UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

In Re: Tasigna (Nilotinib) Products Liability Litigation ROBERT MERCED, ROBERT WITT, TERESA GUSTIN, PAMELA GUSTIN, CHARLOTTE DEAN, RANDY POITRA, DOUGLAS ISAACSON, JEFFREY GIANCASPRO, RONALD HURD, ALLEN GARLAND, ANNETTE SCHIMMING, ESTATE OF GERALD MIELKE, DEBRA CRAIG, CURTIS PEDERSON, BRUCE BECKER, SHEILA COLELLA, RONALD TONGE, STEPHEN LALLY, ROBIN DAVIS, ROGER BURKE, BILLY MILLER, LISA PINSON, EMILY RILEY, MARY ELLEN GALE, POLLY HARRIS, and GREGORY FITCH, Plaintiffs, vs. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	:	Case No.: 6:21-md-3006-RBD-DAB Orlando, Florida February 7, 2022 1:30 p.m.

TRANSCRIPT OF STATUS CONFERENCE VIA VIDEOCONFERENCE
BEFORE THE HONORABLE DAVID A. BAKER
UNITED STATES MAGISTRATE JUDGE

Proceedings recorded by digital recording.
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T A B L E O F C O N T E N T S

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February 7, 2022

P R O C E E D I N G S

THE COURTROOM DEPUTY: In re: Tasigna products liability litigation, Case No. 6:21-md-3006.

Counsel, please state your appearances for the record.

MR. ELIAS: Richard Elias for the Plaintiffs.

MR. SILVERMAN: Raymond Silverman from Parker Waichman on behalf of the Plaintiffs. Good afternoon, Your Honor.

THE COURT: Good afternoon.

MS. WICHMANN: Lawana Wichmann from Onder Law on behalf of Plaintiffs.

MR. BIGGS: Harrison Biggs, Parker Waichman, on behalf of Plaintiffs.

MR. OXX: Christopher Oxx from Parker Waichman on behalf of the Plaintiffs.

MR. JOHNSTON: Good afternoon, Your Honor. It's Robert Johnston from Hollingsworth, LLP, for the Defendant Novartis Pharmaceuticals Corporation.

MR. REISSAUS: Andrew Reissaus from Hollingsworth for Novartis as well.

MR. BOSWELL: Chase Boswell on behalf of Pennington, PA, on behalf defendants.

MS. HOWELL: Kelly Howell from Harris Beach on behalf of Novartis.

MR. JOHNSTON: Your Honor, I believe that two of our client -- client reps, Jennifer La Mont and Eric Meyer are on

but just to monitor the hearing, and then I believe the iPad is Joe Hollingsworth, who is not intending to speak, but I wanted to clarify who everybody was there.

THE COURT: All right. As you may have inferred from the renoticing of the hearing to do this by Zoom in front of me, Judge Dalton and I talked, and since most of the things that are being raised are discovery, we determined that I would preside today.

I'm going to work off your agenda. I've got some other points I want to raise. We've got your motion that came in Friday, and we'll talk about that too.

First item on the agenda that the parties submitted has to do with production of custodial documents. I've read what's in there. Anything new since that was prepared, anything from the Plaintiffs?

MR. ELIAS: Your Honor, since that was prepared, Novartis has made two productions. One was, I believe, January 7th, and they produced roughly over 200 -- a little over 200,000 documents. Friday they produced -- there was an additional production of over 100,000 documents, which we haven't even had a chance to upload yet, and, obviously, that's a chunk of documents that we are trying to sort through and go through in haste, but, you know, our document review continues in that regard, and we're not really sure at this point whether the Friday production is Novartis's complete production or if

there are more documents coming.

THE COURT: Well, tell me, beyond the numbers and the sequencing, where are you in getting to the substance of this case? Are you getting close to where you're going to start taking depositions, or what's going on?

MR. ELIAS: Your Honor, so we are in haste reviewing documents. We have a team of reviewers. We are employing targeted searches, and, yes, we are identifying relevant and material documents and continue to do that. We are -- obviously, there's much more to do with our document review, but we have started the process of trying to set out a timeline for when we will start taking depositions. I believe that we will be in a position to at least start noticing and scheduling depositions probably by the time of our next conference in the next 30 days and start setting that schedule, giving us a roughly three-month period of time to conduct the depositions. So we're moving in the right direction. I will say, you know, we still have a lot of material to go through, but everything is going on pace at this point.

THE COURT: Well, speaking for myself and I think also for Judge Dalton, we would like to see something firmer about making sure you are on target with definite ideas about how many depositions and when they're going to start and get done in time for the expert part of the case to get done.

Anything Defendant wanted to add at this point?

MR. JOHNSTON: Your Honor, I would just add that we're up to production of 1,138,490 documents with over 240 gigabytes of data, and I would note that the Plaintiffs' burden of review is dictated by the breadth and scope of their discovery, and, of course, they're asking for 13 more custodians and other materials at this hearing today, Your Honor. So I sympathize with the Plaintiffs having to review that many documents, but I just would point out that we don't think they needed that many documents and we didn't want to have to produce that many documents, but we've produced well over a million documents at this point.

THE COURT: Well, two comments I'll make. One is, the pure numbers don't mean much to me. I'm more interested in information that's important. But I acknowledge what Defendant says about the dog that chases the car, what are you going to do when you catch it. And you've had a big burden to get the production. Now the Plaintiffs have a comparable burden to get their review done and stay on target. I'll accept for present purposes Plaintiffs counsel's representation that they are moving and they've got their arms around it.

All right. Moving on to the noncustodial production. The report indicates that you've had discussions about three or four other noncustodial databases or sources of documents, that there have been productive discussions about some of those. I want to hear how that -- whether that's concluded and then what's going

on with this clinical trial information.

MR. SILVERMAN: Thank you, Your Honor.

Yes. We focused in the agenda, I think, on the many noncustodial sources that we have been discussing. There are a couple of others, such as discussion of SOPs, which I don't think needed to be -- I don't think either side felt needed to be brought up.

We've reached agreement on production, or at least I believe we have, from the oMAP database. That is promotional materials for Tasigna approved promotional materials. We agreed on a set of search terms. And Novartis has at this point agreed to produce both electronic and hard copy.

The one outstanding issue there, which is not a dispute, is just an idea as to when we think that production is going to be made. We had inquired of Novartis last week on that, and we're just curious if that's -- if there is some indication coming.

The other issue which is still in active discussions is an important issue of the Argus safety database. That is NPC's safety and pharmacovigilance database. We have been in discussions on that for a while and remaining -- and still remaining ongoing. Novartis recently offered counsel -- recently offered to handle -- to potentially address certain questions that we may have for them. In essence, the questions sort of center around how is the database organized, how can it be searched, what kind of formats can be produced out of it,

what is in there. Argus is a common pharmacovigilance and safety database in the pharmaceutical and medical device industry, but it can be designed differently for every company, and every company uses it differently.

We posed those questions to Novartis last week. We are hoping that we'll be able to get back to -- hear something back from them soon so we can have more information. We are trying to do it this way in lieu of serving a 30(b)(6) notice for information regarding the database. We'd prefer -- and Mr. Johnston had offered to handle some questions. We addressed them last week to him.

The two issues which I think do have some disputes that are ripe to be brought before the Court involve Novartis's clinical trials and with respect to Tasigna. Obviously, clinical trials make up a very important part of this case, not the least of which here is because of ultimately a lot of important safety information which came out of one of Novartis's significant clinical trials involving obtaining a first-line indication for CML for Tasigna.

In essence, the two disputes break down like this, Your Honor: First, there is what's called the CREDI database. That is the clinical regulatory documentation and information -- that's the acronym for it -- which basically houses all of the documents pertaining to the clinical trials for Tasigna.

There's not a dispute as to whether production should be

made out of the database. Novartis has agreed to produce documentation out of that database pertaining to certain project codes for Tasigna. The dispute we have at this point is that Novartis has indicated that they will not make production for clinical trials involving Tasigna for project codes that were not related to CML.

So without getting into too much background, but I'm certainly happy to do so if you would like, Your Honor, in essence, there are different -- there are some indications that NPC went ahead and admit did clinical trials for that ultimately either never got approved by FDA or never got any farther than that.

The information we're requesting from there is, ultimately when we're talking about this case, is what the person took the drug for in a clinical trial doesn't make it irrelevant. The information there is relevant. The burden, if any, is incremental coming from NPC, or if there is a burden coming from there, they have not specified what that burden is. We believe it should be produced for all of the project codes for all of the clinical trials relating to Tasigna.

And then the second issue is the issue of Plaintiffs' demand for patient level data, raw data, clinical trial data from 38 clinical trials that NPC conducted. My understanding from our discussions is NPC has outright refused to make this production. This is also clearly relevant. The patient level

data coming from clinical trials is important information. That helps to bear on safety in particular but other issues as well. It is no burden to them to produce this. They control the data. They have custody of it. It is something that should be no burden, and it's relevant. We believe it should be produced. Our expert biostatistician who will be retained in this case has requested it in order to do certain analyses of the data.

Without it, we are left with what NPC chose to do, how they chose to define certain things, and how they chose to do their analyses or what may be, more importantly, what they didn't do, and in an era over the last decade where universities like Yale and BMJ, the British Medical Journal, have been very much out in front that pharmaceutical industries should be putting forth their raw data out there so it can be analyzed independently and verified independently. There's no reason why it shouldn't be done in this litigation as well.

THE COURT: Well, without getting in the merits, you indicated that you wanted a briefing schedule on these issues. How soon can you present it to the Court, by Friday?

MR. SILVERMAN: Yes, sir.

THE COURT: How long does Defendant want to respond?

MR. JOHNSTON: Your Honor, I would like a little more -- a little more than a week, but I would think a week and a half is probably adequate.

THE COURT: The 22nd?

MR. JOHNSTON: That would be fine with us, Your Honor. Obviously, I have a lot to say on the merits that Mr. Silverman chose to speak about, but I don't know that I want to waste the time for you, Your Honor, on that because we're going to be briefing it.

THE COURT: I think I heard some of them in my head.

MR. JOHNSTON: Actually, my team has asked if we can have until the 23rd.

THE COURT: 21st is a holiday, at least on the federal side. All right. I'll make it the 23rd. And I would ask that the Plaintiffs, without revealing too much trial preparation strategy, be as concrete as circumstances permit in terms of why this information needs to be disclosed, as opposed to the more generalized.

MR. SILVERMAN: Yes, sir.

MR. JOHNSTON: Your Honor, I don't know if we're going to talk about the other category or if this briefing schedule applies to all, but one thing I would ask is that -- there is no live dispute, unless they identify a written discovery request that seeks this information. So I would ask the Court to ask them to please identify a written discovery request that encompasses these requests as part of their briefing and to lay out how it complies with Rule 26(b)(1) in their briefing, because the concern I have, Your Honor, is that in this world of ever-expanding informal discovery efforts, which I have no

problem with except when there is a dispute, that this idea of informal discovery somehow starts to shift the burdens inappropriately as to motions to compel. And so I would simply ask that the Court remind all of us of our obligations under Rule 26 and Rule 37 with respect to having actual foundational discovery requests and to explain how both relevance, proportionality, and undue burden is avoided in Plaintiffs' requests in their initial briefing.

THE COURT: Well, I'll leave to Plaintiffs what they want to present, and you can respond. If you think it's barred on some procedural ground, I would just note that if, as Plaintiffs were starting to argue, these are found to be relevant items, they may be covered by Rule 26's initial disclosure requirement. That also gets informally handled different ways than the rules contemplate.

MR. JOHNSTON: Well, Rule 26 does not provide for the production of documents under the initial disclosures necessarily. But, obviously, I completely disagree that these documents are relevant or that they're accessible without undue burden, and we will obviously address that in the papers, Your Honor.

THE COURT: All right. Moving on to the Plaintiffs' fact sheets. It wasn't clear to me whether there was anything that needed to be decided there.

MR. JOHNSTON: Your Honor, I'll go first on that.

We're not asking you to decide anything. There was -- in the orders on the Plaintiffs' fact sheets there was two sections. One explained how the parties were supposed to meet and confer, and we're in the process of getting the letters out to start that process. And then in a separate section, there was a statement that if there was a problem with the PFSs, we needed to alert the Court immediately. Now I think the section of that order was intended in a world in which we were going to somehow, if there was a problem, that totally vitiated the process, and we are not contending that there is. But because of that order, we felt like we needed to let you all -- you and Judge Dalton know what was in play, but we think we can probably work out a lot of this. So we're not asking the Court to do anything at this point.

THE COURT: All right. The issue is up in New Jersey on that. Judge Harz is not with us in this meeting either.

MR. JOHNSTON: So Judge Harz entered an order that tracks what Judge Dalton entered last week with different time frames. At this point, there haven't been any PFSs produced in New Jersey. So that's a down-the-road issue in New Jersey.

THE COURT: All right. Next up is your Rule 502 motion, which I have read. Let me ask -- and I don't know who wants to respond -- how many more documents are there to be produced under Defendant's understanding of things as they stand now?

MR. JOHNSTON: Without any expansion, Your Honor?

THE COURT: Well, just give me a ballpark in terms of are we 10 percent done, 92 percent done?

MR. JOHNSTON: Probably 70 to 80 percent done. We think we can move through the rest of the set of things that are within your orders quickly. So I think that's the answer to the question, Your Honor.

THE COURT: Because the -- I'm just wondering about retroactivity. There's a lot of water that's gone down the bed here.

MR. JOHNSTON: Well, Your Honor, our view of the 502(d) request is not for productions that have been made to these Plaintiffs lawyers so far. We actually have an agreement. That agreement is enforceable under 502(d), 502(e), and the parties have manifested an intention to abide by that prior agreement.

The reason we're asking for a 502(d) order is really targeted at parties not present before you in this litigation who might come along down the road, so that if they get access to this discovery corpus, that they would be bound by our prior agreements, everyone on this call and everyone before you, to have an appropriate inadvertent disclosure callback process.

And so our view is that we actually have a number of protective orders that were entered in many of the cases prior to transfer into the MDL. We have a protective order in place

in New Jersey that implements these provisions. So our request for a 502(d) order from you is really more about X verses the world than it is about anyone in the room here today, if that makes sense, and if not, I'll try to explain it better.

THE COURT: I think I understand. I just point out the commentary from Sedona says these ought not be -- I mean, have you -- has anything come up? Has there been anything that's needed to be --

MR. JOHNSTON: Not so far and hopefully we're catching -- I mean, we are doing a privilege review, but moving this many documents this quickly and having to hire 200-plus attorney reviewers makes it difficult to be absolutely certain of quality assurance on privileged documents. So that's why we need this.

THE COURT: I sort of understand that. And do you -- is your understanding of your prior agreements and what this order might cover, does it include anything beyond claims of attorney-client or work product? Any issue about business confidential or proprietary information?

MR. JOHNSTON: Well, Your Honor, our agreement did address that and has a process in it for them to challenge that, the principle application of 502(d). And 502, in my understanding, is to protect privilege at a subsequent proceeding, not in the same court, so that if this Court rules down the road that there was an inadvertent production that is

not admissible under the Federal Rule of Evidence 502, that that would be binding on other federal courts and state courts down the road, such that it wouldn't constitute a waiver of privilege, and that's what we're focused on with the 502(d) order.

We do have an agreement on a process for challenging and resolving confidentiality designations, but that's not been embodied, I don't think, in the 502(d) order we've asked for.

THE COURT: And in your mind, looking at the universe of these things that have gone on with productions and orders and different courts -- and this is what troubles me most frankly about 502 itself, is the extent to which there's an obligation on the receiving party to do something or erase their Etch a Sketch. I mean, what are they supposed to do with knowledge when they've gotten it?

MR. JOHNSTON: Your Honor, I don't think 5-0 --

THE COURT: This is an evidentiary privilege at trial, which to me, makes it a matter of gamesmanship rather than what the privilege is for.

MR. JOHNSTON: Well, I don't think 502 addresses the cat-out-of-the-bag problem, Your Honor. I think 502(d) is an evidentiary rule that says that an inadvertently produced document that is properly pulled back, either by agreement of the parties or by action of the court, is not admissible at trial on the grounds that it's a waiver of privilege.

Obviously there is no technology available to disgorge from the Plaintiffs' counsel the knowledge of what is in that e-mail, and we're not asking for that. All we're asking for is that an inadvertent production not constitute a waiver of privilege that allows the document on that basis to be admitted into evidence at trial.

THE COURT: Okay. I hear you.

Anything the Plaintiff wants to add on that?

MR. ELIAS: Your Honor, no, nothing from Plaintiffs' side unless, unless Mr. Silverman has something, but from my perspective, we're fine with the order.

MR. SILVERMAN: Nothing here, Your Honor. Thank you.

THE COURT: Let me ask Defendant to submit to me a Word copy of your proposed order, and I'll make a few changes to it and go ahead --

MR. JOHNSTON: Thank you, Your Honor. Should we -- is there -- do we have an e-mail to send it to? We just e-mail that to you, Your Honor?

THE COURT: Yeah, I guess so. Do you have an address for that?

MR. JOHNSTON: Do we have an address? Yes. Can we -- if it's the one on your website, we can send it to that e-mail address.

THE COURT: I have no idea what that one is. It's my first name with an underline, my last name, and then usual U.S.

District Court address.

MR. REISSAUS: Your Honor, you have a chambers e-mail on the --

THE COURT: Don't use that. I never look at that one.

MR. REISSAUS: Okay. So a --

THE COURT: I don't have staff either, so --

MR. JOHNSTON: So can you say it again, Your Honor? It's your first name underscore?

THE COURT: Between my first name and last name is underscore.

MR. JOHNSTON: Right.

THE COURT: And then add flmd.uscourts.gov. Use it but don't abuse it.

MR. JOHNSTON: Yes, sir. Thank you, Your Honor. We will only send stuff to you when you've asked us to send stuff to you.

THE COURT: All right. Okay. The next topic is labeled discovery related, but this one really Judge Dalton has taken a big interest in, and we've talked about it each time. And I know Defendant is anxious to -- more than anxious to dig in to the treating physicians. I would like to get suggestions from the parties about some way to tee up the issues here sooner rather than later in a way that let's Judge Dalton decide whether there's going to be some, if so, how to structure it and so on.

Thoughts from you, Mr. Johnston, to begin it.

MR. JOHNSTON: Well, Your Honor, we've been trying to look at these cases, and we have a number of cases that we're going to be sending out 28 U.S.C. 1927 order letters in the next few days, asking Plaintiffs to dismiss on the basis of the records that we have.

We have a case that was just filed in which the prescribing physician wrote -- and I don't think that's been transferred into this Court yet -- but the prescribing physician actually wrote in his treatment notes that he had a long conversation with the patient about the risk of accelerated atherosclerosis at the time of prescribing. Those are the kinds of cases that we think could be handled if we could just get some discovery, and this grouping of cases could be narrowed to ones that actually have real disputes. There was an article I read the other day that suggests that MDL inventories are considered to have between 10 and 30 percent of claims that are probably not compensable in them. And we would like to get rid of those so we can focus on the real disputes in these cases.

So I don't -- I mean, I've tried, like, three different proposals. So I don't have a proposal, other than that we only have 25 cases -- I guess it will be 26 when that comes in -- and that before we get into briefing and experts, it would be worthwhile to have some sense of what these cases are really about for the defense, and to see whether some of these cases

could be disposed of sooner rather than later, and so we would -- you know, and, look, I know this is an argument I probably have to make to Judge Dalton, but that's the pitch I would make to Judge Dalton at this point, Your Honor.

THE COURT: Well --

MR. ELIAS: Your Honor -- oh, sorry.

THE COURT: Go ahead.

MR. ELIAS: So, Your Honor, from our perspective, at some point, obviously, the treating physicians and the prescribing physicians will be deposed. We are not at all opposed to having their depositions. The question is timing and how does it work best within the process of this MDL. We are focused right now on general discovery, general discovery pertaining to Novartis and expert discovery that's going to apply to all cases. If they want to pick apart a few cases here or there right now, it's not going to impact what we're doing here with the general cases.

So I think the decision needs to be made in determining when these prescribers are going to be deposed and how, is what is going to happen once we get past general discovery. Are the cases going to be remanded, in which case specific discovery will happen in those particular cases, or are there going to be -- is there going to be a bellwether selection in which case at that point specific discovery -- case specific discovery will start.

So it is our position that given the aggressive timeline we have now, it is not an efficient way to handle these cases to start noticing up individual physician case-specific issues before the general issues are addressed.

MR. JOHNSTON: Your Honor, may I just respond to that real quick? The structure right now gives both parties 150 hours for depositions. I don't have anybody I can depose. Plaintiffs presumably are going to use their 150 hours of depositions after gaining a million pages of documents that required us to hire a large law firm to produce pursuant to the Court's orders. This is, right now, all about imposing costs on the Defendant with no comparable effort to resolve cases, and, Your Honor, we believe -- and I know what we believe doesn't matter, but we believe that all 26 of these cases can be disposed of probably on case-specific grounds in favor of the Defendant.

Okay. So it would be actually as in the Seroquel case, where the entire MDL was disposed of on the basis of specific causation, where there were three cases in a row where summary judgment was granted on specific causation in cardiovascular injuries, just like these. That is the fastest way to the end of this MDL, Your Honor, in your opinion.

MR. ELIAS: Your Honor, can I respond?

THE COURT: Well, no. Here's what we're going to do. I'm going to -- I'm going to -- for our next meeting, I'm going

to authorize the defendants to attach an addendum with its best proposal about how to proceed. And the problem I have -- unlike Seroquel, where we had 6- or 7,000 cases, we don't have that many. It's barely MDL. We know that. And it was opposed. I mean, I have no idea what the MDL panel thinks about things, how they think about things. But to me, this was right at the margin for whether it should be handled this way, but here it is. So it gets handled a little differently than some of the bigger ones. One of my colleagues up in the Northern District is helping out on multi-hundred-thousand plaintiff case, and that's just a different, different thing. So given the relatively small number of cases --

And I hear what the Plaintiff is saying about wanting to proceed with the general issues, and that's really the usual point of having an MDL. But Defendant is right too. I mean, I remember those decisions in Seroquel, and I was sort of -- I mean, I'll just tell you, I sort of thought the Plaintiffs had more good cases. They turned out not to be able to prove some of the things they thought they could prove. Tough cases for both sides, I understand that.

Anyway, I'm going to authorize the Defendant to file an addendum to the status report that lays this out for Judge Dalton and tees it out for him in a specific way, giving the Plaintiff -- how far in advance are we requiring the status reports now, two weeks?

MR. JOHNSTON: I think that's right, Your Honor.

THE COURT: I could require the response to be part of that, but I think in fairness what I would like is to have the Defendant put it in an addendum there and give half the time from whenever that's filed until the status conference for the Plaintiffs to file a response and then -- because we're farther down the road than the other times you've talked to Judge Dalton about this, and I think I can -- without revealing any secrets, this is -- I mean, Judge Dalton and I have talk talked about it. We see this as a difficult issue for case management. So we're genuinely up in the air on this about how to proceed. So that's why I want to give Judge Dalton your best summary of how to proceed. So Defendant's addendum should be short, you know, whether it's 3 pages, 5 pages, 7 pages, keep it in that area and response likewise, and you'll have a chance to argue it as well -- or discuss it with Judge Dalton at the next conference.

All right. And I literally cannot tell you where either one of us would be leaning on this, whether we want to authorize it or want to hold it, as we've been doing. Everything is up in the air.

All right. Does that give you enough to proceed on that issue?

MR. JOHNSTON: Yes. Thank you, Your Honor.

THE COURT: All right. Additional custodians. Let's see in here. 13 more you want?

MR. SILVERMAN: Yes, Your Honor.

THE COURT: Does this need to be briefed? You talked about a briefing schedule in the last sentence of that section.

MR. SILVERMAN: Yes, Your Honor. On behalf of Plaintiffs, we have sent a letter to Novartis. We've had a meet and confer. We've tried to follow up on -- you know, not live, but on a teleconference meet and confer. We've sent a follow-up e-mail. And we think that it's now ripe for briefing, and we would propose briefing these issues with the briefing that we'll be submitting on Friday.

MR. JOHNSTON: We agree that it's ripe for briefing because they've asked for several custodians that they've asked for several times before and been rejected. They've reiterated their request for global marketing folks who have no involvement with marketing or labeling decisions in the United States. And they've now added Apex employees, including the global head of oncology for Novartis. So we intend to oppose this. And, Your Honor, while you acknowledged that some marketing discovery might be appropriate at the earlier hearing where you rejected production for many of these folks, you also stated the metes and bounds of that discovery have yet to be decided. And so I guess we're at the point at which the metes and bounds need to be decided so that the parties know where to go moving forward.

I would ask that perhaps we divide this into two separate briefs. I think the issues for CREDI and SAS are similar,

basically CREDI provides the reports that the SAS data underlies, and so we are going to argue those are duplicative discovery. There's no reason to get the raw data sets. That would be *Buckman* preempted efforts to try to investigate fraud on the FDA, et cetera.

The issue with these custodians are -- the issues are different. Although they, you know, fall within the general rubric of burdensome and duplicative, I think we need a very clear record of what -- so Plaintiffs have some documents they want to point to, and I think we need to have them show the documents for each of these custodians, so that the Court can decide whether their interpretation of those documents is fair or not. We don't think it is, which also raises the question of perhaps needing to grapple with documents that have been marked confidential as part of this dispute in a nonsubstantive dispute over discovery, which does not rise to a right of public access under cases from this court and others.

So we need to -- I think it would make sense to do two separate briefs on this and address the confidentiality issues, et cetera, separately.

THE COURT: On the same schedule?

MR. JOHNSTON: I think I have to defer to Mr. Silverman on that in the first instance.

MR. SILVERMAN: Well, yes, we would be the same schedule for Friday for us, and then the same response time for

the Defendants.

THE COURT: All right.

MR. SILVERMAN: Defendant.

THE COURT: All right. Let me ask both sides to include as one of your elements of focus the marginal utility of these documents compared to everything that's been done and as well as the usual burden and so on, but we're a lot farther down the road. It's one of reasons I kicked this down the road a little bit. So I would like your discussions to be informed by how much more you know now than you did two or three or four months ago.

MR. ELIAS: Your Honor, to address an issue that Mr. Johnston just raised, we need -- we do need some guidance. So in order to make the case that we need to make, we have to point to specific documents. We need the Court to see specific documents. What we intend to show is that the highest -- the highest management executives at Novartis were involved in analyzing the financial impact on market share and sales that sending warnings, including dear doctor letters, would have and that those influenced Novartis's decision not to warn and not to send out dear doctor letters. And I don't want to get into too much detail. We'll go into it in our briefing.

But these are documents that Novartis has marked confidential. My understanding is that the Court has a very high bar for what it will allow to be filed under seal. None of

these documents, from my perspective, fall into that category, but we don't want to run afoul of any agreement we have with Novartis or the Court and would like guidance on how best we should go about disclosing this information and whether the Court wants some briefing as to whether -- by Novartis as to whether these should be filed under seal or whether we should just go ahead and file them.

THE COURT: Well --

MR. JOHNSTON: They're absolutely confidential, Your Honor. But go ahead.

THE COURT: I hear you.

MR. JOHNSTON: I'm sorry.

THE COURT: I hear you. There are different ways to do this. One is to describe the documents in a way that doesn't give away the game, but that's often unsatisfactory because the details are crucial and the tenor can be crucial.

How many are we talking about you would want the Court to see?

MR. ELIAS: Your Honor, I think to my best estimate it's about ten exhibits, and, obviously, we'll be referencing them in the document itself. Now, what I would -- what I would -- just for the Court's background, although some of these, not all of them, are new documents, but most of them are new documents, that's why we're raising them to the Court. In the *Laurus* case every single document that was an exhibit at

trial was filed into the public record. So it is -- these confidential documents that Novartis is claiming confidentiality on, although these specific documents haven't been filed in the public record, they are of like kind as to documents that are. So it's not like this information is entirely -- what I guess I'm saying is I believe some expectation of confidentiality has been eliminated by what's already occurred, but, you know, we have about ten documents that we need to point to the Court's attention.

MR. JOHNSTON: Your Honor, I'm not aware of any case law that says my expectation of documents that are different from those that were entered in the public record somehow changes the calculus on those documents. But if they're of the like kind, then that goes to my point that these documents don't need to be discovered, Your Honor, and in fact --

THE COURT: Well, here's what we're going to do. Counsel is right that I really, really don't like sealed documents, but I also don't like arguing about whether business documents are confidential, and those two predilections of mine conflict with each other to certain degrees.

I do want to get to the bottom of this issue about how much farther afield the discovery is going to go without having to get into that. So I'm going to go against the grain or at least my grain -- not to say migraine headache, but just against my inclination. I will authorize up to ten -- well, actually what

you need to do is file your initial memorandum redacted to the extent that it has to talk in detail about the documents and at the same time file under seal a full version of the brief with the exhibits attached and defense, likewise, which obviously you'll have to respond to the same things and talk about the same things.

So I will accept for purposes of this briefing defense counsel's characterization, without actually making a finding that they're entitled to confidentiality, but just so that we can get to the bottom of this, and I'll be able in the next little while get this issue decided about what the scope is going to be.

Does everybody understand what we're doing, and does that meet your needs?

MR. JOHNSTON: Acceptable to the defense, Your Honor.

MR. ELIAS: I believe so, Your Honor. So to reiterate, we will file the brief itself in redacted form and then we will -- not under seal, and then we will file a full copy unredacted of the brief and the exhibits under seal.

THE COURT: Right.

MR. ELIAS: Okay.

THE COURT: And I'll enter an order that authorizes the sealed filing, because otherwise I think you can't do it under --

MR. ELIAS: Right.

THE COURT: -- CM/ECF.

Okay. We started to talk about this, but let me put it to you. Are we going to meet the deadlines in this case?

MR. ELIAS: Your Honor, I can say from Plaintiffs' perspective -- and Mr. Silverman, it looks like he's wanting to jump in. So I've talked enough.

Why don't you go ahead, Mr. Silverman?

MR. SILVERMAN: As of now, Your Honor, right now we feel comfortable that we're going to be able to meet the deadlines in this case. It's going to be a lot of work between now and those deadlines coming up in mid July and then the expert reports from Plaintiffs due on August 19th, but we feel at this point we're not -- at this point we don't have any issue to raise with respect to the schedule. We feel like we'll meet the deadlines.

MR. ELIAS: Your Honor, I'll add one caveat on behalf of Plaintiffs. If discovery is all the sudden opened up into case-specific discovery while we're working hard on doing the general discovery, and Novartis is noticing up multiple treating physicians, then I will say I would have some concern. But as of now, under the current schedule and the way that things are working, I agree that we are on track to meet the deadlines.

THE COURT: Mr. Johnston, any comment beyond that if we were to allow you to take all of the physicians you could have this case over with in a month?

MR. JOHNSTON: No, Your Honor. Other than that if Plaintiffs needed to hire 200 lawyers to achieve their purposes, I think that would be appropriate also.

MR. ELIAS: Your Honor, we don't quite have the income statement that Novartis does, so --

THE COURT: Are there any issues that either side is having with experts, any health problems or logistics or -- I know you've got more data you want to feed them, but anything on the horizon there where there's going to be -- I'm just thinking of things that often go awry.

MR. ELIAS: Not on the Plaintiffs' side, Your Honor, nothing to raise at this time.

MR. JOHNSTON: The only marker I would put down is if the Plaintiffs notice 30(b)(6) depositions for 14 days after their notice, I don't see how those happen on time. So it seems to me that we need to make sure that when we get to 30(b)(6) notices that we're building in enough time to prepare adequately the witness, keeping in mind that many of the folks that Plaintiffs -- many of the folks involved are no longer with the company, and that poses certain challenges. So getting as much time as possible would be helpful. I'm not prejudging anything. I'm just saying that that is going to be a challenge potentially.

THE COURT: Well, keep your eye on that ball, both sides. I do want to say, while there are sharp disagreements

between the parties and between counsel, there's been good professionalism in terms of, you know, maintaining your disagreements but working toward getting the cases ready. You don't need to hear my tale of woe, but I'll just say I have a case I'm working on this morning that I'm furious with lawyers, and just the lack of professionalism is -- and it's an issue just like the one you were just talking about, executives and 30(b)(6)s and scope of -- just they can't agree on what the issues are, and the case has been set for trial four times. Anyway, I'm glad this isn't that case. This is hard enough without that kind of --

I think the last issue I had just to inquire about, because we talked about it earlier and I haven't heard any more about it, third-party discovery. Anything cooking on that we need to worry about now?

MR. SILVERMAN: Nothing from the Plaintiffs' side, Your Honor. I do believe there is a subpoena we are getting ready to serve on a third party, but the issue hasn't even been raised with Novartis yet. The subpoena isn't served. So I don't foresee any -- there are certainly no issues to raise now, and at this moment, I don't see any particular issues on the horizon. If they certainly arise, we will discuss it with NPC and certainly raise any issue with the Court promptly.

THE COURT: All right. Let me summarize where we are.

On the issues about the other project codes and raw patient

data, the CREDI and those related matters, we'll have a briefing schedule for Plaintiffs of February 11th, a response on the 23rd, and I'll enter an order that authorizes redacted and sealed filings. On the same schedule -- well, no. Well, the redacted and sealed has to do with the custodians, right?

MR. SILVERMAN: Right.

THE COURT: But on the same schedule. So my order will direct briefing on both those things with that provision.

You're going to submit to me the 502(d) order, and I'll tweak it a little bit and get it entered.

And then I will put in something, whether it's an endorsed order or some other order, the Defendant filing the addendum and the Plaintiffs' response on the issue of the treating physician depositions or prescribing physician depositions.

Anything else, in terms of homework for any of us?

MR. SILVERMAN: Nothing.

[Indiscernible audio.]

MR. JOHNSTON: Nothing for the Defendant, Your Honor.

THE COURT: All right. I will try to get out my parts of that and wait for yours, and if you discover I've omitted something that I meant to do, if you'd call Judge Dalton's law clerk and have her nudge me, that's probably the best way to do that.

All right. Anything else for the good of the order? Anything from Plaintiffs?

MR. SILVERMAN: Nothing here, Your Honor.

MR. ELIAS: No, Your Honor.

MR. SILVERMAN: Thank you.

THE COURT: Anything from Defendants?

MR. JOHNSTON: No, Your Honor.

THE COURT: Thank you, counsel. Keep up the hard work.

MR. SILVERMAN: Thank you, Your Honor.

MR. JOHNSTON: Thank you, Your Honor.

THE COURT: We are in recess.

(WHEREUPON, this matter was concluded at 2:21 p.m.)

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CERTIFICATE OF REPORTER

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

/s/ Suzanne L. Trimble_____ 2/8/22

Suzanne L. Trimble, CCR, CRR, RPR Date

Official Court Reporter