1	UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF FLORIDA
2	WEST PALM BEACH DIVISION
3	CASE NO. 20-md-02924-ROSENBERG
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5	IN RE: ZANTAC (RANITIDINE) . PRODUCTS LIABILITY . West Palm Beach, FL LITIGATION March 4, 2021
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8	DISCOVERY HEARING (through Zoom) BEFORE THE HONORABLE BRUCE REINHART
9	UNITED STATES MAGISTRATE JUDGE
10	FOR THE PLAINTIFFS: TRACY A. FINKEN, ESQ.
11	Anapol Weiss One Logan Square
12	130 N. 18th Street Suite 1600 Philadelphia, PA 19103
13	215-735-1130
14	ROOPAL P. LUHANA, ESQ. Chaffin Luhana LLP
15	600 Third Avenue 12th Floor New York, NY 10016
16	888-480-1113
17	FOR THE DEFENDANTS: TERRY M. HENRY, ESQ.
18	Blank Rome LLP One Logan Square
19	130 N. 18th Street Philadelphia, PA 19103
20	215-569-5644
21	Official Court Deportor, Dauline A Stipes
22	Official Court Reporter: Pauline A. Stipes HON. ROBIN L. ROSENBERG
23	Ft. Pierce/West Palm Beach, Fl 772.467.2337
24	
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1 THE COURT: Good afternoon, everybody. I know we were 2 a little late getting the room open. That was my fault, so i 3 apologize for that.

Let's go on the record and get started. This is Case Number 20-2924, In Re: Ranitidine Multi District Litigation. This is the continuation of a discovery hearing that we started last week relating to multiple issues attendant to the 30(b)(6) notices for deposition served on what we are calling the generic Defendants.

First of all, let me remind the parties, please, as 10 quickly as you can, file the submissions that you submitted the 11 12 other day. We are going to do a brief written order, but I 13 want to reference those materials in my order, and I can't 14 reference them until they have a docket number. So, if you 15 could just get those filed, even if it is just the unsealed 16 ones, just get the submissions themselves, and if you 17 subsequently want to file the attachments, that is fine, you can file those separately. I would like to get that off the 18 19 docket -- on the docket and off my plate.

20 Second, let me just remind everyone again, whenever 21 you speak please identify yourself for the Court Reporter.

I have a third, and I should know the answer to this, but I will ask again, Ms. Finken, how many generic Defendants are left in this case? I know we had 23 at one point. One of the submissions seemed to suggest 21, but I thought the other

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day someone said 22. If you can help me out on that. 1 2 MS. FINKEN: Your honor, I believe presently there are 3 22 families of generic Defendants, but my understanding is that 4 there is discussion regarding one of those being dismissed. Ιt should be 21, would be an accurate number, I believe. 5 6 THE COURT: When I looked at your submission and you 7 had listed who had responded to things and who had not, there were only 21. I wanted to be sure I had the right count. 8 9 MS. FINKEN: That is correct, your Honor. 10 THE COURT: Okay. Let me sort of frame the issues 11 that I see and give you some perspective and then we will 12 address the specific issues that you have raised in your 13 materials. 14 I understand on at least one, maybe more of those 15 issues, the request of the Court today is not to rule on 16 anything, but to give you a little more time to finish the 17 process. I am inclined to do that, but I did want to talk about it a little bit. 18 19 Let me start with this. I hope everyone saw the order 20 that Judge Rosenberg entered about an hour ago at Docket Entry 21 2930. If you haven't seen it, I can read it to you. 22 Ms. Finken, have you seen it? 23 MS. FINKEN: I have, your Honor. Thank you. 24 THE COURT: Mr. Henry, have you seen it? 25 I have, your Honor. MR. HENRY: Thanks.

1 THE COURT: I think you should assume that the message that is being sent is that Judge Rosenberg is not satisfied 2 that the parties are managing this deposition process 3 efficiently and orderly. More specifically, PTO 60 requires 4 that storage and transportation 30(b)(6) depositions will occur 5 6 in April, so we will be starting those depositions in the next 7 30 to 45 days. Today is March 4th, April 1st is 28 days away. 8 Custodial productions need to occur sufficiently in

9 advance of the depositions to allow for meaningful preparation.
10 We can't do custodial production until we have an ESI
11 protocol and yet, as I sit here today, my understanding, and we
12 will flesh this out, is we do not have an agreed ESI protocol,
13 we have not begin custodial production, and we do not have
14 tentative dates for all the depositions.

The reality is, within the next ten to 20 days one or more of these Defendants is going to have to make and complete a custodial production to allow for the depositions that are going to occur in early April. That is not a lot of time.

The concern is that these deposition notices were formally served as of February 9th, but were in the possession of these Defendants in January, six weeks ago. So, to be where we are today, given where we started six weeks ago, does not give the Court great confidence, and that is why Judge Rosenberg has entered the order.

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I intend to fully utilize the authority that she has

given me to right this ship, get it back on the rails and get these depositions done as contemplated in PTO 60 because those deadlines will not change. Those depositions are going to occur as required in the timeframe set by PTO 60.

Also, and we can talk about this further, my presumption in my default position is there will not be more than two depositions on any given day. There are enough days so the depositions do not have to be stacked with six, or seven, or five depositions on the same day. Two a day should be more than sufficient to get all the depositions taken that need to be taken.

12 You can agree to more than two if you want to, but I 13 am telling you what the Court's presumption is.

14 Let me turn to the specific issues that have been 15 raised by the parties' submissions. Let me start with this. PTO 54 had three deadlines as of February 28th. We were 16 17 supposed to, by the end of February 28th, have an agreement on search terms, the Defendants were supposed to identify and 18 19 propose their initial custodians, and the Defendants were 20 supposed to propose tentative -- that's the word in the 21 order -- tentative deposition dates.

Let me take them in that order. Ms. Finken, was there by close of business on February 28th, an agreement on search terms?

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MS. FINKEN: Your Honor, if I can phone in a friend on

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1 this. Ms. Luhana has been handling that aspect of it and she 2 is here and can talk to that issue.

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THE COURT: Very well. Thank you. Ms. Luhana.

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

Judge, I appreciate what you said earlier because the parties appeared before your Honor and Judge Rosenberg on February 5th, and the same issue was posed, whether the generic Defendants would take the route of search terms or whether they would take the route of TAR and cull the production to produce custodial files.

12 So, that question was posed, they were unable to answer it. They asked for additional information to make that 13 14 decision, but you have to appreciate in terms of most cases, 15 Defendants don't get the benefit of that information earlier on, however, we obliged. We met and conferred, we narrowed the 16 17 search terms and we were hopeful that Defendants would be able 18 to give us their decision on whether they were going to use 19 search terms or use TAR and culling.

To this date, they still haven't provided that information. Most of the generic Defendants haven't given that answer to us. That is why we have requested in our submission specifically for the generic Defendants to provide an answer by the close of business tomorrow, and if they were unable to come to an agreement, that we appear before the Court on Monday.

1 THE COURT: Okay. I appreciate that. You actually 2 got ahead of me there. That is an issue we are going to 3 address in a second. I appreciate that.

The question I was asking is a more straightforward one. As I recall the conversations we had, whether they went the search term route or the TAR route, there had to be an agreement on some initial search terms to allow the process to begin, because even if they opted for TAR, TAR is an iterative process which requires some initial terms for searching.

10 So, I think that is why -- I know that is why, in PTO 11 54 Judge Rosenberg ordered the parties to agree on initial 12 search terms by February 28th. My question was just a yes or 13 no, did you make that deadline or not?

MS. LUHANA: We made the deadline to come to an agreement on a narrowed set of search terms to use for linear review, not a set of search terms to use if there is a TAR protocol in place.

THE COURT: All right. I will accept that you all made the deadline. All right. Close enough, good enough. We can address the TAR issues -- it's my understanding we are not going to address those today, that the request is to let you all have a little more time to work that through and work with the special master, so I'm inclined to do that.

24The second deadline was that the Defendants were25supposed to propose initial custodians by February 28th. Mr.

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1	Henry, did that occur?
2	MR. HENRY: It did, your Honor.
3	THE COURT: As to all 21 of the Defendants?
4	MR. HENRY: I believe it occurred I believe 19 of
5	the 21 made their disclosures, and since Sunday night, the last
6	two have made their disclosures to my understanding.
7	THE COURT: Who are the two who didn't make the
8	deadline?
9	MR. HENRY: I believe it was Novitium and Nostrum.
10	Ms. Finken can correct me if I'm wrong.
11	THE COURT: Ms. Finken, do you know were the two that
12	didn't make the deadline?
13	MS. FINKEN: Mr. Henry is correct, it was Novitium and
14	Nostrum.
15	THE COURT: When did they comply?
16	MS. FINKEN: One complied on Monday, and the other
17	complied on Tuesday.
18	THE COURT: Okay, that is fine. Okay. As we stand
19	here today, you have that information now, Ms. Finken?
20	MS. FINKEN: Yes.
21	THE COURT: Let's turn to the third issue. PTO 54
22	required the Defendants to offer up tentative deposition dates.
23	It is my understanding that has not happened, is that correct;
24	Mr. Henry?
25	MR. HENRY: I'm sorry, your Honor?

1 THE COURT: Let me put it this way. In the 2 Plaintiffs' submission they represent that 21 -- I am sorry, 19 of the Defendants did not meet the February 28th deadline to 3 4 give them deposition dates for the 30(b)(6) depositions that 5 were required under PTO 54. I am just asking you if you 6 dispute that. 7 MR. HENRY: Your Honor, the deposition dates were given, I think the dispute is over whether a manufacturing 8 9 witness was identified in those disclosures. 10 THE COURT: Your position is dates were given, but 11 just not an identity of a witness? 12 MR. HENRY: No, your Honor, let me be specific. We 13 were required to give deposition dates for a pharmacovigilance 14 witness, storage and transport witness, and a manufacturing 15 witness, and several parties, my client, Apotex, being one, did not identify a manufacturing witness. 16 17 THE COURT: I understand that, but you and I are talking past each other. You are talking about the identity of 18 19 the witness. I am asking you, did you give Ms. Finken a date 20 for your client to sit for a manufacturing deposition? 21 MR. HENRY: No, your Honor. 22 THE COURT: Do you dispute that in fact, as Ms. Finken represents in her submission, 19 of the generic Defendants did 23 24 not comply with PTO 54 by providing dates for a manufacturing 25 depo, a storage and transport depo, and a PV depo?

1 MR. HENRY: Your Honor, I don't have the number of 2 Defendants that did not identify a date for each of those 3 categories. 4 THE COURT: Okay. The further representation is, that as we sit here today, four days past the deadline, the Court 5 6 ordered deadline, eight of the Defendants have still not 7 provided deposition dates; is that correct? 8 That may be correct, your Honor. MR. HENRY: Some of 9 those communications are happening directly with Ms. Finken, so I am not in on all of those communications. 10 11 THE COURT: Okay. 12 MS. FINKEN: Your Honor, can I respond to that? 13 I read your submission, but yes, you THE COURT: Yes. 14 may. 15 MS. FINKEN: There were eight that didn't give 16 manufacturing dates, there were two that did not give any dates 17 for shipping and storage, pharmacovigilance, or manufacturing at all. 18 19 THE COURT: As we sit here today? 20 MS. FINKEN: Correct. 21 THE COURT: I think your representation in your motion was that Teva and -- I'm sorry, I don't remember who the other 22 23 one was -- did timely give you dates for all three, and nobody 24 else did; is that correct? 25 MS. FINKEN: No, your Honor, that is not correct, and

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I apologize if it was unclear in my submission. 1 There were a number of Defendants that gave us dates 2 3 on Sunday as they were required to do. The order requested 4 that people start giving dates as early as possible so that we 5 could get them set on the calendar. 6 The only two that gave dates prior to this weekend was 7 Teva and Apotex. Other than that, everyone else waited until 8 the final deadline to provide dates. 9 THE COURT: I thought I saw in your submission that some of them had provided dates on Monday and Tuesday. 10 MS. FINKEN: Yes, the two that we just spoke about, 11 12 Novitium and Nostrum, gave dates Monday and Tuesday. 13 THE COURT: But the other eight have still not given 14 you dates; is that correct? 15 MS. FINKEN: They did not give dates for manufacturing 16 at all, and then there were two that did not give dates at all 17 for any depositions. THE COURT: Mr. Henry, as to those ten, I am going to 18 19 issue an order to show cause why they shouldn't be sanctioned 20 for not complying with PTO 54, and you will have an opportunity 21 to answer for that. 22 MR. HENRY: Are we going to be heard on that today? 23 THE COURT: No, I am going to issue an order to show 24 cause, I am going to allow everyone to brief it, and then we 25 will have a hearing.

1 MR. HENRY: Yes, your Honor. 2 THE COURT: It seems to me when a District Court 3 orders someone to do something, and they don't do it, the Court 4 cannot let that slide. 5 All you were ordered to do was to produce a date. 6 That is all you were ordered to do, give a tentative date. Ιf 7 you didn't do it, you didn't comply with the order, and we will have a hearing to determine what sanctions, if any, should be 8 9 imposed for that. MR. HENRY: Understood, your Honor. 10 THE COURT: Okay. Now, I understand with regard to 11 12 the manufacturing depos, however, there is a substantive issue, 13 and I will get to that in a second. 14 Ms. Finken, at least with regard to the scheduling of 15 those depositions and getting the dates that you need so those depositions can go forward in April, how do you propose that we 16 17 proceed? 18 MS. FINKEN: Your Honor, since we gave our submission 19 yesterday there were -- several people have reached out to try 20 to reschedule and move their dates around so that they did not 21 conflict, which we have been working through that. 22 My proposal would be to allow us to continue to work through getting that scheduled by the close of business 23 24 tomorrow, and if we cannot with certain Defendants, that we 25 issue an order of scheduling on their behalf.

1 I can submit an updated calendar for your Honor as an 2 exhibit tomorrow if that's your preference. 3 THE COURT: First of all, Mr. Henry, any objection to 4 not addressing that today and giving the parties some more time 5 to work it out? 6 MR. HENRY: No, your Honor. I would like to clarify 7 that from Monday through today, and I expect into tomorrow, the Defendants have been working with the Plaintiffs to reschedule 8 9 those depositions. I would also like to point out that PTO 60 gives the parties until Friday to make those adjustments. 10 So, I would suggest that at the close of business 11 12 Friday, if the parties have still not come to agreement, that 13 at that time, the meet and confer process should take over so 14 the remaining Defendants that don't have the right depositions 15 could work with Ms. Finken to find the right date, because when 16 we are talking about 61 depositions or more, with 21 different 17 Defendants, that is not a very simple process. 18 We don't even think there is a dispute until the close 19 of business on Friday. THE COURT: Okay. You can't reset a date that you 20 21 haven't set in the first place. Let's start with that. For 22 example, as to your client in manufacturing, you are not resetting a date, you are setting a date. 23 24 MR. HENRY: Understood, your Honor. 25 THE COURT: Okay. Let's just be clear about that.

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1 Secondly, I have no problem letting the process play 2 its way out, but here is what I am going to do. 3 I will give you until the close of business tomorrow 4 to see what you can do. If you want some time for the meet and conferral process, I will give you until close of business on 5 6 Monday for that. I will accept Ms. Finken's proposal. 7 At five o'clock on Monday, Ms. Finken, submit a notice of what is still left to be resolved, which the Defendants have 8 9 not come to agreement with the Plaintiffs, and I will set a hearing at which I will require the individual lawyers for 10 those individual Defendants to appear. I will hear them and 11 12 then I will order the depositions, and that hearing may occur 13 as early as Tuesday. 14 I want the parties to be clear, I have cleared my 15 calendar Tuesday, Wednesday, other than our discovery status conference, and Thursday. We are going to get these 16 17 depositions scheduled next week. 18 MS. FINKEN: Thank you, your Honor. 19 THE COURT: That is how we will proceed. 20 Let's talk about the substantive issue that I think is 21 on the table. Mr. Henry, I will let you go first on this 22 because I think this is your issue. As I understand it from 23 what I am reading, your position is we don't -- I'll 24 paraphrase, we don't manufacture, so we shouldn't have to sit 25 for a manufacturing depo, at a very broad level, but I want to

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1 give you a chance to flesh that out.

MR. HENRY: Yes, your Honor, and thank you for hearing us on this issue. It is important to my client and to several of the non-manufacturing Defendants, obviously. I would like to frame it this way: This isn't about scope, relevancy, or proportionality, and it is not about whether there are topics that a manufacturing witness could or couldn't answer. We covered those issues on Tuesday.

9 Our concern is about producing a manufacturing witness 10 when the Defendant does not manufacture either API or finished 11 drug product. Right. So, I see my burden today to demonstrate 12 to the Court that causing a non-manufacturing Defendant to 13 produce a witness on manufacturing would have the potential of 14 causing annoyance, embarrassment, or undue burden and expense.

So, that is what we want.

THE COURT: Okay.

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MR. HENRY: In order to produce that witness, I have to first find, or more appropriately, Apotex has to find a witness and has to pick somebody when they don't have a manufacturing function.

Then the second part of that is, I have to educate that person on a function that the company doesn't do. Under the Court's rubric that we talked about on Tuesday, that witness could appear and simply say Apotex Corp doesn't manufacture, we don't have information related to that topic.

We could go down through the 43 topics and we could be done in
 20 minutes. Right. That is not a heavy lift, but that is not
 where we are.

Or we could do the PTO 30(b)(6) process of meeting and
conferring and the Plaintiffs could see that we don't
manufacture and we could not go through a deposition, but
again, that is not where we are.

8 If we simply were to present a witness to do that 9 20-minute deposition, I think the Court is right that that 10 wouldn't be a huge burden, but that is not what Plaintiffs 11 want. How do we know that?

12 Well, number one, the Plaintiffs rejected that idea; 13 and the second one is, the Plaintiffs will not allow us to 14 present a witness on two topics on the same day. For example, 15 I think PAI presented that option this morning to the Plaintiffs and said, can I present my pharmacovigilance and 16 17 manufacturing witness on the same day, with the assumption that the manufacturing part would be 20 minutes. Well, the 18 19 Plaintiffs rejected that.

20 We certainly don't think the Plaintiffs are trying to 21 clog up the system, which we all know is going to be difficult 22 to work out, with 20-minute depositions because that doesn't 23 make a lot of sense.

24 So, what is this about? Remember Ms. Finken's 25 discussion on Tuesday about the manufacturing issue being at

the heart of what their theory is about the degradation of the molecule, different manufacturing processes for API are important, different processes can affect the degradation rates, mechanisms of action reporting, testing, quality control. All of those issues are at the heart of what they want, but how can they dig into those when we don't manufacture?

8 Well, this is how. Many of the non-manufacturing 9 generic Defendants hold ANDAs, the abbreviated new drug 10 application, that the FDA uses to approve a drug to be 11 marketed.

Now, I will represent to the Court that Apotex holds four of those, four ANDAs going back to 1997. Apotex U.S. did not prepare those ANDAs, but it does hold those ANDAs, and those ANDAs do describe how the drug is manufactured because that is what an ANDA is required to do under the FDCA.

Now, I also don't know why all of the non-manufacturing Defendants may or may not hold ANDAs, but I can tell the Court that Apotex holds its ANDA because it has regulatory obligations for the drugs it is marketing in the United States, and it makes periodic reports under the FDCA and regulations, and it has routine correspondence with the FDA, so it has to have those ANDAs.

24 So, what's the burden to me, Apotex, to produce a 25 witness? Well, first, as I said, we have to find somebody.

Now, Apotex has to select who it wants to speak on its behalf for manufacturing when it doesn't manufacture. Most likely it is going to pick a regulatory person because the ANDA file itself sits in regulatory. Right.

5 Then, to prepare that witness they have to review the 6 four ANDA files, again, going back to 1997. They have to 7 understand what is in those ANDAs and, since this is a manufacturing deposition, they have to look and see what those 8 9 ANDAs say about manufacturing. That is over 30,000 pages of documents the witness has to become familiar with. 10 That is not a casual afternoon, that is days of review and research that 11 12 that witness is taken away from his position.

Now, if we were a manufacturer, I could go to the vice president of manufacturing and much of this stuff would be right in his head. That is not what we have here. That is just to have them familiar with what is in the ANDA.

Now, after reviewing those documents, of course, they have to sit with me and prepare for the deposition and then sit for the deposition itself, again, for something we don't do.

Now, the ANDAs do have detailed information about manufacturing. For example, they talk about an agitated thin film evaporator, or they use acronyms like NMSM, or interim chemical formulations like Christopher crude or Christopher pure. That is all great for somebody who knows what manufacturing is, but a person who sits in regulatory doesn't

know what those terms mean. That is outside of what Apotex
 Corp does.

So, other than knowing what is in the document and being able to read the document, that witness provides no value to understanding manufacturing, and we would go through an undue burden and expense to prepare that witness for little value.

8 So, in our view, we see that deposition going one of 9 three ways. The first way it could go is, Apotex's witness 10 appears and they read from the ANDAs. Right. That is a 11 tremendous burden and expense to prepare a witness and clog up 12 a deposition schedule for what the Court has recognized is of 13 suspect value to have a witness just read old documents.

The second way it could go is that the Plaintiffs are going to be dissatisfied with the amount of information they get from this witness and petition the Court, a PTO 32 submission, and we will be back here with the Plaintiff asking for another day of deposition with a different witness that knows more about manufacturing, or a sanction against Apotex for failing to prepare its witness for a 30(b)(6) deposition.

The argument we anticipate that the Plaintiffs would make is that we should have done more to educate our witness about what is in those documents, such as going to the manufacturer and finding out what all those terms mean and how they all fit together, and how the drug is manufactured,

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because it is in your documents.

2 Again, I will submit that that is beyond the obligation of a party witness for a 30(b)(6) deposition, which 3 is what the company knows, not what the company could learn. 4 5 And the third way that that deposition could go is 6 that the Plaintiffs could take this videotaped deposition of 7 our manufacturing witness to put on tape and embarrass that witness, and derivatively embarrass the party for whom that 8 9 witness is sitting as the corporate representative, about the fact that this witness knows nothing about manufacturing, 10 doesn't know the details of the manufacturing that the 11 12 manufacturing witness should know, right, and that is an 13 improper purpose for a 30(b)(6) deposition. 14 So, for all of those reasons, we think that putting a 15 witness up for an operation that the company does not do has a significant potential for annoyance and embarrassment and would 16 17 certainly be an undue burden and expense for what we see is 18 suspect value to the case, your Honor. That is the Defendant's 19 position. 20 Thank you. I appreciate that, very THE COURT: 21 clearly and eloquently stated. Thank you, Mr. Henry. 22 Let me turn to Ms. Finken. Ms. Finken, your response. 23 MS. FINKEN: Thank you, your Honor. As your Honor is 24 aware, under PTO 60, the generic Defendants agreed to produce a 25 witness on those three topical areas. We have engaged in

1 multiple discussions over whether or not they could use 2 interrogatories to answer certain aspects of that manufacturing 3 deposition notice and then rely upon those interrogatories at 4 the deposition.

5 In relation to the specific issue for Apotex which Mr. 6 Henry is arguing for, they used their foreign affiliate to do 7 the manufacturing process for them. The foreign affiliate's documents in terms of the manufacturing specifications and 8 9 processes and the information that would be -- that would be informative for the manufacturing notice is contained in their 10 documents. It is contained in the documents that Apotex has 11 12 produced to the FDA. It is contained in the documents Apotex 13 has produced to the Plaintiffs in this litigation.

As your Honor is well aware, under the Federal rules, the Defendants have a responsibility to produce a company witness to testify about information that is within their knowledge or is reasonably accessible to them, and they have a duty to prepare those witnesses to testify on behalf of the company and educate them to do so.

Given the agreements that have been entered into between the parties in terms of PTO 60, and the manufacturing notice topics that encompass not just the manufacturing specifications and processes, but multiple other areas, it is Plaintiffs' position that the Defendant should produce a witness to testify as to those topics.

As your Honor had said previously, it is a very simple deposition. If they don't know or they are unable to actually answer questions on that, to get up there and say so, but that is something that was agreed upon by the parties, and it is consistent with the rules and it is consistent with some of the guidance that your Honor has provided to us in prior PTO 32 dispute resolution hearings.

8 THE COURT: I guess, Ms. Finken -- I know Mr. Henry 9 sort of said it's not really a relevance question from his 10 perspective because he has the burden on him for a protective 11 order.

12 It does seem to me there is a relevance parameter that 13 needs to be addressed here, which is, if in fact -- and I 14 accept the representation -- company A does not manufacture, 15 they contract with company B to manufacture, and it can be an affiliate or it can a third party, I would assume the analysis 16 17 is more or less the same, if they don't know anything about the 18 manufacturing process, and all they do is they get a box and it 19 has a bunch of pills in it, why should they be required to go 20 and educate themselves about that process? Because if they 21 don't know it, it can't have informed their behaviors.

As I understand it, the gravamen of the case you're bringing at this time against the generics is, they should have changed the expiration date -- we talked about this the other day -- they should have changed the expiration date, they

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should have warned the FDA, and they were negligent -- I forget what the other one is. There is a negligent something count. I don't have my notes in front of me.

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MS. FINKEN: Negligent failure to test?

THE COURT: Thank you, that is the other one.

6 So, it would seem to me that if they know how their 7 supplier is manufacturing, that would, arguably, be relevant 8 because it would inform them, because they happen to know that 9 they are using API that could be contaminated, or they are sourcing materials from a source that is not reliable, or they 10 are using solvents that increase -- all the things we talked 11 12 about the other day with the people who admitted that they 13 manufactured. But if you don't manufacture, it seems to me, at 14 best, what is relevant is, did they know that?

15 If they knew what their supplier was doing and how 16 their supplier was manufacturing that would at least be 17 arguably relevant to the claims you have, which is, armed with 18 that knowledge, they didn't do things they were supposed to do.

19 If they didn't have that knowledge during the relevant 20 time period, why are they required today to go and acquire that 21 knowledge which cannot have been relevant, or could not have 22 affected their decision-making during the relevant time period. 23 That is what I am struggling with.

24 MS. FINKEN: I understand, your Honor. I would submit 25 that they did have that knowledge then, they have it now. It

is required for them to know this when they submit their
 information to the FDA. It is all within their own documents
 that they have to own and submit to the FDA. They knew it
 then, they knew the processes then, they know it now as well.

As it pertains to Apotex, Apotex Canada affiliate does the manufacturing for them, it is essentially the same company. It has the same CEO, it has the same officers, it has the same people from Apotex Canada who is submitting documents on behalf of Apotex in Florida to the FDA.

10 So, there is a lot of intermingling of those two 11 companies as it relates to the manufacturing processes, as it 12 relates to the marketing and selling within the U.S., and as it 13 relates to the submissions to the regulatory agencies, 14 specifically the FDA.

15 *THE COURT:* Let me engage on that. You have those 16 documents. The Apotex Canada documents have been produced? 17 *MS. FINKEN:* Yes.

18 THE COURT: So, presumably, if I require Mr. Henry to 19 produce a witness, you could show that witness speaking on 20 behalf of Apotex U.S. those documents, and the question would 21 be, was Apotex U.S. aware of these documents? They are not 22 your documents, they belong to somebody else, did you know 23 about them? And either the answer is yes or no. Either they 24 knew or they didn't know. That would be the first question. 25 That is the foundational question you would have to ask.

1 So, I get that, but assume the answer to that question 2 No, we never saw it, I never read that email. Where do is no. 3 we qo? MS. FINKEN: Well, your Honor, they are actually 4 5 Apotex U.S.'s documents that they obtain from Apotex Canada and 6 they submit to the FDA. There is no way that they could not 7 know about them. They actually got them, submitted them to the 8 regulatory agencies in the U.S. 9 So, the answer cannot be no, they have to be aware of them. They actually submitted them to the FDA to support their 10 marketing of this product in the United States. 11 12 THE COURT: Okay. Help me walk through this. I am 13 trying to make sure I get all the boundaries and then I am 14 going to go back to Mr. Henry. 15 You show them the document, whether it's their document or a third party document, they say, yeah, we knew 16 17 about that back in the relevant time period. Then you are 18 going to ask them, well, what did you do about it? Did you 19 ever notify your QC people? Did you ever notify your QA 20 people? That is going to be the line of questioning, correct? 21 MS. FINKEN: Presumably. 22 THE COURT: So, that would be what Mr. Henry would have to prep his witness to be prepared for. I'm not limiting 23 24 you to that line of questioning, but a line of questioning akin 25 to that. What did you do? Not what did Apotex Canada do.

What did Apotex U.S. do once they had this information? That is really the boundaries of where that goes, doesn't it?

3 MS. FINKEN: Yes, and it could be, if they truly don't 4 know, they can certainly say that for purposes of their answer 5 and we would move on.

I just want to be clear, your Honor, because Mr. Henry did put this into his submission, that we have talked about the fact that we would sit down, as we are required to do under the rules, and have discussions with these generic manufacturers as we move forward with the depositions to discuss specific scope issues that are relative to their client as well.

Hopefully some of these items we would work out in advance of the deposition on how we would proceed, but as a whole, we think it is appropriate that they produce the witness and that we go through the processes, as we would for any 30(b)(6) deposition, and discuss with them in advance of the deposition, do a meet and confer, and to the extent that any issues need to be narrowed, we would narrow them.

19 THE COURT: I appreciate that. I know I have said 20 this before, I know you have acknowledged it before, I will say 21 it again.

If really what it is going to end up being is they just don't have anybody left who has any personal knowledge at all, and all they are going to be doing, as Mr. Henry suggests, is maybe just reading from the ANDA file, I would certainly --

if the parties couldn't reach an agreement or an accommodation about -- I don't see a need to have a lengthy deposition to just have somebody read a bunch of documents that they have never seen before and simply had to read to get ready for the deposition, and that have already been produced.

6 So, if the parties couldn't reach an accommodation on 7 that, any ruling I make today -- and I certainly haven't ruled 8 yet, but any ruling I make today would be without prejudice to 9 the Defendant saying, well, that is unduly burdensome on an individual basis. Each individual Defendant could come in and 10 say, for us, we don't have anybody left with personal 11 12 knowledge, we manufactured this drug a hundred years ago, we 13 just don't have anybody.

14 That would be without prejudice to them invoking PTO 15 32 and perhaps I might order that the deposition doesn't take 16 place because it is simply cumulative and not proportional.

We are not there, I am not ruling on that today. I just want the parties to be reminded that I consider that a viable option that I would at least assume during your meet and conferral you will discuss.

Let me go back to Mr. Henry. Mr. Henry, you have heard my thoughts. I don't know that it's -- the manufacturing process by your supplier, whether it is your sister entity or an arm's length third party, I don't know that it is wholly irrelevant and I don't know how expensive the burden is if it

is really limited to simply what did you know, and once you knew that, what did you do with that information. That is kind of the line I am looking at, but help me out. Give me your response, please.

5 MR. HENRY: Sure. Maybe I could put it this way. 6 There are aspects of performing the regulatory function that 7 Apotex would have information about. So, lets take for example 8 adverse event reporting.

9 Apotex U.S. does the adverse event reporting to FDA 10 and it also has an adverse event function in the U.S. So, it 11 will have information on those issues as it relates even to the 12 ANDA and the documents that are in the ANDA, but what it 13 doesn't know are the manufacturing details because it doesn't 14 manufacture.

15 So, for example, if there is a change in Apotex Canada to the manufacturing process, they want to move manufacturing 16 17 from Redman Hill to Apedacoke (phon), or whatever, that 18 application is, you know, prepared in Canada and because Apotex 19 U.S. is the regulatory function, Apotex U.S. files the 20 document. It doesn't mean it knows what the change was in the 21 manufacturing process, but yes, it does file the document with 22 the FDA.

I just want to make two comments on something Ms. Finken said. One, a drug distributor in the U.S. like Apotex U.S. doesn't have a legal obligation to know the details

of how the drug is manufactured, one. So, it doesn't have a legal obligation to know the things that the Plaintiffs want to ask a manufacturer.

The second thing I wanted to point out is Ms. Finken's argument about alter ego. While I understand that that is Plaintiffs' position as to Apotex U.S. and Apotex Canada, as well as some of the other Defendants that have foreign affiliates, PTO 60 at A(2) says the foreign affiliate will be treated as a separate corporation for purposes of PTO 60. So they are separate entities under PTO 60.

11 THE COURT: Let me tell you, for purposes of my 12 analysis today, I am considering them separate entities with 13 one caveat, which I have expressed many times to the parties.

If information is within the possession, custody and control, and there is a robust body of case law as to what that means, so if certain materials in the possession -- that Apotex Canada has are, as a matter of law, within the possession, custody and control of Apotex U.S., I am assuming those have been produced and they are deemed to be known by Apotex U.S.

I am, for purposes of my analysis today, accepting that there has been no proof that there is an alter ego or piercing the corporate veil type situation. I am dealing with what I consider an arm's length third party.

Let me circle back. I am sensing, and you can help me with this, that there is some potential overlap here between

the manufacturing deposition and the PV deposition, because we
 are talking about adverse event reporting and things like that.

Doesn't that blend into the pharmacovigilance, Ms. Finken?

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5 MS. FINKEN: There are two separate processes, but 6 both of them are both being reported to the FDA. So the 7 pharmacovigilance adverse events is under the pharmacovigilance notice and they are all being reported to the FDA, as well as 8 9 the manufacturing processes and specifications and solvent use and things like that are also being reported to the FDA as kind 10 of a different animal. 11

I wanted to remind your Honor as well that we also have a claim against the generics for failure to warn the FDA. What they did and did not tell the FDA in relation to testing, specifications, manufacturing processes, adverse events, all of these types of topics, is highly relevant to the claims that are at issue in this case.

18 THE COURT: I meant -- I'm sorry, go ahead.
19 MS. FINKEN: No, that is okay, your Honor. I
20 apologize.

THE COURT: No, I cut you off. Go ahead. MS. FINKEN: I was finished.

23 THE COURT: Okay. Here is my sense of it, and maybe,
24 Mr. Henry, this is the level of abstraction that I have to stay
25 at. I don't know yet.

Anything your clients didn't already know, they don't 1 2 have to go and learn as we sit here today. I find that to be not relevant. If they didn't know it during the time period 3 4 alleged in this complaint, which ended -- I don't know when it 5 ended, whenever they took it off the market. Anything they 6 learned for the first time after that date or they don't know 7 as of today, they do not have to educate themselves on. Let's start with that at one end of the spectrum. 8

9 To the extent they had actual knowledge of the 10 manufacturing processes that their supplier was using, or they 11 had knowledge of the ingredients, or they had a contract, for 12 example, with their supplier which gave them the right to 13 inspect the manufacturing process or to obtain information, I 14 would think that is all relevant to the claim.

Ms. Finken will make the argument, well, you had a right under the contract to go and inspect the manufacturing facility to see if they had rats on the floor and it was 18 115 degrees, and you never did, and that was negligent or reckless, blah, blah, blah. It leads to one of their claims.

I start sort of with those broad parameters. I do think there is some relevant evidence that a non-manufacturer would still have and that could be discoverable relating to the claims in this case.

I go back then to, is it proportional and what is the burden once we sort of narrow the universe to that. I don't

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know how much of what you were arguing to me I have now just
 excluded, or how much I have trimmed or not trimmed.

MR. HENRY: So, we are talking specifically about manufacturing the drug and knowledge about the manufacturing process. Other than the words on the ANDA application and supplements, Apotex U.S., and I would suspect the other non-manufacturing generics, know only the words on the paper.

8 The other issue you raised about, for example, what is 9 the due diligence that a drug distributor in the United States 10 has about a drug supply, it is our view, and Ms. Finken can 11 correct me if I am wrong, that those issues are 12 actually storage and transportation (inaudible) -- how did you 13 get the drug, how did it come into the country, what did you do 14 to assure its purity, or whatever.

Those kind of due diligence questions I believe are wrapped up in the storage and transportation, and we have one, maybe two, storage and transportation witnesses that can address those issues if it's within the company's knowledge.

19 THE COURT: Okay. Again, those lines may blur. I can 20 see where the lines among these three categories of depositions 21 could blur, and I will defer to the parties to figure out when 22 and who is the right witness.

23 Perhaps, after further discussion, if it really does
24 turn out that either Apotex or one of the other generic
25 Defendants tells Ms. Finken, look, you didn't give me what the

judge ordered us to do, which is to have a witness ready to testify about what we knew back in the day, that is going to take 15 minutes, Ms. Finken might agree to consolidate the depositions.

I am going to leave it to the parties to do that on an individualized basis. I am not going to order that they have to agree to that. I think that is -- you all play very nicely and I am sure working together and working with the special master you will get over that hurdle.

Here is where I am right now, and this is going to be my ruling for today.

My ruling for today is, I do believe, as I have said, 12 that there are certain manufacturing related -- there is 13 14 certain manufacturing related information that is relevant to 15 the claims and defenses in the case, and that if properly noticed in the 30(b)(6) notice, the Defendants should be 16 17 preparing a witness to respond to, and that would exclude from 18 that, as I said previously, anything they don't already know 19 today. They are not required to learn anything they don't know 20 and they did not know during the time they manufactured.

21 But it does include what they did know about how the 22 product that they were selling was being manufactured.

You may be right, Mr. Henry, that once it left the plant in India, China, Romania, wherever, that becomes storage and transport, and I get that, and you and Ms. Finken can

1 negotiate the parameters there.

To the extent the question is, does the generic 2 Defendant, Apotex or some other generic Defendant, have -- did 3 4 they in real time have knowledge of how their supplier was 5 manufacturing this drug, either they did or they didn't. If 6 they did, I think that is fair game. If they didn't, they 7 didn't. They may have had a right to get it and they never They may have had no right to get it. I think that is at 8 did. 9 least fair game as a relevance question.

Now, I am not going to foreclose on an individual basis Apotex or Dr. Reddy, or any of these other Defendants, asserting on an individual basis based on their unique circumstances that it would be otherwise disproportionate or unduly burdensome to do what I just ordered. I am not ruling on that question, I am leaving that as an open question.

As a cross-cutting matter, which is what I think we are trying to deal with at this hearing, just the cross-cutting question, I don't adopt the argument that simply because we don't manufacture, we don't have to produce a manufacturing witness. I have now hopefully clearly explained where I think the lines are.

That will be my ruling, and that is without prejudice, as I said, to Apotex or any other Defendant on an individual basis arguing disproportionality or undue burden. That will be my ruling as to that issue.

I hope that gives you some clarity and you can go
 forth and negotiate and work with the special master on that.
 Thank you both, that was very helpful and informative. I
 really do appreciate it.

5 The last issue was the issue that Ms. Luhana was 6 getting to, but I will go back to Ms. Finken, and that is the 7 ESI issue. My understanding is, there has been -- at least 8 from my perspective, I have some ambiguity as to whether the 9 parties have actually agreed upon who is going to do TAR and 10 who is going to do search terms, and who has and who hasn't. 11 So, let me just start with that.

Ms. Finken, I am not asking you to argue it. I am not going to make a ruling today, but just bring me up to speed on the state of the world. Mr. Henry, if you want to go first, that is fine, too.

MS. FINKEN: I am happy to go first. I think that that's the problem, is we are trying to seek clarity here on who is doing what, and that is the crux of the issue. We are trying to seek clarity from the Defendants on what they have chosen, and I think Ms. Luhana can address it in more granular detail if you would like.

THE COURT: I don't, I don't need it to be addressed in granular detail. I am going to delegate this issue to the special master. I know Judge Rosenberg and I have told you many times that when the special master speaks, she speaks with

our authority. On this one, I am explicitly telling you that the special master this weekend speaks with my full authority to convene the parties and she can ask those questions, the individualized questions. Defendant one, what are you doing? Defendant two, what are you doing? Defendant three, what are you doing? And I expect and I order that they need to answer those questions so that we can just get clarity.

I don't care what anybody chooses, we just need to move this process forward, we need to have clarity on that. That could be a five-minute conversation with the special master or it could take you all weekend, but I am delegating full authority to the special master to do that.

Mr. Henry, I am sorry, you wanted to speak and I kind of ran over you, so let me hear from you.

MR. HENRY: Thank you, your Honor. My only comment was that, in our view, the generic Defendants did make the appropriate disclosures on Sunday, and have been willing to have that conversation with Plaintiffs to bring any clarity to it. I think all but one did select the search terms, and the questions about the uncertainty are relatively narrow and can be easily responded to.

THE COURT: All right. Thank you. I appreciate that. Like I said, I am going to fully authorize the special master to convene you and get the explicit answers. Maybe the Defendants feel like the Plaintiffs aren't hearing them and

1 they have answered this question before, so answer it one more 2 time. Let's get it clear so everybody understands where we are 3 and we will go forward from there.

With that -- and I will wait to hear from the parties.
Ms. Finken or Mr. Henry, where do we go on the ESI
issue? Do I need to set another hearing? Is that something we
can reconvene on on a set date, or do you want to wait and talk
to each other and then get back to me?

9 Mr. Henry, let me have you go first on this, or Ms.10 Luhana if you want to weigh in.

MS. LUHANA: What we have requested is that the parties get back to us by the close of business tomorrow as to whether they are choosing one option or the other option, and if we are not able to come to an agreement, that the Court hear us on Monday.

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THE COURT: Mr. Henry, any thoughts?

MR. HENRY: Your Honor, I wasn't aware that there was any dispute, and this is just a matter of communication that the parties need to work out. So I will just leave it at that.

20 Maybe I need to be updated on where those discussions 21 are tomorrow to see what the next step is.

THE COURT: Sure.

23 MR. HENRY: Your honor, I just see this as a Defendant 24 to Defendant issue, I don't see the ESI issue being a 25 cross-cutting issue.

MS. LUHANA: Your Honor, there is a dispute issue here. We need to hear from the generic Defendants whether they intend to use TAR to cull the documents. If they intend to use TAR we have to come up with a TAR protocol, and that is going to take the parties significant time.

6 As your Honor has mentioned many times and why we are 7 here, there are depositions that are going to begin in April, 8 and then per the depo protocol, documents are due to us at 9 least 21 days before the deposition. We need to move forward and decide what path they are going down. Are they going down 10 path A of the limited search terms we have narrowed and 11 12 refined, or are they going down path B, which is TAR for 13 culling, in which case we need to come up with a TAR protocol.

14So, that's what we are seeking. We are seeking15clarity and guidance from these Defendants.

THE COURT: Here is what I am going to order. It is 1:30 today, this shouldn't take very long. By five o'clock today, I want each of the generic manufacturers to in writing inform the special master of the answer to that question, whether you are going to use TAR or whether you are going to use search terms.

The special master will collate that information, provide it to all parties so that everybody knows what everybody else is doing. At that point, if a TAR protocol needs to be done, then the special master will embark on that.

1 So, by five o'clock today I am directing the 2 Defendants to answer the question Ms. Luhana just asked: Is it 3 TAR or no TAR, what are you doing? MS. LUHANA: Thank you, your Honor. 4 5 THE COURT: Thank you all very much. I will leave the 6 ESI, and if there is an additional issue with the ESI or the 7 TAR protocol or anything else, the parties can invoke PTO 32 on that. 8 9 Let me address one other issue if I can, and then I will ask the parties if they have anything. 10 11 Mr. Henry and Mr. Yoo, Mr. Barnes, let me start with 12 this, I feel your pain. I can only imagine trying to cull and 13 coordinate 21, 22, 23 different lawyers on lots of different 14 issues. I understand being the generic liaison in this 15 particular litigation is a difficult job to be put in. But I do have to say, over the couple of hearings we 16 17 have had, my impression is that there are -- some part of that 18 process seems to be falling apart, because I have hearings and 19 I have one person saying we are agreeing to this and somebody 20 else saying, well, I won't agree to that, or I thought we 21 agreed to that. 22 There seems to be a lack of communication both internally within the generic manufacturers and externally 23 24 between the generic manufacturers and the Plaintiffs. 25 I am not casting blame on anybody, I realize it is a

difficult situation. I just want to point to a couple of things that I hope everyone will take to heart.

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PTO 33, which codifies the authorities and the duties of the generic liaisons, includes the obligation, quote, "to negotiate for and ultimately bind generic Defendants on procedural issues and orders, subject to the right of any Defendant to present objections based on individual or unique circumstances first to the special master and then to the Ocurt," end quote.

10 So, the default should be that the liaisons step up, 11 make a decision, bind as many people as they can who are 12 agreeable to be bound, and anybody who wants to be an outlier 13 or opt out is free to opt out and they can go to see the 14 special master or they can go to see me, but it seems to me it 15 is no way to run a railroad -- and I don't know if this is what 16 is happening, but it seems to be what is happening.

17 It is no way to run a railroad if we are waiting 18 around to get unanimous consent from 21 or 22 or 23 people. At 19 some point, the liaisons on behalf of the generics have been 20 empowered by the Court to bind their constituents and they need 21 to do it and let the chips fall where they may.

Now, maybe we are past the point now, after I have ruled on all this, of the cross-cutting global issues and I am seeing an issue that is not an issue. Going forward, the individual Defendants will come forward and invoke PTO 32 on

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1 their individual issues.

Again, I am not casting blame on anyone, I recognize it is a difficult situation, but I did want to emphasize that is the Court's expectation, that at some point, we are not here to get unanimous consent, the liaisons are empowered to make decisions and are expected to make decisions.

7 That is all I had to say this afternoon. Ms. Finken, 8 anything else you wanted to raise or any issue you wanted to 9 address that I haven't ruled on?

10 MS. FINKEN: Thank you, your Honor. I am sorry, Tracy 11 Finken on behalf of Plaintiffs. I just have a housekeeping 12 procedural question that I wanted to ask.

You previously said that we should file the PTO 32 submissions on the docket. Would you like a proposed order filed with those as well or is that something you will handle?

16 THE COURT: To the extent you want file some of the 17 submissions under seal, we will have to do a separate order. 18 We will prepare the order to seal. That's not a problem.

The others, you can just do a notice of filing, and just file the submissions. You can do it jointly, file all of them in one. The Plaintiffs can file theirs with all their exhibits as exhibits, and the Defendants can file theirs with all of their exhibits, or you can do one -- that is the best way to do it, have the Plaintiffs file theirs with all their exhibits, and the Defendants file theirs with all their

a notice of filing, no order necessary. 1 2 MS. FINKEN: Okay. Thank you. 3 THE COURT: Anything else, Ms. Finken, either any 4 objections that you haven't preserved or any issues I haven't 5 addressed that you wanted addressed, or any clarifications that 6 you want while I'm still here? 7 MS. FINKEN: No, your Honor, I think that your directions were very clear. I'm sure that if we have any 8 9 questions, we will be back in front of your Honor in the 10 future. THE COURT: I always look forward to seeing you, it is 11 12 informative for me. I am learning a lot about the drug 13 manufacturing process. 14 Mr. Henry, not waiving any objections you may have to 15 the rulings I have made, is there any issues you wanted to raise or any clarifications that you wanted? 16 17 MR. HENRY: No, your Honor. Thank you very much for your time this afternoon. 18 19 THE COURT: Thank you all. You made it in just under 20 an hour so I am very happy. Thank you, everyone, and have a 21 good afternoon. 22 MS. FINKEN: Thank you, your Honor. 23 MR. HENRY: Thank you, your Honor. 24 (Thereupon, the hearing concluded.) 25

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1	I certify that the foregoing is a correct transcript
2	from the record of proceedings in the above matter.
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4	Date: March 6, 2021
5	/s/ Pauline A. Stipes, Official Federal Reporter
6	Signature of Court Reporter
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