification from Ms. Goldenberg, that they are not asking every of the 23 generics to report everything they have ever told to every regulator agency in the world about PV, do you have a sense, if it is limited to countries overseas where you have manufacturing facilities,

plus the E.U. and Canada, does that affect the burden issue?

MR. YOO: It does. Thomas Yoo for the generic Defendants.

It does and I can't give you a reliable answer for every country that may be involved for all of the generics without all of us literally speaking to the pharmacovigilance people in those countries. Suffice it to say the regulatory framework is different from country to country, and therein lies a large part of this problem.

Let me address, if I can, your Honor, the things that Ms. Goldenberg raised.

First, the Plaintiffs' definition in their notice -- this is page four of their deposition notice, Exhibit A to our pharmacovigilance motion: Regulatory agency means the United States Food and Drug Administration, or any equivalent regulatory authority globally or in other countries, that is charged with the regulation of RCPs, that is Ranitidine containing products, including, but not limited to the European Medicines Agency, Health Canada and the World Health Organization.

So, it is not limited to specific countries, it literally includes anywhere in the world. But even if it were limited to the E.U. and Health Canada, that would still require the Defendants to go work up two separate pharmacovigilance areas, have those witnesses learn those regulatory files,

understand what the legal framework is in those regions, and then testify based on those contacts.

So, the burden problem is still there, the proportionality problem is still there. And to the extent that there are X U.S. issues that affect the U.S. market such as inspections of manufacturing facilities abroad, the FDA -- Ms. Goldenberg will agree with this, the FDA routinely sends people around the world to inspect manufacturing facilities, do reports and all the other things that FDA does for anything that affects the U.S. market.

So, those things are going to be contained in the U.S. regulatory files. We don't have to go look at everything in our EMA file or Japanese file to prepare someone to testify about any and all of those communications and regulations. We believe that is not relevant and it's not proportional and shouldn't be permitted here.

You know, if Plaintiffs want to come back and demonstrate good cause after they get a U.S. pharmacovigilance deposition and say we have these specific questions and the witness couldn't answer them, and we think we need a second deposition to get to those questions, by all means, but we don't feel we should be burdened with obligations across 20 to 30 generics to go talk to our pharmacovigilance people around the world.

THE COURT: I understand. Ms. Goldenberg, let me go

back to you.

What are you shooting at here? Are you just trying to establish this is what they said, to try to lay a predicate that -- to your example that you used, if you told the Europeans this causes cancer and you waited to tell the FDA for a year, we have a negligent failure and a failure to tell the FDA -- I forget what count that was -- failure to warn through the FDA, et cetera, et cetera.

Is really the relevance of these files simply what was said and you just want a record of what was said and what wasn't said, or is it your intention at the deposition to drill down, well, why didn't you do this, and why didn't you do that, and what procedures did you follow to make sure that you were reporting to the Israeli authority? How deep are you intending to dive on this?

MS. GOLDENBERG: I am glad you asked that, your Honor, because there is the theoretical fight about this and there is the practical fight about this. The theoretical fight is the one that we have already had, so I am not going to rehash it except to say that Mr. Yoo has our definition wrong because he doesn't have the right notice, and we pointed that out in our chart.

Beyond that, every one of these companies has a global head of pharmacovigilance, they all run through the same department. The reason for that is because they have global

pharmacovigilance obligations because they have to determine for causation purposes in this case especially, does Ranitidine cause cancer, and the way that you make that assessment is based on the totality of the information available through medical literature and through adverse events.

I don't want to get into in a deposition why didn't you tell the Israeli authorities this, I don't have that kind of time. What I do want to get into is what does the totality of the evidence look like, is there a safety signal here, and what did you do to track your adverse events.

Because while we have been sitting on this hearing I logged into the U.S. FDA adverse event reporting database and found that in some years there are less than 300 adverse events total being reported for generic Ranitidine, so we are not talking about that many.

You know, what information did they collect, how did they collect it, and what did they do with it in terms of adjusting their expiration dates and storage and handling conditions, because this is their real world test for how their product functions.

THE COURT: Right. I hear you on that and I appreciate that. Just to make sure you and I are taking about the same thing here -- let me put it this way:

I think, to the extent what you are asking for is simply what did you say, that's a statement of a party

opponent, binding on them, it shows that they were on notice, that they knew certain things and you could lay that against what they have said to the public, or they have said to the FDA, or they have said to other people, and try to make an argument, try to draw an inference that they had knowledge that they were trying to conceal. I am not saying they did, I am just saying, if I understand it, that is sort of the evidentiary trail you want to go down.

MS. GOLDENBERG: That is part --

THE COURT: It would seem to me that that would be relevant. Let's start with that. To drill down much deeper than that and get into why didn't you do and why did you do starts, to me, to get farther and farther away from what is really relevant and proportional to the needs in this case.

Now, what I think I am inferentially hearing from you, Ms. Goldenberg, is that your impression is -- and I am going to simplify this -- that somebody at Glenmark sitting in the United States can push a button and go into the pharmacovigilance database and get all that. They can find relatively quickly what they told the EMA and what they told the Israelis and what they told the Romanians, and everything else, and that wouldn't be burdensome.

But you, I think, would agree that if they have to prep a witness to talk about what are their policies and procedures and practices in every single country for how that

reporting gets done and whether that reporting gets done and that kind of thing, the burden starts to increase.

So, that's what I am hearing from the two of you, and I think that is what I am being asked to balance, but I want to make sure you have a chance to fairly comment on that.

MS. GOLDENBERG: Yes. I agree with everything you said so far. The only caveat is, we also want to know, in analyzing the adverse events the Defendants have gotten, how did they use that data, or did they use that data to adjust their expiration dates or to look at their storage and handling obligations, and whether they did anything with that.

So, I guess that would be the only thing I'd tack on, but otherwise I agree.

THE COURT: Temporally, that seems to me -- the point I am focused on is what did they say. Okay. There is a trail of evidence that flows temporally after that, meaning you said that, you knew that, and what did you do with that information.

MS. GOLDENBERG: Correct.

THE COURT: And there is a trail of evidence that goes temporally before that, which is what led up to and caused you to do, and how did you, and why did you report that information.

MS. GOLDENBERG: Right.

THE COURT: I hear you on the temporally after, but what I hear Mr. Yoo arguing primarily is temporally before.

Again, maybe I am missing the argument here so let me turn to Mr. Yoo to educate me if he needs to.

MR. YOO: I am tracking what you are saying, your Honor, and if I am understanding you correctly, I agree with you. If they want to know what did we tell other regulatory agencies regarding a root cause analysis, for example, they can ask that in an interrogatory and then they can use that interrogatory answer and ask our U.S. pharmacovigilance witness whatever question they want about compare and contrast, why did you tell them this, but you told the FDA that.

You are absolutely right, the main burden concern we have is to produce a 30(b)(6) witness on our dealings with regulatory agencies globally would require us to do the whole thing, the legal structure, why we report, when we report, what we report in Israel, Japan, Romania, and to what end other than driving up the costs on our side.

At a very minimum, we would be talking about counting each of those as a separate 30(b)(6) deposition because that is not one person.

I would also note for the record that it is not correct to say there is a global head of pharmacovigilance at every one of the generic companies who has a laptop and all he or she has to do is press a couple of buttons and the data pops up. That's not how it works.

THE COURT: No, I understand, I was over simplifying.

I understand that. I think I understand the lay of the land here.

I will say this, it is an interesting characteristic of the 30(b)(6) witness process that -- and actually you could have one 30(b)(6) pharmacovigilance witness to testify to all of these things, you just have to educate that person. That is the beauty of 30(b)(6), the person doesn't have to have personal knowledge.

So, it could be one person, it could be three people, it could be five people, that is entirely up to you, and we'll cross the bridge later as to whether that counts as one deposition, two depositions, or five depositions, but I don't want to dip my toe into that quite yet.

Ms. Goldenberg, anything further from you -- I will tell you, my inclination is that what they told these foreign agencies, as limited by your new definition -- not new, but the one that you claim is the correct definition, what they told them is fair game and what they did with that information going forward is fair game. I am not inclined to require them to prep a witness to explain everything that sat behind that in a foreign country.

Let me hear you on that before I formalize that as a ruling.

MS. GOLDENBERG: I think we are fine with that, your Honor. Frankly, the only thing I was going to say is, our

topics actually do that for them already. That goes back to my there is the theoretical fight and there is the actual practical fight.

So, the topics that we have given that implicate regulatory agencies ask for very targeted and specific things like risk management plans, health hazard analyses, and I think those all go to what you were just saying about what they told those regulatory authorities about things that matter to this case.

THE COURT: All right. Mr. Yoo, anything further you would like to be heard on?

MR. YOO: Your Honor, unfortunately, if we have to provide information related to EMA and Health Canada, for example, what that information is that we would be required to provide I think is important.

Number 14 on their pharmacovigilance deposition notice is incredibly broad. I think we would have to be very specific about what we have to prepare a witness on or what interrogatory response we would have to provide.

Currently, number 14 says any evaluations, analyses, discussions, recommendations, statistical analyses or reports pertaining to Ranitidine containing products and/or H2 blockers and NDMA, N-nitrosamines, nitrite, dimethylamine, genotoxins, Class 1 residual solvents, precancer, cancer markers, cancer, carcinogenicity, nitrosation, tumor development, tumor inducer

and/or tumor promoter.

MS. GOLDENBERG: Once again, I am sorry to cut in, but Mr. Yoo has an old notice.

THE COURT: Is that not the operative notice? Okay. I will tell Mrs. Stipes that is in a document that she will have, so she will get the proper spellings from the document.

Ms. Goldenberg, what, in your view, is the correct document I should be looking at? Was it the one attached to your submission, not to the Defendants' submission?

MS. GOLDENBERG: Correct.

THE COURT: Hold on, let me pull that up.

MS. GOLDENBERG: I could read it into the record, but I think Ms. Stipes might be angry at me if I do.

THE COURT: Hold on. I don't think I -- I have it somewhere else.

MS. GOLDENBERG: I am happy to read it if that's easier.

THE COURT: Here is my point. I don't think I need you to read it. I think that starts to get more granular than I am comfortable ruling on in advance on a 30(b)(6). I think further meet and conferral -- it sounds to me like again the notice is written in a way to be overly inclusive, as they always are. Mr. Yoo is being a good lawyer and reading it very strictly and going to try and make his client comply with the obligations that would otherwise be imposed if the Court

construes it strictly.

I think we all understand, as Ms. Goldenberg has said, in the real world this case is about Ranitidine, it's about whether the companies were on notice that Ranitidine decomposes into a carcinogen, and that carcinogen causes cancer. That is the bulls-eye that I assume number 14 is shooting at, what did you tell these agencies about that kind of stuff?

Am I right, Ms. Goldenberg?

MS. GOLDENBERG: Yes.

THE COURT: I would agree, and I assume Mr. Yoo would agree, that if it is limited in that general fashion they would not object and they would prepare a witness for that. If you all need to wordsmith the language to memorialize that sort of scope, but I think that is a reasonable scope.

MS. GOLDENBERG: Noted.

THE COURT: Does that address your concern, Mr. Yoo?

MR. YOO: Yes, your Honor. We will work with that and continue to discuss with Plaintiffs.

THE COURT: Very good. It is one of those situations where everyone understands what we are trying to define. Sometimes putting that into words is a little difficult, which is why lawyers get paid a lot of money to try to write things down. I am confident that, having worked with both of you for over a year now, you will be able to get there. If not, you can come back to me or the special master and we will nail it

down.

Mr. Yoo, to the extent your concern is, if we reported that tobacco causes cancer and tobacco is a carcinogen, we now have to turn over all of our tobacco related communications, no one thinks that is what this is going to cover. I don't think that's what it is intended for and it is certainly not my ruling that you would have to turn over anything like that.

If that is your concern, I will allay that concern.

MR. YOO: Thank you, your Honor.

THE COURT: Very well. Mr. Yoo, is there anything else in the motion that you wanted to address this afternoon? Neither side waiving any objections to rulings I may have already made.

MR. YOO: No, your Honor, nothing that has not already been covered. Thank you very much for your time.

THE COURT: Thank you all very much.

It is barely 4:30, good, we are in under budget here.

I shudder to ask this question, but I feel compelled to always ask this question. While we are all together this afternoon, is there any other issues that we need -- let me look at my notes.

Any of the submissions that I have referenced that I relied on, the parties' submissions, should all been filed in the docket. The attachments, if they were marked confidential should be filed under seal. If they were not marked

confidential they do not have to be filed under seal.

We have scheduled another hearing for Thursday at one o'clock relating to the -- for other issues related to the generic manufacturing. We scheduled a hearing for Monday -- what time on Monday did I schedule this for, Ms. Finken?

MS. GOLDENBERG: I think you said it was four o'clock, Your Honor, but I will let Tracy correct me if I'm wrong.

THE COURT: I don't think so. I don't usually schedule things that late in the day. So, 2:00 to 4:00 for that. Okay.

I have ruled on everything everyone wanted me to rule on today. Everybody has preserved all of their objections.

Let me do this if I can, I hate to burn everybody's billable time. Let's take a five minute break. I want to review my notes, make sure there is nothing else I wanted to talk to you about today. If not, we will recess and I will let everybody go.

It is 4:37. How about we come back at 4:45, and you all think about if there's anything else that you wanted to raise while we're together today. We will be in recess until 4:45.

MS. FINKEN: Thank you, your Honor.

(Thereupon, a short recess was taken.)

THE COURT: Let's go back on the record. I am waiting for Ms. Finken. Ms. Goldenberg, you will have to stand in for

a second.

Let me ask the generic Defendants, any problem if I move the hearing on Thursday from one o'clock to 12:30?

MR. HENRY: Your honor, Terry Henry for Apotex. There is no problem on this end.

THE COURT: Okay. Ms. Goldenberg?

MS. GOLDENBERG: No problem with me, but I would like Ms. Finken to make sure that she can confirm the same.

MS. THOMPSON: Your Honor, Sara Thompson for Teva. I am not available on Thursday due to a conflicting hearing, but I don't think I am, hopefully, necessary.

THE COURT: Okay. You are going to trust Mr. Henry and Mr. Yoo to carry the water for you?

MS. THOMPSON: Correct, your Honor.

THE COURT: Thank you, Ms. Thompson. Subject to Ms. Finken weighing in, we will move the hearing to 12:30 for Mrs. Stipes to be with Judge Rosenberg at 2:30.

Other than that, Ms. Goldenberg, anything else that you wanted to raise on behalf of either yourself or your clients today?

MS. GOLDENBERG: No, your Honor, and Tracy and I talked off line, and we agreed there is nothing else from the Plaintiffs, although she is now here to weigh in on the schedule.

THE COURT: Okay. Ms. Finken, I was going to move the

hearing on Thursday from one o'clock to 12:30.

MS. FINKEN: That is fine.

THE COURT: Great, we will do that. No other issues from the Plaintiffs. Mr. Yoo, Mr. Henry, or Ms. Thompson, any other issues on behalf of the generic manufacturers this afternoon?

MR. YOO: Nothing from us, your Honor.

MR. HENRY: No, your Honor.

MS. THOMPSON: No, your Honor.

THE COURT: Thank you all very much, extremely well argued, extremely well briefed and very helpful. I will look forward to seeing some of you on Thursday, some of you on Monday, and all of you at our next discovery status a week from tomorrow.

Thank you, everybody. Have a good afternoon. We will be in recess.

(Thereupon, the hearing concluded.)

* * *

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

Date: March 5, 2021

/s/ Pauline A. Stipes, Official Federal Reporter

Signature of Court Reporter