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UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

CASE NO.: 6:21-md-03006-RBD-DAB

IN RE:

TASIGNA (NILETINIB) PRODUCTS LIABILITY LITIGATION.

ROBERT MERCED, ET AL.,

Plaintiffs,

Orlando, Florida
September 28, 2021
10:03 a.m. - 12:43 p.m.

v.

NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant.

_____ /

BEFORE THE HONORABLE ROY B. DALTON, JR.
UNITED STATES DISTRICT JUDGE
AND
THE HONORABLE DAVID A. BAKER
UNITED STATES MAGISTRATE JUDGE

APPEARANCES:

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THE COURTROOM DEPUTY: This is In Re: Tassigna Products Liability Litigation, Robert Merced, et al. v. Novartis Pharmaceuticals Corporation.

Will counsel, starting with the plaintiff, please make your appearance for the record.

MR. ELIAS: Richard Elias on behalf of the plaintiffs.

JUDGE DALTON: Good morning.

MS. WICHMANN: Lawanna Wichmann on behalf of plaintiffs.

JUDGE DALTON: Good morning.

MR. SILVERMAN: Good morning, Your Honor. Raymond Silverman on behalf of the plaintiffs.

JUDGE DALTON: Thank you.

You-all keep your voices up, if you would, please. The court reporter, I know, is struggling, as are we, in our masked environment, to try to hear one another.

MS. MUHLSTOCK: Good morning, Your Honor. Melanie Muhlstock for the plaintiffs.

JUDGE DALTON: Good morning.

MR. OXX: Good morning, Your Honor. Christopher Oxx for the plaintiffs.

JUDGE DALTON: Good morning.

MR. BIGGS: Good morning, Your Honor. Harrison Biggs

1 for the plaintiffs.

2 **JUDGE DALTON:** Good morning.

3 **MR. JOHNSTON:** Your Honor, Robert Johnston for the
4 defendant, Novartis Pharmaceuticals Corporation.

5 **JUDGE DALTON:** Good morning.

6 **MR. THOMAS:** Good morning, Judge. Mike Thomas on
7 behalf of the defendant as well.

8 **JUDGE DALTON:** Good morning.

9 **MR. BROOKS:** Good morning, Your Honor. Lauren Brooks
10 on behalf of defendant.

11 **JUDGE DALTON:** Good morning.

12 **MR. REISSAUS:** Good morning. Andrew Reissaus on
13 behalf of Novartis.

14 **JUDGE DALTON:** Good morning.

15 **MR. HOLLINGSWORTH:** Good morning, Your Honor. Grant
16 Hollingsworth on behalf of Novartis.

17 **JUDGE DALTON:** All right. Good morning, all. I know
18 we have some folks that are on the telephone. I'm not going to
19 take those appearances other than I think Judge Harz has joined
20 us from New Jersey. I do want to welcome Judge Harz. Are you
21 with us, Judge Harz?

22 **JUDGE HARZ:** Yes, I am here. Thank you very much.

23 **JUDGE DALTON:** All right. Good morning.

24 And I'm Roy Dalton. I'm the sitting United States
25 District Judge that's been assigned responsibility for managing

1 the litigation, and with me is my colleague, David Baker, one
2 of our long-serving United States magistrate judges.

3 Judge Baker will be serving as the magistrate judge.
4 I've asked him to join me this morning so that we could try to
5 cover as comprehensively as possible some preliminary matters
6 to see if we can't get everybody off on a good start in terms
7 of moving the case forward consistent with Rule 1 of the
8 Federal Rules of Procedure, doing it in an efficient and
9 cost-effective way.

10 I guess one of the first things I'd like to talk with
11 you-all about is the schedule from the standpoint of fact
12 discovery versus expert discovery. As you-all talk, I'm going
13 to be taking some notes, along with Judge Baker, and we'll
14 circle back to a number of things that we need to cover this
15 morning. But, obviously, our goal, when we leave here today,
16 is to try to have all the information that I need in order to
17 get a scheduling order entered and so that you-all have some
18 marching orders with respect to how to proceed in connection
19 with discovery and so that we work in a -- a cooperative and
20 collegial way with Judge Harz in New Jersey and make sure that
21 we don't, first of all, get off on different tracks and that we
22 don't make either the responsibility or work of the Court more
23 difficult in either jurisdiction. And, of course, you-all can
24 go a long way towards helping us achieve those goals.

25 So who's going to speak principally for the plaintiff

1 on the questions of -- on the issues of discovery?

2 **MR. ELIAS:** Your Honor, this is Richard Elias. I
3 will be speaking on those issues as long -- as well as
4 Mr. Silverman.

5 **JUDGE DALTON:** Okay. Well, we're going to talk a
6 little bit later this morning about leadership roles. I
7 appreciate you--all submitting the information that you
8 submitted to me for your applications. I don't have any real
9 strong objection to the leadership recommendations that you
10 made.

11 We -- I see that we do have at least some gender
12 diversity, which I'm happy about in terms of the case going
13 forward. We could do a little better in terms of our broader
14 diversity goals. But, you know, one of the things that I try
15 to make it a point to do in assigning these leadership roles
16 and responsibilities is to make sure that we, first of all,
17 give newer, younger lawyers an opportunity to step up and to
18 take on some responsibility if they've demonstrated that they
19 have a sufficient amount of experience. And then, of course,
20 also, to try to look more broadly across the Bar to make sure
21 that we've got good representation. Because I'm confident that
22 if we look at the roster of all of the individuals who are
23 potentially harmed -- based on the allegations at least in the
24 complaint -- by this particular product, if the allegations are
25 warranted, then I'm sure they come from all different walks of

1 life, both ethnic, racial, socioeconomic. So it's always
2 helpful to have a set of lawyers that represents and reflects
3 the clients' backgrounds as well.

4 But Mr. Elias, let me invite you to come to the
5 podium, if you would, and give me your insight as to what you
6 think the fact discovery will look like in general terms. And
7 then, of course, I do want to talk about experts as well. I
8 know that there have been at least two prior cases, the case
9 out in California and the case in southern Florida. I've had a
10 chance to look at the docket in both of those cases and
11 familiarize myself with the course of those. So let me ask
12 you, Mr. Elias, to give me your view as to a couple of things.
13 You can take them in any order that you'd like.

14 But I'd be interested to know, what do you think it
15 is, the utility of the discovery, perhaps, that's been done
16 previously in southern Florida and in California? What about
17 the ranks of the experts that were employed both by the defense
18 and the plaintiffs in the prior litigation? Do you expect that
19 those individuals will make a reappearance here? If not, why
20 not?

21 And let's talk a little bit at some point about how
22 much deposition -- how you think deposition time ought to be
23 managed, whether in terms of numbers of depositions or hours of
24 depositions. I personally think numbers is not a good way to
25 go. But you're obviously much more familiar with the details

1 of the litigation than I am, although I've done a fair amount
2 to try to inform myself between today's date and the time that
3 I received the assignment from the multi -- from the JPML.

4 So, Mr. Elias, I'll be quiet and turn it over to you.

5 **MR. ELIAS:** Thank you, Your Honor. I appreciate it.
6 And I guess I'll try to answer all of those questions as I
7 paint the broader context. I was personally involved in the
8 first two cases that were filed.

9 In terms of the utility of the prior discovery, we
10 did get a fair amount of documents in the original case from
11 Novartis. But I want to qualify that. We got nowhere near the
12 amount and -- the discovery that we need for these cases. And
13 I'll tell you -- and the reason why is this. In that case, we
14 dealt with -- and also, let me make clear, the only case that
15 we got a production from Novartis was the *Lauris* case. There
16 was another case, the *McWilliams* case, in southern Florida. We
17 did not get any additional discovery from Novartis in that
18 case. Okay? So all the discovery that we have to date in a
19 prior case comes from the *Lauris* case.

20 In the *Lauris* case we did have a battle over
21 custodians, a battle of search terms. And the judge in that
22 case ordered certain search terms be run over, I think, about
23 14 custodians -- okay -- but limited the time and scope of that
24 discovery.

25 He limited the time and scope, the judge did, because

1 he expressly held in his order that this is not an MDL, this is
2 a single case, and applying the principles of proportionality
3 determined that limiting the discovery up until, I think it
4 was, April of 2014, and the custodians to, you know, a core 14
5 custodians was a reasonable measure in that case.

6 That is not going to be the case here because, first
7 of all, this is a much more complicated series of cases. And
8 we have clients whose use ranges well outside the range of use
9 that was involved in that case, in the *Lauris* case. So we have
10 clients who have used the drug prior to 2014, into 2014, 2015,
11 2016, 2017, up to present date. So we had a cutoff of 2014 in
12 those cases.

13 So in terms of priority from the plaintiffs'
14 perspective, is to get caught up on the discovery that's
15 outstanding from Novartis, which is discovery running more
16 custodians, broader search terms. And Mr. Silverman can speak
17 more in terms of what those custodians and what those search
18 terms are. But up to present date, which is what we need. And
19 we also have some parameters that date further back in time, as
20 well, that we need discovery on.

21 So --

22 **JUDGE DALTON:** Let me interrupt you for a second.
23 Tell me what progress, if any, have you made with meet and
24 confers with your colleagues on the other side to try to come
25 to an agreement about custodians and search terms for

1 development of the ESI request going forward.

2 **MR. ELIAS:** Extensive, Your Honor.

3 So these cases, we filed the first -- the first batch
4 of the current Tassigna cases in, I think, March of 2020, right
5 as the pandemic hit. By the fall of that year -- so a year
6 ago -- we began in earnest trying to negotiate custodians and
7 search terms with Novartis and have gone through multiple
8 iterations of letters. We did take a -- two 30(b)(6)
9 depositions on custodians and on ESI, which -- to try to get a
10 better sense of, you know, what exists and what we need to be
11 searching for.

12 I can tell you that I think the reason that we're
13 here today is because those efforts were not successful. So,
14 to date, Novartis has not made a single custodial production
15 from any custodial files running search terms from -- in the
16 current litigation other than reproducing what they produced in
17 the *Lauris* case. So ...

18 **JUDGE DALTON:** So I have two questions for you.
19 Where do you-all stand now in terms of what I will call your
20 competing views of a designation of appropriate custodians and
21 search terms? That's question one.

22 In other words, when Judge Baker and I step into the
23 breach here in terms of trying to get the ESI under way, which
24 obviously has to be done, has to be done quickly in order for
25 us -- in order for me to do my job. I can't do that without

1 input from the lawyers other than to do it in a sort of
2 machete-like approach, which is not usually helpful for either
3 side. So I'm interested to know how you would describe the
4 environment into which I'm arriving.

5 And then, secondly, do you anticipate using any
6 machine learning or artificial intelligence with respect to the
7 refinement of search terms as you move forward?

8 **MR. ELIAS:** So, Your Honor, I think that given the
9 efforts that we've been going through in Jersey, I think that
10 we've been able to refine the dispute and define the dispute in
11 terms of who the custodians are and who are the custodians that
12 have been agreed to, who are the custodians that have -- that
13 are in dispute, as well as the search terms that we propose.
14 And there are objections to those search terms.

15 So, Ray, I think you can confirm that that's been
16 fully briefed to Judge Harz, at least outlining what the
17 dispute is. And I think that that would be the same -- we
18 would be seeking the same direction from this Court on those
19 issues.

20 **MR. SILVERMAN:** There's been -- there has been -- to
21 answer Your Honor's question, and to follow up a little bit --

22 **JUDGE DALTON:** I'm sorry. This is not going to work
23 because I can't hear you from over there.

24 Yes, sir.

25 **MR. SILVERMAN:** Is that better, Your Honor?

1 **JUDGE DALTON:** Yes.

2 **MR. SILVERMAN:** To follow up on what Mr. Elias was
3 indicating regarding custodians and search terms, there has
4 been some progress over the course of the last year. But I
5 think at this point we are at an impasse.

6 Briefing had been submitted to Judge Harz about a
7 month ago, six weeks ago, on both the custodians and search
8 term issues. Right now, I believe what is in dispute is 24
9 custodians. There's been agreement, I believe, to 33 of the 57
10 that plaintiff had requested. And I believe the search term
11 dispute is down to 34 terms that remain in dispute. There was
12 some recent movement by Novartis after the briefing -- or at
13 the time of the briefing to agree to some additional search
14 terms that were in dispute before then.

15 At this point, I don't believe any further efforts at
16 meeting and conferring on these issues would yield any benefit
17 to the parties. We've met and conferred extensively, as
18 Mr. Elias said, and I think we are at the point now where
19 this -- this batch of custodians and this batch of search terms
20 which remain in dispute are going to remain in dispute absent
21 decision by the Courts.

22 **JUDGE DALTON:** All right. Is there any reason that
23 that briefing that you provided to Judge Harz can't be provided
24 to me without any additional delay?

25 **MR. SILVERMAN:** No reason from plaintiffs'

1 perspective, Your Honor.

2 **JUDGE DALTON:** All right. Let me ask you-all to step
3 back for just a second. Let me hear from your colleagues on
4 the other side on this question of search terms and custodians.
5 Because we need to get this -- we need to get this business
6 handled.

7 **MR. JOHNSTON:** Good morning, Your Honor. Robert
8 Johnston for Novartis.

9 I agree that we are at a point where there is a
10 narrow dispute that needs to be resolved with Court
11 intervention. I disagree with several other things that were
12 said.

13 In the first instance, there hasn't been briefing
14 before Judge Harz on this issue. We made submissions where we
15 gave her the list of disputed search terms, and she said she
16 was going to look at them. And we made brief submissions about
17 certain custodians. But there's been no discussion of law.

18 And, of course, the New Jersey standard on discovery
19 is different than the federal standard in that it doesn't
20 involve proportionality, which is a clear requirement in the
21 federal cases. So although --

22 **JUDGE DALTON:** Mr. Johnston, let me just interrupt
23 you for a second and make sure you understand what my marching
24 orders are going to be. We're going to work in lockstep with
25 Judge Harz. We're not going to have two different tracks of

1 discovery. We're not going to have two different standards of
2 discovery.

3 So you-all need to resign yourself to the fact that
4 whatever happens -- and I can't speak for Judge Harz. I don't
5 know how -- you know, she has -- she'll be able to speak for
6 herself. But we're not going to -- we're not going to work at
7 cross purposes with respect to the document production because
8 none of that would be productive at the end of the day.

9 **MR. JOHNSTON:** Your Honor, we agree with that. And
10 we argue -- is that we want to make one production that covers
11 all of these cases and have it be done. And we would like to
12 have had that done already. And so I'm not suggesting that
13 there's a dispute, but there are different standards in federal
14 court for deciding what discovery is appropriate.

15 And my only point is that none of that has been
16 briefed before Judge Harz. All that's been given to Judge Harz
17 so far is the factual material. So we could get you that
18 pretty quickly. But --

19 **JUDGE DALTON:** Well, it sounds to me -- you correct
20 me if I'm wrong, Mr. Johnston. But it sounds to me like you're
21 arguing that the federal rules, with respect to the
22 proportionality overlay, is going to make the document
23 production more narrow in the federal jurisdiction than it
24 would be in New Jersey. Am I reading you correctly?

25 **MR. JOHNSTON:** Well, I don't think that that's

1 correct. I think that --

2 **JUDGE DALTON:** Well, then, what is the point?

3 **MR. JOHNSTON:** The point is that the idea that
4 because we're an MDL, that the plaintiffs get everything they
5 want is not appropriate.

6 **JUDGE DALTON:** I don't think anybody has suggested
7 that. I'm trying to understand from you, at the risk of us
8 getting sideways early on, what it is that you think is
9 different with respect to applying the proportionality overlay
10 to the discovery requests here in the MDL versus what you would
11 be asking Judge Harz to do in New Jersey.

12 As I've already said, unless Judge Harz tells me that
13 she disagrees with me, we're going to get one set of standards,
14 at least that we are comfortable is going to be fair and
15 equitable to both sides.

16 The plaintiffs are going to get the information that
17 they need and are entitled to in order to prosecute their
18 claims. And you're going to be able to cabin their request for
19 discovery such that it's not overly burdensome and it's not
20 economically onerous to your clients to respond to them. I
21 mean, that's the goal at the end of the day.

22 **MR. JOHNSTON:** Yes, Your Honor. I agree with that.
23 I'm simply saying that if that decision is made here first,
24 that will govern and inform what Judge Harz's decision should
25 be as well.

1 **JUDGE DALTON:** Well, you know, Judge Harz, of course,
2 is an independent judicial officer.

3 **MR. JOHNSTON:** I understand that.

4 **JUDGE DALTON:** She'll do what she thinks is the right
5 thing to do.

6 **MR. JOHNSTON:** Right.

7 **JUDGE DALTON:** What I'm trying to find out from
8 you -- so far unsuccessfully -- is do you think that the
9 universe of documents is more narrow under the federal rules
10 than it would be under the New Jersey rules?

11 **MR. JOHNSTON:** No. I think that they're the same.
12 but I think that New Jersey courts have had a tendency to allow
13 broader discovery than the federal rules allow. But I think
14 the standards should be the same and are the same.

15 **JUDGE DALTON:** Okay. So what additional briefing
16 would you like to do on behalf of your client in order to put
17 me in the position to make a decision with respect to the
18 designation of custodians and the descriptive search terms that
19 would be employed?

20 **MR. JOHNSTON:** I would simply like to be able to
21 submit some case law. We were not permitted to do that in
22 New Jersey, Your Honor.

23 **JUDGE DALTON:** Okay. How much time do you think you
24 need to do that?

25 **MR. JOHNSTON:** I don't think it would take more than

1 a couple of weeks, Your Honor.

2 **JUDGE DALTON:** Okay. Well, let's make some notes as
3 we go along. Why don't I ask you, Mr. Elias, to -- you and
4 your team -- submit to me -- you've told me you're comfortable
5 with your submission to Judge Harz. Why don't you submit that
6 to me. I'll give Mr. Johnston's team 10 days to respond to
7 your submission with case law. And then if you think the case
8 law that they've submitted requires a reply, I'll give you
9 seven days to reply to that.

10 And let's get -- let's get these -- this situation
11 resolved because one of the things that I'm wrestling with is
12 whether or not it's going to be necessary for us to get some
13 sort of -- I have an ESI guru sitting just here to my left, but
14 whether we're going to need another ESI special master of some
15 sort to look at this. And, frankly, I don't want to spend a
16 lot of time treading water on the universe of documents that
17 are going to be susceptible to production by ESI.

18 I will tell you, just so that you know, I have
19 absolutely zero patience for lawyering that submits grossly
20 overbroad requests for production without any thought. You
21 know, this notion of belt and suspenders, "We better ask for
22 everything because we might overlook something." Your
23 responsibility is to deliver to the Court and to your
24 colleagues on the other side a thoughtful, carefully vetted and
25 curated production request that asks for things that are

1 relevant to the prosecution of your claim.

2 On the other side -- Mr. Johnston, you need to hear
3 this. So you-all need to hear this from me loud and clear.
4 You know, boilerplate objections about, "This is, you know,
5 overbroad, but, by the way, we don't have any documents of that
6 sort," that's going to -- you know, those kinds of things are
7 viewed with great disfavor here.

8 And so you just know -- and I don't want to speak for
9 Judge Baker because he's an independent judicial officer
10 himself, and he'll be managing the discovery. But having known
11 him for 20-plus years, I'm confident that if they're
12 boilerplate objections, they'll just be summarily overruled.
13 And you'll be ordered to produce the documents, and that will
14 be the end of it. So just move forward with those -- with
15 those sort of parameters in place.

16 If you -- if you ask for things, if your production
17 request is not properly curated, properly vetted, and it
18 appears to be issued without any particular thought, then you
19 can expect it will be probably generally unproductive. If your
20 responses to a properly curated -- vetted production requests
21 are obstreperous and raise frivolous objections, you can expect
22 that whatever cabining you might have been able to fashion to
23 the request, you will lose the opportunity to do that.

24 **MR. JOHNSTON:** Your Honor, can I just make two other
25 points? Or maybe it's three.

1 **JUDGE DALTON:** Sure. Of course you can.

2 **MR. JOHNSTON:** This dispute is actually not based on
3 discovery requests. This dispute is based on an effort by the
4 parties to reach an agreement on discovery. I'm not sure they
5 have discovery requests that match up with these custodians and
6 these sales reps. We were trying to move that ball forward.

7 And the other thing I wanted to make clear is that we
8 have agreed to 30 of the custodians and 34 of the 94 search
9 strings that is in addition to what they got in the *Lauris*
10 case. We've been told so far not to produce that material to
11 them.

12 I've actually run it, and I could turn over 39,000
13 pages of documents today, but the plaintiffs have told me not
14 to do that because they don't want that until the Court
15 resolves this dispute. So I've been stymied in an effort to
16 move this discovery forward with the stuff we have agreed to,
17 not to mention the stuff that we need resolution on.

18 So we're prepared, as soon as we get a resolution on
19 this, to put the pedal to the metal and get this discovery from
20 the company complete because what's really important in this
21 case is the discovery that we need to get from the plaintiffs
22 and their doctors.

23 **JUDGE DALTON:** Okay. Well, good. I'm glad to hear
24 that.

25 So my guess is -- you know, I don't -- I don't know

1 the lawyers on the other side. I don't know the lawyers on
2 either side yet. But my guess is that the plaintiffs are
3 concerned that if they accept a production of documents now
4 with a narrow -- without a full field of search, that they are
5 going to compromise themselves going forward. They want to
6 make sure that they've got a comprehensive list of search terms
7 and custodians to be searched so that the production will be
8 complete and robust and fulsome and they'll be done, they won't
9 have to do it over again. So that's my guess just from my --
10 you know, my experience.

11 **MR. JOHNSTON:** And while I understand that, to get up
12 here and say that I haven't produced anything since the *Lauris*
13 case -- which is not true, I've produced custodial sources, and
14 I've been told not to produce -- sorry. I've produced
15 noncustodial sources, and I've been told not to produce
16 custodial sources. So when they come up and tell you that we
17 haven't done anything since *Lauris*, that's not the whole story,
18 Your Honor.

19 **JUDGE DALTON:** Well, I'll tell you this,
20 Mr. Johnston. I'm going to -- as I have done throughout my
21 years on the bench, I'm going to make my own decisions about
22 the lawyers' behavior. When one lawyer tells me another lawyer
23 is misbehaving, usually, a couple of things that I will respond
24 with is that, you know, I'm not a homeroom monitor. You know,
25 the lawyers are going to comply with my rules and procedures

1 and, if they don't, there will be consequences. The lawyers
2 are going to conduct themselves in a professional, cordial,
3 collegial way and, if they do not, there will be consequences.

4 So that's my expectation. Until you demonstrate to
5 me that my expectations are not going to be met, I'm going to
6 afford you-all all the rights, courtesies, and deference that
7 you're entitled to as prominent members of the Bar and as
8 skilled, professional lawyers until you show me otherwise. So
9 we're starting off in a good place. But all we can do from
10 here is -- you know, you're going to build your own reputation,
11 at least in front of me, from this point going forward.

12 But I appreciate your concern, and I appreciate your
13 representation that you-all stand ready to produce the
14 documents as soon as the parameters of the search are properly
15 defined. And that's my goal, is to try to get that done. And
16 I do want to hear from you about discovery that you need from
17 the plaintiffs, but I'm not quite there yet. So ...

18 **MR. JOHNSTON:** Do you -- do you want me to -- you had
19 asked two other questions about experts and depositions. Do you want
20 me to address any of that or do you want to confirm them first?

21 **JUDGE DALTON:** Yeah. I'm going to -- I haven't heard
22 anything from them about experts yet. So I want to circle back
23 to that.

24 **MR. JOHNSTON:** Thank you, Your Honor.

25 **JUDGE DALTON:** You're welcome. Thank you,

1 Mr. Johnston.

2 Mr. Elias, let me ask you to come back to the podium.

3 **MR. ELIAS:** Thank you, Your Honor.

4 **JUDGE DALTON:** So one of the -- we've at least gotten
5 accomplished that I'm going to get some briefing from you so
6 that I have what I need in order to get the decision made about
7 custodians and search terms. And Judge Baker and I will work
8 on that. And he may have some additional thoughts on that once
9 we get farther along.

10 But let's talk about experts. What about the stable
11 of experts that was used by the plaintiff in the prior
12 litigation? Do you anticipate that those individuals will
13 continue to play a role? Are they adequate? If they're not
14 adequate, why are they not adequate? And who else do you
15 intend to bring into the fold, if anyone?

16 **MR. ELIAS:** Yes, Your Honor.

17 So we -- we have some experts -- at least one -- that
18 we will continue to use as of this time. And we have another
19 significant expert who we will not be using because that expert
20 is no longer doing expert services. So --

21 **JUDGE DALTON:** So let me tell you what would be
22 helpful for me.

23 **MR. ELIAS:** Yes.

24 **JUDGE DALTON:** So if I ask you a question like that,
25 I'd like to have specifics. You know?

1 **MR. ELIAS:** Absolutely.

2 **JUDGE DALTON:** "We hired Dr. Samuels to do X.

3 Dr. Samuels is going to continue to serve as an expert, and his
4 area of expertise is Y."

5 "We hired Dr. Jones. Dr. Jones is no longer going to
6 be an expert for" -- and I don't really care about the reason.

7 **MR. ELIAS:** Okay. So with respect to the categories,
8 we have a general causation expert, an epidemiologist,
9 Dr. Sonal Saingh, S-A-I-N-G-H. And as of this time, he is --
10 we're going to continue to use him. He did an epidemiological
11 report on general causation.

12 With respect to the other -- one other major
13 category, regulatory labeling expert, we used Dr. Cheryl Blume.
14 We are no longer going to be using Dr. Cheryl Blume. And
15 she -- she is no longer providing expert services. So --

16 **JUDGE DALTON:** Okay.

17 **MR. ELIAS:** And that is an expert that we have -- we
18 are -- I don't think at this time we're prepared to disclose
19 who that is, because I think we're still doing some internal
20 vetting as to who that will be. But we think that we have --

21 **JUDGE DALTON:** We'll have a labeling expert.

22 **MR. ELIAS:** We will have a labeling expert, yes, Your
23 Honor.

24 **JUDGE DALTON:** Okay. Fair enough.

25 **MR. ELIAS:** With respect to some specific issues on

1 labeling and causation with respect to oncologists and
2 hematologists, we don't currently have -- well, we had an
3 expert in the -- in the prior cases. And frankly, Your Honor,
4 as I'm sitting here right now, his name escapes me. But I do
5 know we will not be going forward with him because he, too, is
6 no longer able to provide expert services.

7 **JUDGE DALTON:** All right.

8 **MR. ELIAS:** So we will need one, maybe two,
9 hematologists/oncologists, to address mechanism issues as well
10 as general issues related to CML.

11 **JUDGE DALTON:** All right. Would you also expect that
12 individual to address the -- some component of the labeling
13 issue as it relates to learned intermediaries?

14 **MR. ELIAS:** Yes, Your Honor.

15 **JUDGE DALTON:** Okay.

16 **MR. ELIAS:** Particularly with respect to oncologists.

17 **JUDGE DALTON:** Okay.

18 **MR. ELIAS:** Yes.

19 **JUDGE DALTON:** All right.

20 **MR. ELIAS:** And also to discuss and describe where
21 Tasigna fits in in the portfolio of TKI's -- that's the class
22 of drugs -- and what alternatives are available and what the
23 side effects are of those other drugs as compared to Tasigna.

24 **JUDGE DALTON:** All right. So if I'm looking at
25 general categories, you're going to have a category of a

1 general causation expert, epidemiologist. You're going to have
2 an expert in the area of labeling in terms of governmental
3 requirements, things of that sort. You're going to have an
4 expert in what I'll call more specific causation in the field
5 of oncology to also address questions with respect to what a
6 reasonable prescribing physician would know or want to know in
7 order to make the decision to prescribe the medication. Am I
8 correct so far?

9 **MR. ELIAS:** Yes. Yes, you are, Your Honor.

10 **JUDGE DALTON:** Okay. And --

11 **MR. ELIAS:** And then there --

12 **JUDGE DALTON:** -- any others?

13 **MR. ELIAS:** Oh, I'm sorry.

14 **JUDGE DALTON:** Any others?

15 **MR. ELIAS:** So every case you have to have an expert
16 for specific causation. So not just general causation, that
17 the drug can cause this disease or can cause rapid accelerated
18 atherosclerosis, but that it did, in fact, in this case. So
19 that's going to be -- we used one expert, Dr. Wagmeister, in
20 *Lauris* and *McWilliams*.

21 We're going to need to employ several different
22 vascular -- you know, medical doctors with vascular expertise,
23 depending on the plaintiff, to provide specific causation
24 opinions. And that will be specific to the case.

25 **JUDGE DALTON:** Okay. Well, let's talk about the

1 things that we need to do as far as the MDL is concerned.

2 **MR. ELIAS:** Yes, Your Honor.

3 **JUDGE DALTON:** Because my charge is to get the case
4 prepared. We're going to talk about whether or not you guys
5 want to do bellwether trials or not while we're here. But
6 assuming that -- just for discussion purposes -- that we're not
7 doing bellwethers or we would put that off until some later
8 point, this -- when you talk about several vascular surgeons on
9 the issue of specific causation, I thought you had told me, at
10 least in terms of the common issues, that your oncology expert
11 who was going to address learned intermediary issues was also
12 going to connect the dots for you in terms of this drug and its
13 causal connection to the injury suffered by your group of
14 plaintiffs. Is that not -- did I misunderstand?

15 **MR. ELIAS:** I guess what I would say is that -- the
16 experts that I named, the oncologists and the epidemiologists
17 are going to be speaking more to general issues that would
18 apply across all cases, not, "This plaintiff, in this case, you
19 know, developed atherosclerosis because of this drug," or they
20 would do a differential analysis to come up with a causation.
21 So every case is going to have to have that expert, and that's
22 more case specific. So, you know, those -- those are -- and
23 those would be more applicable to, if we had bellwether cases,
24 the bellwether cases, not all cases.

25 And my colleague, Mr. Silverman, just raised the

1 issue, we possibly -- I'm not saying that we are -- but another
2 expert we may need is a biostatistician. But we did not use
3 one in the prior cases, and we do not have one retained.

4 **JUDGE DALTON:** What would you need a statistician
5 for?

6 **MR. ELIAS:** I think the statistician can -- and,
7 again, I'm not saying that we need it. I'm just --

8 **JUDGE DALTON:** I understand.

9 **MR. ELIAS:** -- leaving open the possibilities.
10 The biostatistician would complement the
11 epidemiologist and provide some different -- more depth in some
12 of the statistical analysis.

13 **JUDGE DALTON:** Well, I mean, correct me if I'm wrong,
14 but isn't the field of epidemiology -- isn't, intrinsic to the
15 opinions of the epidemiologists, going to be a biostatistical
16 evaluation of the impact of the medication on the field of
17 users and potential users?

18 **MR. ELIAS:** Certainly, Your Honor.

19 **JUDGE DALTON:** Isn't that what they do by definition?

20 **MR. ELIAS:** Yes. That is by definition what they do.

21 I think there are some nuances, and it just depends
22 as we -- as we try to prepare the case whether they think
23 there's some gaps that are left that a biostatistician can
24 fill.

25 But I'm just raising that as a possibility. That is

1 not something that we are actively seeking at this point.

2 **JUDGE DALTON:** Okay. Well, this is going to be true
3 for the other side as well. We're not going to have a huge
4 stable of experts that are going to consume a lot of time in
5 discovery, and then you get an opportunity to sort of, you
6 know, mix and match and decide who you're going to use and plug
7 in by developing, you know, three or four people that have
8 cumulative testimony. We just don't have the time luxury to be
9 able to do that. And you-all are very familiar with the facts
10 and circumstances of the -- this case and your own theories of
11 liability. So --

12 **MR. ELIAS:** Your Honor, it is not in our interest to
13 provide duplicative experts and duplicative discovery. So we
14 will endeavor to avoid doing that and make that priority for
15 us.

16 **JUDGE DALTON:** Have you made any disclosures of
17 experts in the New Jersey state cases?

18 **MR. ELIAS:** No, Your Honor, we have not.

19 **JUDGE DALTON:** Okay. And I'm assuming that you would
20 not anticipate any different stable of experts in the state
21 court cases than you would here in the MDL?

22 **MR. ELIAS:** No, Your Honor.

23 **JUDGE DALTON:** Okay. All right. Mr. Elias, what's
24 your assessment of the time that you would need for -- if you
25 were king for a day and you wanted to describe the limits of

1 fact discovery, the date for disclosure of experts, the amount
2 of time for expert discovery, and then a date for closing all
3 discovery, what would you think would be a reasonable
4 approximation of the time?

5 **MR. ELIAS:** Well, a lot of that depends -- and I want
6 to answer your question, Your Honor. I'm just trying to think
7 out loud here. We've had some general discussions about that.

8 But a lot of it depends on when we get the documents
9 from Novartis. So from my standpoint, the way that discovery
10 would play out is assuming we can get the documents from
11 Novartis in the next month or so, you know, we would be, I
12 think, in a position -- and that's probably not realistic.

13 **JUDGE DALTON:** It's not "probably not realistic." I
14 mean, we've already got 20 days of briefing built --

15 **MR. ELIAS:** Okay. So --

16 **JUDGE DALTON:** -- in, right? From what I just
17 described.

18 **MR. ELIAS:** So -- so assume that we realistically get
19 the production in early 2022, which is probably more realistic,
20 we would, of course, need time to review those documents, and
21 we would do that quickly. And then, you know, I would say --

22 Ray, how much time do you think we would need to --
23 to review the docs?

24 **MR. SILVERMAN:** If I may, Your Honor.

25 Assuming, as Mr. Elias just said, that we were

1 getting the document production from Novartis -- and another
2 issue on that production which isn't before any of the courts
3 yet is some discussion about production from noncustodial
4 sources, which we can talk about in some detail or we can
5 provide some further information for the Court. Certainly, we
6 need time to review the documents.

7 We would need time to be able to start taking
8 depositions of the Novartis witnesses. We would look for
9 discovery here to be sequenced to some degree. Maybe there
10 could be some overlap between doing some case-specific
11 discovery like towards the tail end of generic discovery. But
12 I think, ultimately -- and then building in time to do
13 case-specific discovery and experts.

14 **JUDGE DALTON:** Whoa, whoa, whoa. We're not going to
15 do case-specific discovery of experts. We're in an MDL
16 proceeding here.

17 **MR. SILVERMAN:** Your Honor, I said case specific
18 discovery and experts. I'm sorry if I misspoke.

19 **JUDGE DALTON:** Well, case-specific discovery,
20 that's -- I mean, what are you talking about, "case-specific
21 discovery"?

22 **MR. SILVERMAN:** Well, Your Honor, we have here in --
23 in this situation, we're going to have the generic discovery,
24 which is going to be the discovery coming from NPC. That's
25 going to be applicable for all of the cases. Those are going

1 to deal with the generic issues that apply to every case.

2 Then when we talk about case-specific discovery,
3 we're talking about depositions of plaintiffs. I know you
4 mentioned discussing the potential bellwether process, which we
5 can speak about, depositions of treating physicians, things of
6 that nature.

7 **JUDGE DALTON:** This is the MDL proceeding. We're not
8 going to be taking depositions of treating physicians or
9 individual plaintiffs. We're going to be using fact sheets. I
10 can promise you that. We're going to have an exchange of fact
11 sheets with respect to the plaintiffs are going to make a
12 disclosure of who they are, what kind of claim they're
13 bringing, whether or not they're married, what are their
14 injuries, when did they take the drug, how long have they taken
15 the drug, what is their underlying medical condition for which
16 the drug was prescribed. That's going to be a fact sheet that
17 we're going to promulgate.

18 One of the things that you-all are not -- we're not
19 communicating. We are absolutely not going to be doing
20 deposition testimony of individual plaintiffs, nor are we going
21 to be doing deposition testimony of individual prescribing
22 doctors in the context of the MDL case unless we get to the
23 point of doing some bellwether trials.

24 And if we do bellwether trials, then, of course, the
25 scope of discovery will need to be expanded. But we're going

1 to do that in a streamlined way where you're going to develop
2 the information that the defendants need in order to evaluate
3 your constellation of plaintiffs. And they're going to do the
4 same thing from their side, at least in terms of -- to the
5 extent that there are any case-specific pieces of information
6 for Novartis, and none of which immediately come to my mind.
7 But maybe you can think of some. I can't at the moment.

8 **MR. SILVERMAN:** Thank you for -- thank you for
9 clarifying that, Your Honor. Because from the plaintiffs'
10 perspective -- obviously, we can discuss it more, but that
11 makes perfect sense to us, everything you just said in terms of
12 fact sheets and the like and how we would view the discovery
13 here.

14 With that in mind, assuming that we got a production
15 from Novartis in, let's say, January, which I think is probably
16 somewhat realistic at this point, I think we'd be looking at at
17 least, from that point, to do depositions as well, and review
18 the discovery, I think we'd need at least six months to be able
19 to do that, and then we'd need some time to get expert reports
20 generated from there. So realistically, I think you're talking
21 about probably being in a position for maybe about 12 months
22 from today, around that time, fall of next year.

23 **JUDGE DALTON:** Okay. I can't speak for Judge Harz,
24 obviously, and she'll make her own decisions with respect to
25 how her discovery is going to proceed. But it would seem to me

1 that it would make sense for this case-specific discovery in
2 the state court cases to also be delayed until all of this
3 common discovery is done and everybody knows at least the
4 stadium in which the contest is being played. You know, we may
5 not know where the ball is on which yard line, but at least
6 we'll know what stadium we're in.

7 **MR. SILVERMAN:** Thank you, Your Honor.

8 **MR. ELIAS:** Your Honor, we agree.

9 **JUDGE DALTON:** Let me ask you-all to take a seat, if
10 you could, and let me hear from Mr. Johnston.

11 Mr. Johnston, I'd like for you to educate me, if you
12 could, on what sort of discovery that you think you would need
13 to undertake from the plaintiffs, and what are your thoughts
14 about the timetable.

15 **MR. JOHNSTON:** So I run the risk of going against
16 what you just said. But I have to strenuously object to the
17 idea that all we would do in this MDL is take discovery from
18 Novartis, which is what I believe I heard that discussion
19 suggest.

20 We have the need to develop case specific --

21 **JUDGE DALTON:** I just invited you up here,
22 Mr. Johnston, to tell me what you need. So if you want to
23 start off your comments with a strenuous objection, you can
24 just object. It doesn't need to be a strenuous objection or a
25 vehement objection or a violent objection. You can just tell

1 me what you object to.

2 I haven't even ruled on anything yet. So I don't
3 know how you can have an objection.

4 I am soliciting, now, your input to tell me what you
5 need and why you need it. We need not start off this way,
6 Mr. Johnston. But I'm going to tell you, you and I are going
7 to have a problem if every time we get together it's going to
8 be combative. So --

9 **MR. JOHNSTON:** I didn't intend to be combative,
10 Your Honor.

11 **JUDGE DALTON:** So --

12 **MR. JOHNSTON:** My point is that the company,
13 Novartis, needs a chance to defend itself against these --

14 **JUDGE DALTON:** It has never been my practice to
15 discriminate between the plaintiffs and the defendants in terms
16 of the opportunity to have a fair proceeding. I don't
17 anticipate to start now.

18 **MR. JOHNSTON:** I understand that, Your Honor. I'm
19 going to try to tell you what I think and what we think we need
20 in this MDL.

21 What we need is a chance to win summary judgment in
22 some of these cases. And in order to do that, we will need the
23 doctor -- the treating physician's deposition who will tell us
24 whether they knew of the risks that are alleged to be at issue,
25 whether they were aware of certain labeling, and whether or not

1 they would have prescribed the drug no matter what was said
2 about this alleged side effect and the labeling.

3 Because our view is that the company did nothing
4 wrong here. And I know everyone says that, but these cases are
5 cases involving folks with cardiovascular disease in their
6 fifties, sixties, and seventies. Cardiovascular disease is the
7 number one cause of mortality in that age range.

8 These folks had terminal cancer that would have
9 killed them but for tyrosine kinase inhibitors like Novartis's
10 Tassigna. And so even if the drugs caused the sorts of side
11 effects plaintiffs contend -- which we don't think they can
12 prove as a matter of general causation, given the large
13 background rate of cardiovascular disease in the relevant
14 population. But even if they can show that, the doctors are
15 likely to tell the jury or the Court that they would have
16 prescribed the drug even if they completely understood
17 everything there was to understand about the risk of
18 cardiovascular disease because this drug was that important for
19 their patients to keep their cancer in check, their blood
20 cancer, chronic myeloid leukemia, and in some instances to
21 allow them to go off therapy completely for extended periods of
22 time because of the level of remission achieved through the use
23 of Tassigna. If we can't get that discovery, then we can't move
24 for summary judgment, Your Honor.

25 And we'd also need to know from the plaintiffs, were

1 they told about the risks? What were their other risk factors
2 for cardiovascular disease? Many of the 20 plaintiffs in this
3 collection in the federal court, many of those have prior heart
4 attacks, strokes, or other events involving their athero- --
5 other atherosclerotic conditions diagnosed before they ever
6 started Tasigna.

7 **JUDGE DALTON:** Sure. Most of which will be reflected
8 in their medical records.

9 **MR. JOHNSTON:** But not necessarily entirely and not
10 necessarily clearly. Because, first of all, the plaintiffs are
11 taking the position that we only get medical records for three
12 years, I believe it is, before CML diagnosis. So someone who
13 had a heart attack --

14 **JUDGE DALTON:** Well, I haven't made that
15 determination, obviously. So --

16 **MR. JOHNSTON:** That's what I --

17 **JUDGE DALTON:** The only thing I'm encouraging you to
18 do, Mr. Johnston, is to try to think about, how can we most
19 efficiently get your client the information that they need in
20 order to put forward their defense?

21 I am completely on board -- meaning that I understand
22 completely -- the argument of Novartis that someone who is
23 suffering from CML, with a very abbreviated life expectancy
24 absent some other type of intervention, would likely be
25 inclined to use a TKI even in the face of some of these

1 contraindications that the plaintiff suggests exists. I'm not
2 saying that they do or they don't. But even assuming that they
3 did, taking all of the facts in the light most favorable to the
4 plaintiff, it's certainly not lost on me that, A, a reasonable
5 doctor would prescribe it notwithstanding those risks, and that
6 a reasonable patient would take it notwithstanding those risks.

7 Isn't that what the risk benefit standard in a strict
8 liability for product warning is all about? Right?

9 **MR. JOHNSTON:** Yes, sir.

10 **JUDGE DALTON:** I mean, that's what we do every day
11 when we try one of these cases that involves the dissemination
12 of a product or the distribution of a product that provides a
13 significant medical benefit -- arguably a significant medical
14 benefit -- to someone who is suffering from an otherwise fatal
15 malady presented with the opportunity to extend their life.
16 Now, I understand that. I understand that that's what this
17 case is about.

18 I also understand that your client would like to
19 know, to the extent they can, what is, as comprehensively as we
20 can understand it, the preexisting medical condition that this
21 individual was experiencing at the time that they were
22 prescribed this drug. What was their comorbidity? What were
23 their other conditions? What was their susceptibility to
24 negative sequela with or without this drug? So I understand
25 all of that.

1 The point is, how do we get there in a way that's as
2 efficient as possible? I can tell you that my initial
3 reaction, as you heard when I talked to Mr. Elias, is the most
4 efficient way to do that is not to tee up 50 different
5 independent treating, prescribing physicians. There's a better
6 way to do it.

7 It's not to depose for days at a time each of these
8 individual plaintiffs about their background. That may become
9 necessary at some point in time, but for starters, we need to
10 figure out how to get your client the information they need, at
11 least get started. So --

12 **MR. JOHNSTON:** Thank you.

13 **JUDGE DALTON:** So what sort of medical authorizations
14 would allow you to collect that information? Over what period
15 of time? How extensive should your ability to go into the --
16 to the plaintiffs' -- I'll call it life, just for lack of a
17 better term, in terms of generating information about them?
18 What was their -- what was their medical situation? What was
19 their general life situation? You know, what was their life
20 expectancy notwithstanding taking the drug?

21 So all of those things I understand. But what I'm
22 going to put back on the lawyers is, you-all are going to need
23 to put your thinking caps on and come up with ways that you can
24 get access to this information that don't include asking me to
25 give you warrant to do all the discovery that you would do in a

1 single Novartis case, which I can appreciate would be
2 significantly different than what we're going to do here. It's
3 just not the purpose for which this process was designed, and
4 it's not going to happen. So you need to accept that. It's
5 just not going to happen. So now what? Now what do I do?

6 **MR. JOHNSTON:** Well, I think, actually, with respect
7 to medical records, we had done a pretty good job until the
8 plaintiff succeeded in getting centralization in New Jersey and
9 in the federal system. We have not gotten any new medical
10 records releases since then.

11 And the one problem we're having with medical records
12 releases is that some jurisdictions -- some hospitals and
13 practices will not accept whatever form we all created amongst
14 ourselves and want a specific form with a what they call
15 "wet-ink signature." Every time we've requested the use of
16 those specialized forms with a real signature, we've not heard
17 anything back from the plaintiff.

18 So that -- we are actually getting medical records to
19 some degree. And I assume that now that we're centralized,
20 they'll start responding to our requests for particularized
21 medical releases for institutions that require a particular
22 form or a particular signature. We'll certainly let Your Honor
23 know if that doesn't happen, but I'm hopeful that it can.

24 I can learn a lot about the plaintiffs' background
25 through those records. We certainly need more than three years

1 before they were diagnosed with CML because some of these
2 people, we actually have cases in the inventory where folks had
3 events 10 or 15 years earlier, like a heart attack or a stroke.
4 And we would need to know that. So we'll have to deal with
5 that.

6 But none of those forms of medical records or
7 plaintiff fact sheets are going to allow me to ask the doctors:

8 "Did you know?"

9 "Yes.

10 "And you prescribed, knowing?"

11 "Yes, I did."

12 Or "Did you know?"

13 "No, I didn't.

14 "If you had known this, would you have prescribed
15 anyway?"

16 "Yes, I would have."

17 That question, I don't think, can be done through a
18 PFS or a medical records request. So that's one that's going
19 to be critical in this case. The proximate cause question is
20 going to be a critical question, and I don't have a good
21 solution as to how to get at that other than taking the
22 deposition of the prescribing physician.

23 **JUDGE DALTON:** Okay. "Okay" meaning I hear you.

24 **MR. JOHNSTON:** I mean, I'm not expecting you to tell
25 me that you agree with me right now, but I want to state why I

1 think at least that's got to happen.

2 **JUDGE DALTON:** I hear you.

3 **MR. JOHNSTON:** Okay. Do you want to hear -- I mean,
4 on experts?

5 **JUDGE DALTON:** Well, two things that I want you to
6 address before you sit down is I do want to hear about your --
7 I mean this in a non-pejorative sense -- your stable of
8 experts. I mean, do you anticipate using the people that you
9 used before? If not, why not? Do you want to add to them?
10 And tell me the categories where you think that you would need
11 to have an expert if you were not -- well, whether you
12 succeeded at summary-judgment level or not. Because once we
13 get beyond that, you won't be adding any anyway.

14 So tell me what you -- and then the followup question
15 would be, maybe react to the plaintiffs' suggestion that fact
16 discovery -- sometime in -- and I'm sort of extrapolating from
17 what they said -- sometime in the summer, and then close of all
18 discovery sometime near year-end of 2022 is a reasonable time
19 period.

20 **MR. JOHNSTON:** May I start with the experts, Your
21 Honor?

22 **JUDGE DALTON:** Yes. Sure.

23 **MR. JOHNSTON:** I think that we essentially have the
24 same type of roster that they do. We'll have an FDA expert
25 which we'll use if their FDA expert is allowed to testify.

1 We'll counter that.

2 We'll have an epidemiologist. By the way, on the FDA
3 expert, I am going to be using the one I used before. But
4 because we have so many cases in New Jersey, I may add people
5 to that stable. And so for a particular case -- when we get to
6 particular cases -- I may have somebody different than him in a
7 particular case.

8 **JUDGE DALTON:** I understand. I just -- and again, I
9 don't know what Judge Harz is going to do.

10 **MR. JOHNSTON:** I understand.

11 **JUDGE DALTON:** She'll make up her own mind. But I'm
12 not going to give you -- you're going to have to have a limited
13 number of experts. So you're going to have to probably make
14 some choices earlier than you might otherwise want to do in
15 terms of designating who your experts are going to be. Because
16 I'm not going to give you the opportunity to have a stable of
17 three or four and then pick one.

18 **MR. JOHNSTON:** I understand that, Your Honor.

19 We will have an epidemiologist. We didn't have one
20 before, but we will be adding one this time.

21 We will have oncologists, cardiovascular surgeons to
22 speak to specific causation in a situation where there's a
23 cardio -- you know, a stent or a -- some sort of other
24 procedure like a stenting procedure. We'll have a stroke
25 doctor --

1 **JUDGE DALTON:** You're saying "cardiovascular
2 surgeons," plural. So, again, harken back to my advice --

3 **MR. JOHNSTON:** Yes.

4 **JUDGE DALTON:** -- you're not going to get multiple.

5 **MR. JOHNSTON:** I'm just identifying categories,
6 Your Honor.

7 **JUDGE DALTON:** Okay.

8 **MR. JOHNSTON:** We'll need somebody to address strokes
9 for those folks who had strokes, which is not a cardiovascular
10 doctor.

11 **JUDGE DALTON:** Why not?

12 **MR. JOHNSTON:** Because that's just the way it goes.
13 Neurologists deal with strokes. Cardiovascular doctors may
14 deal with cleaning out your artery that might lead to a stroke,
15 but they don't deal with the diagnosis of the stroke and what
16 the other causes of strokes are.

17 **JUDGE DALTON:** Color me unpersuaded.

18 **MR. JOHNSTON:** Okay.

19 **JUDGE DALTON:** But go ahead.

20 **MR. JOHNSTON:** And then cardiologists are often --
21 who deal with actual heart attacks are not usually --

22 **JUDGE DALTON:** I just can tell you, Mr. Johnston,
23 this is not going to work. You're not going to get four
24 different types of cardiovascular experts. You know, one
25 that's like a cardiologist who specializes in the heart, one

1 that's a cardiologist that specializes in the thorax, one
2 that's a cardiologist that specializes in the carotid artery.
3 It's just not going to happen. Again, I want to harken back to
4 what Rule 1 of the Federal Rules of Procedure is designed to
5 do. It's to make the case move in a way that is efficient and
6 cost effective.

7 **MR. JOHNSTON:** My experts will essentially be
8 responsive to plaintiffs' experts, and so to some degree we'll
9 be guided by what they're putting forth too.

10 **JUDGE DALTON:** So if I were to require them to make
11 their Rule 26 disclosure here in some reasonable period of
12 time, especially since two of these cases have already been
13 litigated to the summary judgment stage, I would think that
14 could be done in a relatively short period of time. How much
15 time would you need to designate your experts?

16 **MR. JOHNSTON:** I would think a normal 30 days after
17 they designated or something like that.

18 **JUDGE DALTON:** Okay. What about -- speak to the
19 proposed -- I don't know they actually proposed it, but the
20 discussion about schedule of half a year for fact discovery,
21 the balance of the year or maybe four to six months thereafter
22 for expert disclosure and expert discovery. How does that ring
23 to you?

24 **MR. JOHNSTON:** Well, it rings awfully optimistic to
25 me given that we've already had most of these cases pending for

1 a year and we're still sort of not off the ground. But, you
2 know, the concern I have is that the discovery that they are
3 basing that schedule on is all discovery from Novartis. So
4 that makes that determination based unilaterally on discovery
5 from Novartis without any consideration of discovery from
6 plaintiffs.

7 **JUDGE DALTON:** Well, you-all can walk and chew gum at
8 the same time.

9 **MR. JOHNSTON:** I'm happy to walk and chew gum at the
10 same time, Your Honor. But they asked you a few minutes ago
11 for a staged process where the discovery from Novartis went
12 first. And so I'm concerned that that's what's baked into
13 their year -- their estimate of a year from -- discovery of
14 Novartis in early 2022.

15 **JUDGE DALTON:** Well, I can tell you I didn't hear
16 that, but there's not going to be any staged discovery where
17 Novartis goes first. I mean, we're going to move forward with
18 the discovery bilaterally.

19 **MR. JOHNSTON:** Good.

20 **JUDGE DALTON:** You know? So there's not going to be
21 any -- there's not going to be any staged discovery.

22 **MR. JOHNSTON:** Good. Because our view is that we
23 should go ahead with discovery with all 21 of these cases and
24 not have some sort of staged process at all. So -- but that
25 may mean that there's a little bit of time at the end that's a

1 little longer than one year to get to being completed with
2 experts. I think that that's going to be a little longer than
3 that, but I don't think it's dramatically longer than that
4 barring unforeseen troubles.

5 **JUDGE DALTON:** All right. What do you think are the
6 prospects of you-all being able to reach an agreement with
7 respect to exchange of mutual fact sheets? Do you-all think
8 that's something that you could get together on a meet and
9 confer and come to an agreement on in terms of the fact sheet
10 from the plaintiff? And as I said, I'm trying to imagine what
11 it is, outside of discovery, in terms of a defense fact sheet
12 that they might need. And I'm -- I don't know what that is,
13 but I do know what you-all probably need, at least at a
14 minimum.

15 **MR. JOHNSTON:** Well, we -- we actually have a PFS
16 that is submitted to Judge Harz that she, presumably, will take
17 up at the hearing tomorrow. There are some disputes still on
18 that fact sheet, but I think we've made some progress. It
19 currently embodies a fairly short limit of time for medical
20 records before diagnosed with CML, which we are not happy with.
21 But given that, I think after tomorrow in Judge Harz's court,
22 maybe we'll actually have a PFS that we can get for Your Honor.

23 They've asked for a DFS. We're essentially opposing
24 a DFS that goes beyond information about sales reps' calls on
25 the treating physicians. Plaintiffs want to have custodial

1 productions from everyone who called on any treating physician,
2 whether they were a nephrologist or a cardiologist or a
3 podiatrist. We're opposing that. But Judge Harz will have
4 that before her tomorrow as well. So it's possible that after
5 we are before Judge Harz tomorrow --

6 **JUDGE DALTON:** What -- tell me, what's the basis of
7 your opposition to that? Is it because it's too onerous or
8 because you don't think it's relevant or some combination of
9 the two?

10 **MR. JOHNSTON:** Well, combination of the two. The
11 sales forces that would call on nephrologists, which are kidney
12 doctors, are not trained on or authorized to speak about
13 Tassigna. So there is no reason to think that there would be --

14 **JUDGE DALTON:** Aren't they required to be able to
15 address all the contraindications associated with the use of
16 the medication regardless of the specialty for which it's
17 prescribed?

18 **MR. JOHNSTON:** Well, the Tassigna sales force would be
19 but not the people call- -- the Tassigna sales force does not
20 call on nephrologists. A separate nephrology sales force
21 that's talking about bile drugs or something, is calling on
22 that sales force. And they are not expected to, and they are
23 not allowed to, talk about drugs that they are not tasked with.

24 So I want to make sure I'm clear. We're not talking
25 about the Tassigna sales force selling Tassigna going and calling

1 on nephrologists. They don't do that. They call on
2 oncologists and hematologists. If anybody from Novartis is
3 visiting a nephrologist, they are not there to talk about
4 Tassigna, and they're not trained to talk about Tassigna. And
5 they are not -- if they get a report of a side effect, they
6 report that back to the company. But they can't engage those
7 doctors in a discussion about Tassigna and its side effects
8 because that is not a product for which they're detailing, and
9 they're not trained.

10 **JUDGE DALTON:** What is your understanding --
11 recognizing that you don't agree with it, what is your
12 understanding of the plaintiffs' rationale for asking for that?

13 **MR. JOHNSTON:** Bias. And they're hoping that they
14 can find a needle in a haystack of one communication somewhere
15 that they can use to say Novartis encouraged the doctor not to
16 report it or to not think Tassigna was the culprit or something
17 like that.

18 **MR. SILVERMAN:** Your Honor, may I respond to that?
19 Because I think it's important.

20 **JUDGE DALTON:** Well, I'm going to give you a chance
21 too. You're going to get another turn at bat. I'm just trying
22 to -- I'm trying to understand the shape of you-all's dispute
23 here in terms of these fact sheets.

24 **MR. JOHNSTON:** They also want all payments to
25 Novartis to any doctor who treated them, whether they're a

1 general care physician, an ER doctor, a nephrologist, a
2 podiatrist, a on- -- we understand wanting to know what
3 payments might have been made to the treating oncologist that
4 prescribed the drug, but to require us to search for -- I mean,
5 we're talking -- this is not true here.

6 In New Jersey, we're talking 214 cases. Sometimes
7 there's been as many as five Tasigna sales reps that called on
8 the prescribing physician. And who knows how many that called
9 on any other specialities that the person was treated by.

10 We could be looking at thousands of sales rep
11 production, searching and production. And that seems undue
12 given the fact that these sales reps outside of the Tasigna
13 sales force are not trained on Tasigna and are not allowed to
14 talk about Tasigna. The best they could do is say, "I'll take
15 your question to the medical affairs department." And we will
16 give them the medical affairs database where any such questions
17 would have come in.

18 **JUDGE DALTON:** All right. But you would agree that
19 they would be entitled to information about any perks, monetary
20 or otherwise, that were provided by Novartis to the prescribing
21 physician?

22 **MR. JOHNSTON:** That's actually public information.
23 So we're not going to dispute the --

24 **JUDGE DALTON:** Almost all of it is. I just finished
25 trying a three-week pelvic mesh case. So I had -- you know,

1 un- -- I started to say unfortunately. I guess it depends on
2 your point of view. But I had an opportunity, let's put it
3 that way, to review the very comprehensive online disclosures
4 of payments made by, in that case, Boston Scientific and
5 Coloplast. So I -- again, it's not my first rodeo. I know how
6 that works.

7 **MR. JOHNSTON:** Right.

8 **JUDGE DALTON:** It's all -- it's public information.
9 So it's not really particularly onerous for Novartis to comply
10 with that on a defense fact sheet, right?

11 **MR. JOHNSTON:** It would be publically -- it would be
12 onerous if we had to do more than just say, "It's publicly
13 available. You can go look yourself." Because then people are
14 having to do things that's available to them.

15 **JUDGE DALTON:** Well, but it's a little bit different
16 though, Mr. Johnston, because now it's a representation from
17 Novartis in the context of the legal proceedings.

18 "Isn't it true, Mr. Jones from Novartis, that you
19 paid Dr. Smith X number of dollars as reflected on this
20 internet sheet?

21 "Well, I don't know."

22 It's a little different than, "Isn't it true,
23 Mr. Jones, that you told me, in response to my request, that
24 you paid Dr. Jones, on this date, this amount of money, in
25 return for his endorsement of your product or use of his

1 product?" Or even for -- "You took him to play golf in
2 Scotland?" You know, whatever it was.

3 It's a little bit different. So it's not so easy to
4 say -- and I say this is true for both sides -- "Hey, you want
5 this information. It's out there in the public domain, go find
6 it yourself."

7 **MR. JOHNSTON:** Well, we're prepared to give them the
8 output of our database, which will generally track that public
9 information with respect to people who actually prescribe the
10 medicine.

11 **JUDGE DALTON:** Well, and it will, again assuming that
12 it was all properly reported. I'm not suggesting --

13 **MR. JOHNSTON:** Right.

14 **JUDGE DALTON:** -- that it wasn't.

15 **MR. JOHNSTON:** Right.

16 **JUDGE DALTON:** But assuming that it was all properly
17 reported.

18 **MR. JOHNSTON:** What we object to is doing that for
19 every doctor that the person saw.

20 **JUDGE DALTON:** Okay. I mean, I hear you. I
21 understand. I guess I started off the question "As you would
22 agree" -- I'm asking you if you would agree that at least as to
23 the prescribing physician, that that information about -- I'll
24 use the term "perks" for lack of a better one, whether it's
25 trips to Scotland, monetary payments, grants, you know, adjunct

1 professorships, whatever it is, teaching at a Novartis, you
2 know, doctor conclave, that as to the prescribing doctor, all
3 of that information is something that the plaintiffs ought to
4 get.

5 **MR. JOHNSTON:** And we haven't objected to that,
6 Your Honor.

7 **JUDGE DALTON:** Okay. All right.

8 Let's see, Mr. Johnston. Let me give you a rest and
9 get Mr. Elias back up here, and let's talk for a little bit
10 about -- I'm interested to know whether you--all think --
11 Mr. Johnston seems to think that after your hearing with
12 Judge Harz tomorrow, that you--all may be in a position to
13 agree, at least about the plaintiffs' fact sheets. I'd like to
14 know about both fact sheets because I'm going to require them.
15 I suspect Judge Harz will, but I don't know that. But I'm
16 going to require that we develop fact sheets in order to try to
17 streamline the discovery process.

18 So the choice you have, I guess, is to work it out
19 between yourselves or not be able to do that and leave it up to
20 me to decide what it is that I think you need, and same for
21 your colleague.

22 **MR. SILVERMAN:** Judge, one point of clarification.

23 **JUDGE DALTON:** Just for the record, would you mind
24 giving us your name every time you--all swap just so the --

25 **MR. SILVERMAN:** My apologies. Raymond Silverman.

1 **JUDGE DALTON:** Thank you.

2 **MR. SILVERMAN:** Thank you, Your Honor.

3 One point of clarification to something that
4 Mr. Johnston just spoke about. In the context of the
5 discussions that the parties have had about the DFS -- and
6 there's been pretty substantial discussions over the past month
7 and a half since Judge Harz asked us to meet and confer on the
8 PFS and the DFS. We had reached an agreement with them that we
9 wouldn't require them to search custodial files of sales reps
10 at this time in terms of making those productions.

11 We viewed that as being something, at this point,
12 would be down the line, if we were looking at certain --
13 potentially bellwether cases. So just to clarify that. That's
14 why Mr. Johnston talking about these searches of custodial
15 sales rep files at this time in connection with DFS is
16 something that we already agreed we wouldn't require them. And
17 we actually put language to that effect into what was our
18 proposed governing CMO on defense fact sheets.

19 In reference to the fact sheets themselves,
20 Your Honor, we also -- both sides have submitted competing
21 proposals on the PFS. The defendant's PFS, just to be very --
22 you know, very brief and to the point here, is beyond onerous.
23 It is 33 pages in length, which, when you start accounting for
24 the multiple questions that go into it, is likely going to be
25 asking each plaintiff somewhere probably in the range of two to

1 250 questions for each plaintiff, both in the state and federal
2 court, which is -- it contains much irrelevant information
3 being requested, as well, stuff that is completely duplicative
4 and cumulative of what's going to be in the medical records.

5 Plaintiffs, on the other hand, submitted what we
6 believe is a pretty fair fact sheet that should give defense
7 counsel all the information that they would need at this time,
8 plus authorizations for medical records, which, of course,
9 we've been providing and been providing for years.

10 I just wanted to make that point clear about the
11 custodial files because I wasn't sure if Mr. Johnston was aware
12 that that was an agreement the parties had reached already.

13 **JUDGE DALTON:** Lauren, do we have the proposals for
14 the fact sheets that were submitted in New Jersey?

15 **LAW CLERK:** Not yet, Your Honor.

16 **JUDGE DALTON:** I'm going to direct you all to deliver
17 those to me to -- whatever you gave to Judge Harz in terms of
18 the proposed fact sheets, if you-all would have someone, by the
19 end of the week, submit those to my chambers electronically.
20 And submit them in Word form, if you would, please, so that I
21 can modify them.

22 **MR. ELIAS:** We will do that, Your Honor.

23 **JUDGE DALTON:** One thing, I don't know -- I've had a
24 couple of very pleasant conversations with Judge Harz, and I'm
25 sure we'll have many more. I'll just say, I don't know if --

1 we're in the season now, baseball season. I don't know if any
2 of you are baseball fans. But if you are, you're probably
3 familiar with baseball arbitration, which I'll put out there
4 for you-all to just again consider.

5 When you -- let me just pick something that has
6 nothing to do with what we're here about. But when you have a
7 \$10,000 case, and you ask for a million five, and you have --
8 or you have a million-dollar case and you offer 10,500, the way
9 baseball arbitration works, is there is no in between. Right?
10 So you submitted two proposals. One of those proposals is
11 going to get selected.

12 I would ask you to think about baseball arbitration
13 when you make your respective positions, when you stake them
14 out in front of me. Because if you ask for things that I think
15 are ridiculous, then I'm going to treat them with that amount
16 of respect. So just be mindful of that.

17 And I say that, Mr. Johnston, I'm not assessing -- I
18 haven't looked at your fact sheet at all. So I'm not accepting
19 the representation that it's grossly overbroad.

20 I'm just telling you both, you know, if your fact
21 sheet says, "My name is Bob Jones. I live in New Jersey, and I
22 took this drug in 1988, and that's all I intend to share with
23 you," or 2008, that's equally as ridiculous. So you know, at
24 the end of the day, if you-all can't reach an agreement, you
25 know, then I'll decide because that's what I'm here for.

1 But I do want you to -- I do want you to hear from me
2 loud and clear that when you're directed to meet and confer,
3 you need to recognize that you've got to give something up.
4 You know, if you're not willing to give something up, you
5 better be prepared for the possibility that you're going to be
6 left with the other side's offer, which, out of context, is
7 absurd, if you get my point.

8 I mean, that's what happens in baseball arbitration.
9 You wonder, how did this contract possibly get signed for, you
10 know, \$8 million for a guy that made \$200,000 a year before?
11 That's how it happens.

12 **MR. ELIAS:** Understood.

13 **JUDGE DALTON:** Okay. All right. So if you-all --

14 **JUDGE HARZ:** Can I just say something? This is
15 Judge Harz.

16 **JUDGE DALTON:** Yes. Yes, ma'am.

17 **JUDGE HARZ:** I'm inclined to just postpone my
18 conference schedule for tomorrow because the focus of that
19 was -- I received significant submissions dated September 20
20 from both sides. And the main crux of the disputes involve the
21 defendant fact sheets and the plaintiff fact sheets. And I
22 would like to have an opportunity to have the federal court
23 review the requested fact sheets and then for us to meet and
24 confer. Because it would seem to me that the same fact sheets
25 should be used both in the MDL and the MCL.

1 So I would like to postpone my conference for
2 tomorrow. And I will certainly let counsel know, you know,
3 within the next two days, when I will be having such a
4 conference or perhaps we could have a joint conference. But I
5 just wanted it made known I'm not going to have a conference
6 tomorrow with regard to the fact sheets. Thank you.

7 **JUDGE DALTON:** Thank you, Judge Harz.

8 All right. One of the things that I know I touched
9 on, but we haven't really drilled down on it, is the proper way
10 to cabin the deposition time in terms of -- I'm not a fan of
11 numbers, but I am a bigger fan of hours. It doesn't mean I
12 can't be persuaded that numbers is the best course.

13 But what do you think, Mr. Elias, from your point of
14 view, would be a reasonable allocation of hours for discovery?

15 Let me try to give you some context while you're
16 thinking. So if you look at the federal rules just generally,
17 in the ordinary case you would have ten depositions limited to
18 seven hours each without leave of court to expand that or
19 70 hours in total worth of discovery time. My own experience
20 has been that the lawyers don't need as much time as they think
21 they need and that the -- putting some hour time limits on it
22 allows you to not be too burdened, too concerned, about, "Gee,
23 we shouldn't depose this individual that we need for 15 or 20
24 minutes because that's going to count against us." You could
25 take some 30-minute depositions if you felt they were going to

1 be useful or helpful to you. But I also feel an obligation to
2 protect the witnesses on both sides.

3 I mean, for instance, I'm not a fan, I'll just tell
4 you, of the plaintiffs taking 30(b)(6) depositions from
5 Novartis for day after day after day after day, recognizing
6 that sometimes lengthy depositions are necessary. So I'm not
7 saying it never happens, but I'm not a fan.

8 I'm also not a fan of experts, even though most of
9 the time, for a lot of these folks -- not true for all. But
10 for a lot of these folks, they know what they're signing up
11 for. But I'm not a fan of them being deposed, you know, for
12 days on end when it could be done much more efficiently.

13 I also don't think -- and, again, I don't want to
14 speak for Judge Harz, but I can't imagine that I would be in
15 favor of allowing these individuals to be deposed in both
16 jurisdictions. So we're going to figure out a way, I suspect,
17 between Judge Harz and myself, with your input and cooperation,
18 to have these individuals identified and deposed for use in
19 both the federal and the state proceedings.

20 **MR. ELIAS:** Of course.

21 **THE COURT:** So with that little bit more of context,
22 tell me, what do you think would be a reasonable amount of time
23 for you to get your work done?

24 **MR. ELIAS:** And does the deposition limit include
25 expert depositions as well?

1 **JUDGE DALTON:** Well, if you want to break it up, we
2 can break it up. You know, I'm not opposed to that.

3 **MR. ELIAS:** Before I get -- set anything in stone --

4 **JUDGE DALTON:** You want to take -- why don't we take
5 a break. Let me give the court reporter a break. And let's
6 take a 10-minute recess.

7 Judge Harz, are you able to stay with us?

8 **JUDGE HARZ:** Yes, I am. No problem. Thank you.

9 **JUDGE DALTON:** I need to give my court reporter a
10 break. So I'm going to take a 10-minute break and give the
11 lawyers a chance to confer on time for discovery and maybe
12 you-all confer individually and then collectively. And let's
13 see if we're in the same ballpark when I come back in terms of
14 what you think you might need.

15 So we'll be in recess until 11:30.

16 (Recess from 11:20 a.m. to 11:40 a.m.)

17 **JUDGE DALTON:** Back on the record In Re: Novartis,
18 6:21-md-3006. The Court notes all counsel are present.

19 A couple of things lest I forget. I'm not sure that
20 I gave you a time to submit your copies of the New Jersey
21 briefing that you submitted on custodian and search terms,
22 Mr. Elias. But let me have that by the end of the week, if I
23 could have that by Friday. And then I know I gave you-all
24 times for -- 10 days to respond and seven days to reply.

25 With respect to the proposed fact sheets, I know I

1 asked you to send those to me via my court email. I am going
2 to direct you-all to meet and confer about that again before
3 you send me that submission. Because it sounds to me like
4 there's a lot of daylight between your respective positions.

5 And I'm going to encourage you, Mr. Johnston, to take
6 a -- you and your team to take a close look at your submission
7 and try to pare that down to something that is manageable and
8 useful.

9 And Mr. Elias, I'm going to encourage you and your
10 team to look at their submission with an open mind in terms of
11 recognizing the scope of information that they might think that
12 they need, whether you necessarily agree that it's something
13 that they need.

14 Because I don't want to start off with a situation
15 where you guys are, you know, miles apart. You-all, I'm sure,
16 can come closer to an accommodation on these fact sheets than
17 you are at present.

18 So let's do this. Let me give you some time for
19 that. Let me give you seven days to meet and confer, and then
20 let me have your filing within 10 days. So I'm going to
21 require you-all to meet and confer within seven. And you'll
22 have a couple of days to sort out your proposal. I would hope
23 that at the end of that meet and confer I might get a joint
24 submission that you-all agree on, but maybe that's too
25 optimistic. Failing that, if you'll give me your competing

1 proposals within 10 days, then I'll take it from there.

2 Let me also give you a date for your Rule 26
3 disclosures. And as I do that, let me just remind you about
4 Rule 26 in terms of what its purpose is. You need to
5 understand, under Rule 26, that the whole point of Rule 26
6 disclosures is to require the parties to exchange information
7 that they know is going to be relevant to both the prosecution
8 and the defense of the claims and to do that without the
9 necessity of a request for production. So I'm going to expect
10 you-all to do that and make your Rule 26 disclosures by -- I
11 think the Monday in the middle of October is the 18th.

12 Somebody check -- with a calendar can check that and
13 make sure that that's right. Is that right?

14 **THE COURTROOM DEPUTY:** Yes.

15 **JUDGE DALTON:** Thank you, Anita.

16 So the 18th your Rule 26 disclosures will be due.

17 And then I'm going to follow that up with a
18 scheduling order, but I didn't want to forget to mention the
19 date for your Rule 26 disclosures.

20 I've been thinking, Mr. Johnston, about your dilemma
21 in terms of the treating physicians as it relates to the
22 learned intermediary defense. And I haven't decided how I'm
23 going to solve that problem yet, but I'm thinking about it. So
24 I don't want you to think that I've not been receptive to your
25 arguments. I appreciate that you may have a need to ask these

1 individual prescribing physicians some questions.

2 What I may do -- and I say "may" because I'm thinking
3 about it. I haven't decided what to do. I may allow you to
4 take some limited deposition testimony from them limited to
5 that topic with your request to -- with respect to their -- the
6 logic tree or the decision-making process of prescribing the
7 drug in terms of if they had known this or if they had known
8 that. And you could probably do that in a relatively short
9 session of, you know, not more than an hour. That's not a
10 ruling. I'm just thinking out loud.

11 All right. How did we do in terms of coming up with
12 some estimates for the amount of discovery that you might need?

13 Mr. Elias, let me invite you back up.

14 **MR. ELIAS:** Yes, Your Honor.

15 First, with the discovery, you asked a direct
16 question, and I'm going to give you an answer. I do want to at
17 least caveat this and say it's very hard for us, at this point
18 in time, to know what -- how many hours we need because we
19 don't know how many custodians we're going to get, and we
20 haven't seen the full production of documents. So this is a
21 best guesstimate that we're making.

22 But, you know, I think what we've determined is -- in
23 most of the cases, I believe, the presumptive limits for
24 depositions were raised from 10 to 15 for fact witnesses. That
25 was -- that comes out to about a hundred hours. So we would

1 ask for a hundred hours on fact witnesses and then 40 hours for
2 experts.

3 **JUDGE DALTON:** Okay. And Mr. Johnston, what do
4 you-all think?

5 **MR. JOHNSTON:** Well, Your Honor, it's very difficult.
6 We talked a little bit about this. Here's my difficulty. If
7 you don't allow me to take treater and prescriber and plaintiff
8 depositions, then I have no depositions to take in this MDL.
9 Because that's the depositions that I would be taking on a fact
10 basis.

11 If we assume that you will allow me somewhere -- to
12 take some depositions of some of those folks, I'm okay with the
13 hundred-hour idea because that would be about five hours of
14 deposition time per case.

15 I would note that the plaintiffs already have in
16 excess of 60 hours of deposition testimony of Novartis
17 employees, including two depositions, one on corporate
18 structure and one on a data issue, as well as six depositions
19 of the people who were in charge of the label change in 2014,
20 in evaluating this, which they, frankly, shouldn't have to take
21 again and which should, frankly, give them the discovery they
22 need from Novartis. But they've already got 60 hours of
23 deposition testimony that is usable. And at the prior trial,
24 they had designated 24 hours of that testimony to be played to
25 the jury.

1 So I'm a little worried about a world in which I face
2 another hundred hours of fact discovery from my client with
3 essentially no discovery of the plaintiffs in a deposition
4 context. So that's my concern, Your Honor.

5 With respect to expert discovery, I would like more
6 than 40 hours, but, of course, it all depends on the number of
7 experts that ultimately get designated. But I would still want
8 the full seven hours for all of the experts. And so if I'm
9 guessing, I'd say I'd like 70 hours, which sort of is assuming
10 10 experts from the other side. But if it's less than that, I
11 wouldn't need that many. It just depends on how many experts
12 they designate.

13 **JUDGE DALTON:** All right. Thank you, Mr. Johnston.

14 **MR. ELIAS:** Your Honor?

15 **JUDGE DALTON:** What?

16 **MR. ELIAS:** Oh, I'm sorry.

17 **JUDGE DALTON:** Yes.

18 **MR. ELIAS:** Whenever is a good opportunity, we would
19 like to address, before we leave today, the issue that you're
20 considering -- we understand that you're considering -- about
21 allowing some deposition testimony of treating physicians.

22 **JUDGE DALTON:** Okay.

23 **MR. ELIAS:** Your Honor, if the Court is inclined to
24 allow case-specific discovery into the prescribing physicians,
25 we need an opportunity to discuss some sort of staging of

1 discovery in that manner or deferring those depositions until
2 we get discovery from Novartis.

3 In particular, these depositions, which are very
4 important depositions, are as important to us, the plaintiffs,
5 as they are to the defense. And there are documents that need
6 to be produced for each of the treating physicians, including
7 custodial files of the Novartis sales reps that we need to see,
8 including text messages and communications that the sales reps
9 and the sales force had with the treating physicians before the
10 treating physicians can be properly deposed. Otherwise, we're
11 going to be looking at duplicative, multiple depositions of the
12 same individuals.

13 So while the Court is considering doing that, we --
14 the plaintiffs would suggest that it's best handled in a more
15 case-specific process, like a bellwether process, on individual
16 treating physicians and case-specific discovery rather than
17 allowing Novartis to notice up 20 -- and there will very likely
18 be more cases before this is -- before this is all over, but
19 noticing up 20 to 30 to 40 depositions of treating physicians
20 without having the full discovery to proceed on those
21 depositions.

22 **MR. JOHNSTON:** Your Honor, may I respond?

23 **JUDGE DALTON:** No. I hear you both.

24 I'm not going to -- we're not going to litigate this
25 question. What I will tell you is that -- so Mr. Elias, you

1 have unfettered access, relatively, to your clients'
2 prescribing doctors. You have access to whatever it is that
3 you've been able to accumulate in order to -- obviously, I'm
4 assuming -- and I know correctly -- that you've discharged your
5 Rule 11 obligations with respect to knowing what the
6 fundamental tenets of your claim are. You know the industry.
7 You know what your claims are. You know what your experts are
8 telling you. You have the ability to sit down and share that
9 with the treating physicians, the prescribing physicians, in a
10 conference before the deposition goes forward in almost all
11 cases.

12 I know you get, occasionally, some noncooperative,
13 noncompliant physicians. I've lived that life so I -- I know
14 it well.

15 But the point is there's a little bit of asymmetry of
16 information here and asymmetry of access. As I said before,
17 I've not decided what I'm going to do with respect to these
18 prescribing physicians. I'm simply acknowledging to
19 Mr. Johnston that I hear him, I understand his view about what
20 he thinks he needs in order to mount a defense based on the
21 transmission of information to a learned intermediary and
22 whether or not that is going to break the causation chain that
23 you need to establish in order to prevail.

24 We're going to get that done. You know, we're going
25 to get it done in one way or another. Mr. Johnston is not

1 going to probably be completely happy with the solution. You
2 may not be completely happy with the solution. But what I'm
3 not going to do, as I said at the outset, I'm not going to
4 build in -- we're not going to get to see until after we've
5 gotten to be. We're not going to get to why -- you know, I'm
6 just not going to do that because it never works. And then I
7 end up with -- and Judge Baker end up with -- having to
8 constantly resolve squabbles between you-all in terms of,
9 "Well, I can't -- I had to cancel this deposition so now I need
10 more time." "I had to cancel this deposition because I didn't
11 have Document D." I'm just not going to do that. You know,
12 we're not going to do it.

13 So I just need both of you to hear me loud and clear.
14 We're going to set the time frame. You-all are going to
15 cooperatively exchange discovery. If you don't cooperatively
16 exchange discovery, then there are going to be consequences for
17 that. And, you know, I don't know how to be more direct about
18 it.

19 **MR. ELIAS:** Understood, Your Honor.

20 **JUDGE DALTON:** So I think -- David, let me give you a
21 chance to speak a little bit.

22 I know Judge Baker has some thoughts on what we might
23 need to do in order to move forward with the ESI. And while
24 he's doing that, I'm going to look back over my notes. I have
25 a couple of things I want to circle back to.

1 **JUDGE BAKER:** I have not seen what your disputes are
2 about custodians, search terms, protocols. I don't know how
3 complex these searches are, how many iterations you're
4 planning. I don't know why this hasn't been resolved. I don't
5 know how Novartis organizes its information either within a
6 location or across the company. I don't know how hard or
7 expensive it is to retrieve things. I don't know how more
8 expensive an extra search term is or an extra custodian is.

9 My assumption is that once you set up a protocol for
10 a search and you understand what databases are available, it
11 doesn't stand to reason to me that it's much more expensive to
12 add a few more custodians or a few more search terms. Maybe
13 you've briefed that; maybe you haven't. But it does seem like
14 you've been through this before out in California and in the
15 Southern District. So I don't know what the mystery is here.
16 These are -- you both know -- you both know what the universe
17 is of information that's pertinent to the case. So getting to
18 that shouldn't be this yearlong struggle.

19 Now, having said that, if you can't resolve it, as
20 Judge Dalton has said, it will get resolved. But it won't be
21 pretty. And it won't be -- there's nobody else in the world
22 who's going to be more knowledgeable than counsel and your
23 clients, at least the defense side, as to how this information
24 is stored and how to retrieve it and what the ins and outs of
25 it are and how much it costs. I can find that out, but I don't

1 think that's the Court's role, even if we're applying the new
2 proportionality -- relatively new proportionality principles.
3 I'm never going to know as much about that as you do.

4 So one thing I have done in the past, on a rare
5 occasion where either something has gone drastically wrong or
6 it's just heat of the battle and counsel not being quite as
7 cooperative as we'd like them to be, is to appoint a special
8 master who will get down and dirty and tell you which search
9 terms are going to be used. That's expensive and cumbersome,
10 but it does get the job done.

11 So I'm not directing that we're going to do that, but
12 I have done it. And I can do it again. There are certainly
13 people out there, both practitioners and retired judges, who
14 take on that kind of work. Because I don't think it's the
15 sitting judge's responsibility, on a day-to-day basis, to tell
16 you how to do your work.

17 So to the extent that you are submitting to the --
18 this Court the speech you've got about search terms and
19 custodians, if it does not have specifics about what the extra
20 cost is or why you need this information, or why you can't get
21 it on a second pass, we're going to have a problem. Because I
22 can't evaluate it without that. If it's just the two of you
23 jousting about 30 people versus 50 people, that's not helpful.
24 And if it's jousting over hand-waving categories of documents
25 that, as Judge Dalton said, aren't curated as to the request,

1 we're going to have a problem.

2 So I anticipate that as Judge Dalton enters his order
3 following this hearing setting dates for you to do various
4 things, that we're going to have to come back to this. Judge
5 Harz may intervene and rule on some of these things, and that's
6 to be expected. And I may -- and Judge Dalton and I may both
7 follow her lead or we may take the lead, depending on how
8 things shake out. But to the extent that any issues about
9 protocols and the scope and the search terms are going to come
10 back to me for a decision, if we need to have monthly
11 conferences, we will. But I've given you how I think they need
12 to be briefed and flavored so that we don't get bogged down.

13 If we follow the schedule that Mr. Elias suggested,
14 there's not going to be time for that. That schedule assumes
15 everybody is moving forward in good faith and without needling
16 disputes.

17 **JUDGE DALTON:** All right. A couple of things I want
18 to mention.

19 Mr. Elias, I'd like to talk a little bit about this
20 question of medical authorizations in terms of how far back. I
21 know you-all have some submissions, I guess, in front of
22 Judge Harz about that, and that's part of your PFS meet and
23 confer. I don't need to spend any time on it if you think that
24 you and Mr. Johnston might be able to come to an agreement
25 about that in connection with your meet and confer on the PFS.

1 But if you think it's likely that you can't, then maybe we
2 could spend a few minutes on it here this morning.

3 **MR. ELIAS:** Can you give me one second, Your Honor?

4 **JUDGE DALTON:** Yes, sir.

5 (Court was at ease.)

6 **MR. ELIAS:** Your Honor, just to make sure that I'm
7 clear, I think that there's issues of how far back we go into
8 the PFS in terms of what we answer and in terms of how far back
9 we have to make certain disclosures in the PFS on medical. But
10 as terms of authorizations, I think what we have been doing --
11 and my cocounsel is going to correct me if I'm wrong -- is we
12 have been giving them blank authorizations for the treaters
13 that they have asked for. And there has been no limitation in
14 time and scope in those.

15 So in terms of the medical records, in every single
16 case that is pending in this court, to the best of my
17 knowledge, they already have extensive medical records and have
18 for several years. We went into an entire process where we
19 tried to resolve these claims prior to filing them and gave
20 them very expansive releases. And they have medical histories
21 going back, you know, 10, 15 or more years on most of these
22 clients.

23 **JUDGE DALTON:** What did I misunderstand when
24 Mr. Johnston told me that there was some debate about whether
25 they got three years' history from the date of the prescription

1 or some longer period of time?

2 **MR. ELIAS:** I believe -- and I think Mr. Silverman
3 would be better to speak to that particular dispute. That
4 might be a disclosure in the PFS but has not been an issue with
5 the authorizations that we've been giving, certainly not in my
6 cases.

7 **MR. SILVERMAN:** Raymond Silverman again. Thank you.

8 What Mr. Johnston was referring before Mr. Elias just
9 indicated, is there's a dispute in the PFS over medical
10 history. There's a few of them. But I believe the one that
11 Mr. Johnston was referring to was we have proposed that we
12 would reveal medical history, treating physicians, hospitals,
13 clinics, the whole gamut, save for any psychological treatment
14 only for individuals who are making specific psychological
15 claims, going back three years prior to the date of their CML
16 diagnosis. And, of course, the date of many of these folks'
17 CML diagnosis --

18 **JUDGE DALTON:** Aren't all of these people making a
19 claim for emotional injury?

20 **MR. SILVERMAN:** Most of them, Your Honor, I think are
21 just going to make your garden variety emotional, you know, "I
22 was upset that I can't do the things that I do because I" --

23 **JUDGE DALTON:** Well, they're going to include claims
24 for mental anguish, right, associated with it? I mean, why
25 would their psychological records not be relevant?

1 **MR. SILVERMAN:** My understanding, Your Honor, is that
2 unless you're making a specific psych claim, meaning you're
3 claiming a specific psychiatric condition like a DSM-5, like
4 you have posttraumatic stress disorder, garden variety
5 emotional distress claims do not open up discovery into prior
6 psychological history.

7 **JUDGE DALTON:** I'm not sure what treatise you rely
8 upon for that proposition, but I'm not sure I share your view.

9 **MR. SILVERMAN:** Fair enough, Your Honor. That's
10 always been my understanding, but I could certainly be wrong as
11 well.

12 So I think the issue Mr. Johnston is raising is not
13 an authorization issue unless I'm mistaken. My understanding
14 is the same as Mr. Elias's, that we've been giving them
15 authorizations, essentially, that they can fill in on their own
16 for any medical provider whose record they --

17 **JUDGE DALTON:** I guess the point is, if they don't
18 know a treating physician in year four, how could they send him
19 or her an authorization? So I don't want to spend a lot of
20 time, you know, getting bogged down, and I don't want our ships
21 to pass in the night. In order for them to make a reasonable
22 inquiry of medical records, they have to know who to inquire
23 of.

24 So I guess the point is, what is it about this three
25 year -- I mean, where are you guys in terms of negotiating this

1 three versus five versus seven? I mean, it just doesn't seem
2 to me that -- I mean, if we can't decide that, we're in for a
3 long haul here.

4 **MR. SILVERMAN:** Your Honor, I totally agree with
5 that. That -- the PFS issues that exist that I alluded to
6 before, that you'll see in certain briefing if we can't come to
7 agreement, are well beyond that simple issue. I don't see
8 that -- I also don't see this as being the issue.

9 Tying it to the CML diagnosis brings it back well
10 before Tassigna use in a lot of cases. Some of these folks were
11 diagnosed with CML back 20, 25 years ago. And to the extent
12 that, you know, there's going to be a medical history contained
13 in everyone's medical records, so if Mr. Johnston is concerned
14 that somebody had a heart attack 10 or 15 years before that,
15 that's going to be noted in their records.

16 If Mr. Johnston was to call me up and say, "Ray, I
17 see that on this particular plaintiff there was a history of
18 this information, would you be able to obtain that -- you know,
19 that doctor's name for me," I -- that, to me, is -- and it's
20 something relevant to the case, I'm not -- you know, we don't
21 consider that to be unreasonable.

22 **JUDGE DALTON:** Okay.

23 **MR. SILVERMAN:** It's just trying to keep the contours
24 of things with what now is 250 plaintiffs to a reasonable fact
25 sheet.

1 **JUDGE DALTON:** All right. I'm just going to -- and
2 I'm happy to hear from you, Mr. Johnston, if you have something
3 you want to add to that. But I just -- that should be part of
4 your conferral process. And I can't imagine that you-all
5 couldn't come to some accommodation with respect to whether
6 three years, four years, five years is -- is an appropriate
7 period of time for which you would be required to make
8 disclosures.

9 And anyway, let me give Mr. Johnston a chance to
10 speak.

11 **MR. SILVERMAN:** Yes, Your Honor.

12 **JUDGE DALTON:** I think he wants to.

13 **MR. JOHNSTON:** Just briefly, Your Honor. That was
14 one issue, and you nailed it right on the head. It's the
15 failure of disclosing who the treaters are.

16 The other issue is that some special -- some
17 hospitals have asked for special forms or for actual ink
18 signatures, not electronic signatures, and they haven't been
19 responding to those requests. So that's the other issue on the
20 authorizations.

21 **JUDGE DALTON:** Okay. Well, we -- that's all
22 manageable. We'll deal with that. If the hospital is balking,
23 then Judge Baker can enter an order and direct them to make the
24 disclosure. That's going to be an outlier. That's not going
25 to be the main -- that's not going to be the mine-run to

1 document production.

2 **MR. JOHNSTON:** What Mr. Silverman just said is
3 imminently reasonable, which is as we move forward,
4 notwithstanding what we start with, if we find out about
5 things, that we could expand discovery on those things. I've
6 been making that offer for a year, and I've been told that
7 that's not acceptable. I think that's a great way to go, that
8 we move forward and, if we have good reasons to expand, we
9 expand. And that's why I have never refused to give more
10 documents.

11 I've agreed to give 20-plus custodians out of their
12 54. I've already tried to compromise, and I keep getting told
13 "No" and "Don't produce any documents."

14 So I hope that we can all actually move forward in
15 the spirit that you conveyed, Your Honor --

16 **JUDGE DALTON:** Okay.

17 **MR. JOHNSTON:** -- on that.

18 I do have an issue about preemption that I need to
19 make before we go home, and I don't --

20 **JUDGE DALTON:** Well, we're not ready to go home yet.
21 And I've got -- preemption is on my list too. So we're going
22 to talk about that.

23 **MR. JOHNSTON:** Thank you, Your Honor.

24 **JUDGE DALTON:** All right. So I just want to mention
25 a couple of other things.

1 We're not going to have any motion practice as it
2 relates to discovery unless Judge Baker directs you to make
3 some sort of filing. So if you have a discovery issue, we're
4 going to meet -- we're going to have some scheduled meetings
5 once a month. If you have a discovery issue that arises, I'm
6 going to let Judge Baker tell you how he wants you to contact
7 him, under what circumstances. But we're not going to get into
8 a back and forth briefing schedule on discovery issues as they
9 arise because we'll lose too much time.

10 So I want Judge Baker to be thinking about how he
11 wants you-all to contact him. And, of course, I'm always
12 available as well, if Judge Baker is not available, if in the
13 middle of a deposition or in the course of something a question
14 arises, I'm going to expect you to reach out and get some of
15 the Court's assistance. And if we feel like it's being abused,
16 then, of course, there will be consequences for that as well.
17 And I don't anticipate that it's going to be abused.

18 I do want to mention something as it relates -- I
19 don't know if we have privilege issues here in terms of
20 proprietary documents or things that you-all are concerned
21 about. I don't need to get involved in that unless there's
22 some dispute about it. If you-all reach an agreement with
23 respect to the production of confidential documents, you don't
24 need to get my blessing of your agreement with respect to the
25 sharing of confidential information. If you think a protective

1 order is going to be required, then tell me that and tell me --
2 tell me why.

3 Yes, Mr. Johnston?

4 **MR. JOHNSTON:** I just wanted to let you know we
5 actually have an entered agreed protective order in the
6 cases --

7 **JUDGE DALTON:** Okay.

8 **MR. JOHNSTON:** -- I believe all of them that have
9 been transferred in, right? As well as an agreed ESI order.

10 **JUDGE DALTON:** Okay.

11 **MR. JOHNSTON:** So we may need to come back to those,
12 but I think we've handled that part.

13 **JUDGE DALTON:** Okay. Great. That's good to hear.

14 If we end up in a situation where you are withholding
15 documents, either of you -- of course, it's primarily a
16 Novartis issue, I suspect -- on some privilege claim,
17 Judge Baker will tell you -- he'll give you his standard
18 protocol for privilege claim. But you should expect that it's
19 going to require you to produce a specific privilege log. And
20 if it is extensive -- again, Judge Baker will do what he wants
21 to do. But if it comes to me, what I have done in the past is
22 I may just pick three to five of those privileged claims and
23 ask you to submit those documents to me in camera. And that
24 way I can get a -- I'll assess whether or not I think the
25 privilege claims are being asserted in a way that's overly

1 broad or obstructionist. And then you may have to live with
2 the consequences of that.

3 So just be mindful of the fact that privilege logs
4 with some specificity are going to be required and that I will
5 probably look at those by -- I'll use the sample method to
6 evaluate those if they are extensive.

7 I want to give Mr. Johnston a chance to talk to me a
8 little bit about preemption. But what about bellwether cases?
9 What do you-all think in terms of -- do you think bellwether
10 trials here in the MDL are going to be useful? Have you gotten
11 to the point of -- hopefully, you've thought about that. But I
12 would like to talk about that in the context of where do
13 you-all think -- and you may not agree -- but where do you-all
14 think the point of remand makes the most sense here in terms of
15 should we contemplate bellwether? Should we not contemplate
16 bellwethers? And if we don't contemplate bellwethers, at what
17 point should we begin to look at the MDL work as having been
18 concluded?

19 You want to go first, Mr. Johnston? Sure.

20 **MR. JOHNSTON:** We won't be making a *Lexecon* waiver,
21 Your Honor, in this case. And so we will expect the cases to
22 be remanded back for trial except for the ones that were filed
23 here.

24 **JUDGE DALTON:** Okay. The absence of a *Lexecon* waiver
25 doesn't eliminate the possibility of bellwethers. Of course --

1 **MR. JOHNSTON:** I understand that.

2 **JUDGE DALTON:** -- we have other cases here in the
3 Middle District of Florida that I'm certainly authorized to
4 try.

5 **MR. JOHNSTON:** Sure. Of course. And I just wanted
6 you to know that we weren't going to be giving a *Lexecon* waiver
7 in these cases.

8 **JUDGE DALTON:** I also could get an inter-circuit
9 appointment --

10 **MR. JOHNSTON:** Sure. Of course.

11 **JUDGE DALTON:** -- which would solve the problem as
12 well.

13 **MR. JOHNSTON:** Right. Absolutely.

14 **JUDGE DALTON:** That's not a threat by the way.

15 **MR. JOHNSTON:** I understand. No, I realize that
16 that's the point.

17 Our view is that you can try the cases that are here,
18 and we would expect to remand. And, in fact, in the Zometa
19 MDL, which I handled for a decade, we remanded out for damages
20 discovery to the trying courts. We actually ended up trying 16
21 cases out of that MDL, all in remand courts. And we won a
22 number of defense verdicts there.

23 So, you know, I have experience remanding cases out
24 with some discovery left and trying them -- other cases. And
25 we would be in favor of that. And that seems to me to be

1 consistent with your view of the role of an MDL court to some
2 degree. I don't know how that helps, but I think we would be
3 willing to consider that.

4 We only have 21 cases. It seems to me we should work them
5 up, and we should try them.

6 **JUDGE DALTON:** Okay.

7 **MR. JOHNSTON:** That's our view.

8 **JUDGE DALTON:** All right. Thanks, Mr. Johnston.

9 Mr. Elias, what's your view?

10 **MR. ELIAS:** Your Honor, we do think that we should
11 have a bellwether process. And, to be clear -- actually, this
12 is another point to address, which I think I know the answer
13 to, but I thought I would raise it. We have -- as I've alluded
14 to earlier -- I would say at least 15 to 20 more cases that
15 we've been holding off and waiting to file. We wanted to get
16 some guidance as to whether we should -- if there's an
17 opportunity for direct filing into this MDL versus filing those
18 in the individual courts. So we haven't yet filed them, but
19 they will be filed within the next probably 30 days and either
20 transferred over to here or filed directly into this court. So
21 we're going to be looking at more than just 21 cases.

22 We think that it does make sense to have a bellwether
23 process and that we should probably come up with some sort of
24 deadline to a cutoff in terms of when the pool to be selected
25 would occur. And we have some sort of process for selecting

1 those bellwether cases and working those cases up.

2 **JUDGE DALTON:** Okay. Well, we'll -- we'll see where
3 we end up on that. I don't have a strong view about it one way
4 or the other.

5 I think the question with respect to direct filing is
6 in my initial order, is it not, Lauren?

7 Yeah. I want to find that language.

8 **MR. ELIAS:** You did say that the cases should be
9 filed in the individual districts. And certainly we'd -- if
10 the Court is open to it, we'd like to explore opportunities to
11 do direct filing. We think we have authority from Florida
12 courts that allow it. But, obviously, we're going to defer to
13 the Court's preference on that.

14 **JUDGE DALTON:** Okay. All right. Mr. Johnston, let
15 me give you a chance to talk to me about preemption.

16 **MR. JOHNSTON:** Briefly, for the record, we would
17 oppose direct filing. We don't need to talk about it. I just
18 wanted to put that on the record so that if we're going to
19 consider that, we would need to, I guess, argue that later.

20 With respect to preemption, we have filed a -- fully
21 briefed the question of changes being affected preemption in
22 the Second Circuit -- well, in the district -- I think it's
23 Connecticut case -- of Colella.

24 **JUDGE DALTON:** Colella. Yeah. I've read your
25 papers.

1 **MR. JOHNSTON:** It's fully briefed. We believe that
2 the approach there potentially resolves many and perhaps all of
3 the cases. Maybe we're wrong, but we think it's important that
4 we find out who's right about preemption in that context sooner
5 rather than later because it may truncate the MDL or maybe not.
6 So we would ask that the Court accept and refile those briefs,
7 accept them as filed. They are not in the Court's
8 local-rules-compliant format. But we would like to do that and
9 perhaps have one page to give you -- there is no Eleventh
10 Circuit case addressing this. There are a couple of Eleventh
11 Circuit district court cases that have favorably considered the
12 sort of motion that we've made, and we'd like to give you those
13 cites without argument. But we'd ask the Court to go ahead and
14 put that on calendar so that we can make some progress on that.

15 **JUDGE DALTON:** Okay. I'm going to -- you can submit
16 your motions. But I am going to direct you to make them
17 compliant with the filing format here. And if you want to
18 update them to include Eleventh Circuit authority, I'll give
19 you the opportunity to do that. I'll give you 10 days to
20 submit your motion, and then I'll give you an opportunity to
21 amend your responses consistently and also make them meet our
22 formatting requirements and to address any new authorities that
23 are described in Mr. Johnston's papers.

24 So I'll give you 10 days to submit and 10 days to
25 respond.

1 **MR. ELIAS:** Your Honor, can I respond briefly to that
2 just to -- obviously, they are entitled to file their motion.
3 And we -- we are prepared to address it. The -- the question
4 that you -- that we -- you raised and that we raised in the
5 filings was whether we thought it would make sense to have a
6 master complaint. Preemption is certainly, from our point of
7 view, not something that can be handled on a motion to dismiss
8 or a motion for judgment on pleadings. They've filed two
9 preemption motions for summary judgment in the *Lauris* and the
10 *McWilliams* case. They were denied on summary judgment. But
11 clearly, given the factual inquiry, it's not something that can
12 be handled on a motion to dismiss.

13 In any event, preemption is going to vary the
14 analysis on the time of use and where the label was at that
15 period of time. So it seems, rather than -- if the Court is
16 going to make a preemption analysis, it needs to do it in the
17 context of the entire litigation, and it would seem that it
18 would make sense to have some sort of a master complaint that
19 they would be filing against on a preemption motion.

20 **JUDGE DALTON:** Well, I'm going to make the -- I'm
21 going to rule on the motion that's submitted. And if your
22 argument is that the record is not sufficiently mature or
23 developed in order for the Court to reach that determination,
24 I'll allow a Rule 56 sort of evaluation. And then if you
25 persuade me that that's correct, then the motion won't be

1 granted.

2 So, I mean, I appreciate your point, but it -- if
3 Mr. Johnston wants to -- if he wants to ask the Court to make a
4 preemption ruling based on the current record, he can do that.
5 And if it's -- if it's not appropriate based on the state of
6 the record, then he'll lose.

7 **MR. ELIAS:** Understood.

8 **JUDGE DALTON:** All right. So -- so 10 days for your
9 motion and 10 days for the response.

10 What about this question -- I did read the long-form
11 complaint that is in the New Jersey case. Let me ask Mr. Elias
12 first. Does the long-form complaint encompass all of the
13 claims that you think are going to be raised by any of the
14 members of your group of plaintiffs?

15 **MR. ELIAS:** Yes, Your Honor, I think so.

16 **JUDGE DALTON:** All right. So at the risk of being --
17 simplifying it too much, which sometimes is my want, you're
18 going to have a claim for negligence with respect to labeling
19 and then -- and a strict liability claim that has its origin in
20 labeling as well?

21 **MR. ELIAS:** Yes, Your Honor.

22 **JUDGE DALTON:** And if you have a decedent, you'll
23 have a wrongful death claim and a consortium claim?

24 **MR. ELIAS:** Yes, Your Honor.

25 **JUDGE DALTON:** How about you, Mr. Johnston, what

1 about the long-form complaint in the New Jersey case? Does it
2 include all of the defenses that you think -- your response to
3 it, does it include all of the defenses that you think you
4 would assert with respect to all of these defendants -- I mean,
5 all of these plaintiffs?

6 **MR. JOHNSTON:** It does, Your Honor. We don't think a
7 master complaint is necessary. In fact, the plaintiffs'
8 complaints are virtually similar, that have already been filed,
9 and we're just adding -- we're adding process to process to do
10 a master complaint that will very much look like the complaints
11 that are already on file in each of these cases. They're
12 essentially identical except for the plaintiffs' specific
13 allegations in these cases that have already been filed. It
14 just is a -- it's an extra waste of time to do a master
15 complaint here, Your Honor.

16 **JUDGE DALTON:** What's the benefit of a master
17 complaint, Mr. Elias?

18 **MR. ELIAS:** Well, I think the benefit of a master
19 complaint is if they -- if Novartis, as I've discussed, is --
20 is going to attack the complaint as a whole --

21 **JUDGE DALTON:** Come over to the --

22 **MR. ELIAS:** Yes, sir.

23 If Novartis is going to attack all of the claims as a
24 whole for the plaintiffs on preemption, for example, it would
25 seem to make more sense to me that they address it in a motion

1 that applies to a complaint that's been -- that's been filed on
2 behalf of all the plaintiffs. And the long-form complaint that
3 we filed in New Jersey, the master complaint would probably
4 look very similar to that and is -- is different than some of
5 the complaints that have been filed. And so it would make
6 sense that we would be filing -- they'd be filing a preemption
7 motion against one complaint, and the Court can address the
8 issue across the board.

9 **JUDGE DALTON:** Well, I guess what I'm not
10 understanding -- and I'm sure the failing is mine, but what I'm
11 not understanding is that the preemption argument is
12 essentially going to require Mr. Johnston's client to
13 demonstrate that it was not possible for them to comply with
14 both the FDA regulations and the state court duty of care that
15 they would have with respect to the labeling. If they can show
16 that it was not possible for them to comply with both of those
17 standards, then they might be entitled to preemption. If they
18 can't meet that impossibility standard, then their motion is
19 likely to fail.

20 I'm not sure I'm understanding what it is about a
21 master complaint that's going to change what I just described,
22 which is that the claims have their origin in negligence with
23 respect to failing to do or -- to doing or failing to do
24 something you should have done in connection with the
25 promulgation of the label or that the product was defective at

1 the time that it left the hands of the manufacturer as a
2 consequence of ineffective or insufficient, inadequate
3 labeling. That seems to me to be the nut of the problem.

4 **MR. ELIAS:** I guess maybe we're -- maybe the
5 disconnect is that my understanding is they're not going to be
6 filing a motion for summary judgment. They're going to be
7 filing a motion on the pleadings. That's what they filed in
8 the Colella case, a motion for judgment on the pleadings, that
9 the Court needs to look exclusively within the -- with some
10 exceptions, but within the four corners of the complaint. So
11 if they're planning on filing a motion attacking a complaint in
12 this case, it would seem to make sense that they would attack
13 it -- that they would file a motion on a master complaint
14 rather than a single complaint, and then the Court is left to
15 decide how that ruling applies to other claims and other
16 complaints.

17 **THE COURT:** Okay. "Okay" meaning I hear you. I'm
18 not sure I agree with you, but I hear you.

19 Okay. All right. What I think I'm going to do in
20 terms of the discovery time --

21 Mr. Elias, is there any reason that you-all would
22 seek to exclude or carve out the time that you've already had
23 with the Novartis folks from your allotted time here? I mean,
24 is there any reason you need to redo that or can't use it in
25 its current form?

1 **MR. ELIAS:** Your Honor, if I understand, are you
2 asking whether the depositions that have occurred, whether we
3 would count that towards our total hours?

4 **JUDGE DALTON:** Well, it sound -- let me back up. It
5 sounded like Mr. Johnston was open to the notion that that
6 prior discovery would be utilized as if it had been taken in
7 this case and that it need not be repeated. He's nodding that
8 I understood him correctly. Do you have -- do you resist that
9 notion?

10 **MR. ELIAS:** I do resist that notion, Your Honor. And
11 I want to make clear we're not going to retread old ground and
12 just get people in and show them the same documents and ask the
13 same questions that were already asked. But we are dealing
14 with, with respect to those witnesses, different time frames,
15 and we're going to be dealing with a different universe of
16 documents. So we deposed them, and we deposed them not just
17 for --

18 **JUDGE DALTON:** Well, I'm not suggesting -- I'm not
19 suggesting that I would say you can't redepose them. I'm
20 asking you whether or not there's any reason that I shouldn't
21 count that time as time already expended by the plaintiff.

22 **MR. ELIAS:** Yes. If -- if the question is when we've
23 said a hundred hours, if we should now subtract 60 hours or 40
24 hours from that in our total time, we would object to that,
25 Your Honor. And the reason is, is because that hundred hours

1 is assuming the additional depositions, and re-depositions of
2 people that have already been deposed, on new documents that is
3 going to have to occur. And the stuff that happened back in
4 the *Lauris* case is not nearly sufficient to cover that.

5 So when I -- when we said a hundred hours, we weren't
6 saying that so that, you know, we could have 50 hours or
7 whatever it is held against us and shorten the time to 50.

8 **JUDGE DALTON:** Well, how much -- so here's my
9 concern, is I want to make sure that I give you an appropriate
10 amount of time, but I also want to be sensitive to my
11 obligation to be respectful of the time of the witnesses
12 involved and that we not do things over again just to see if we
13 can do them better or differently.

14 I guess what I'm trying to find out -- I wasn't
15 there. I didn't participate in these depositions. I don't
16 know what the scope of the notice was. I don't know how
17 extensive they were. So, obviously, I'm at a significant
18 disadvantage in terms of trying to evaluate whether or not they
19 were useful, and if they were not -- if they were useful,
20 should not we, in the interest of efficiency, capture that
21 work?

22 **MR. ELIAS:** Well --

23 **JUDGE DALTON:** And if we are going to capture it, how
24 do we capture it and make sure that everybody starts off even?

25 **MR. ELIAS:** Well, we certainly -- the work has been

1 done. And certainly it's going to be, you know, part of this
2 case. But you have to keep in mind that those depositions
3 occurred on a document universe that ended in 2014. Okay?
4 Before, you know, many of our clients in this case even started
5 taking Tassigna. So this is an evolving timeline of documents,
6 of doctors, investigators, science, that is continuing to pile
7 up in their records about these warnings of severe
8 atherosclerosis and the side effect.

9 So the fact that we deposed, let's say, somebody in
10 charge of Tassigna safety team in 20 -- with a universe that
11 went up to 2014, is basically leaving out seven, eight years,
12 at this point, of documents and knowledge. So that person has
13 to be deposed again, and we're going to be covering new ground,
14 not old ground, with that person.

15 **JUDGE DALTON:** Okay. So, Mr. Johnston, I guess the
16 question I have for you is, if I do nothing with respect to
17 these prior depositions -- I'm not saying that's where I am.
18 But hypothetically, if I were to do nothing with respect to
19 these prior depositions, why wouldn't it be sanction enough for
20 the plaintiffs to -- in other words, if they -- if they go back
21 and plow old ground -- which I know you don't want to happen
22 both for the time waste and for the inconvenience to your
23 witnesses, but if they do that at the cost of their own clock
24 time, so how do I -- how do I solve this problem? What's your
25 suggestion?

1 Because Mr. Elias makes, I think, at least a couple
2 of reasonable points that if they were limited in their inquiry
3 of these witnesses to document production in 2014 or 2015, and
4 they get documents subsequent to that, they would need to make
5 inquiry about those documents. How -- do you have a thought on
6 how that might be managed as opposed to just a complete do-over
7 with them getting docked for whatever time they spend?

8 **MR. JOHNSTON:** Well, I think the answer is going to
9 be the Colella motion to that, Your Honor. Because that is a
10 case that involves first use after 2014. And the reality is
11 that the label was changed out of warning and precaution in
12 January of 2014. They have discovery through the end of
13 2014 -- not May, through December of 2014 -- from those prior
14 cases. The label was approved seven times after that 2014
15 labeling by the FDA with essentially no change. So if there's
16 preemption for the claim --

17 **JUDGE DALTON:** You know, I --

18 **MR. JOHNSTON:** -- falls in that period --

19 **JUDGE DALTON:** I'm going to --

20 **MR. JOHNSTON:** -- then there's no discovery.

21 **JUDGE DALTON:** I'm going to interrupt you because I'm
22 not going to rule on your preemption claim today.

23 **MR. JOHNSTON:** I understand that.

24 **JUDGE DALTON:** And I'm not going to make an
25 assignment of discovery time today based on the expectation

1 that I'm going to grant or deny the preemption motion.

2 **MR. JOHNSTON:** I'm not asking you to do that,
3 Your Honor. What I'm saying is --

4 **JUDGE DALTON:** So try to answer my question.

5 **MR. JOHNSTON:** Yes, sir.

6 **JUDGE DALTON:** How would I -- if you were king for a
7 day, how would you decide how to utilize this prior testimony?
8 Would you reopen it entirely and simply put the onus on them to
9 try to use their time efficiently? Would you try to limit it
10 in terms of no more than, for instance, another hour or two?
11 Or would you try to take the position that you can't redepose
12 these people at all, you should just be limited to what you
13 asked them when you deposed them before? So -- or something I
14 haven't thought of.

15 **MR. JOHNSTON:** Well, I think the answer is something
16 that we haven't thought of because it's person specific. Many
17 of the people they deposed left their roles, essentially, at
18 the time that they deposed them or were gone from their roles
19 prior to the close of this prior discovery period at the end of
20 2014. And new people would have taken over their role. So I
21 think for many of them, there isn't a lot of time --
22 individually a lot of time after their roles to ask them
23 questions about Tasigna because they weren't in the role.

24 Now, I have no problem conceptually with the idea
25 that they would take discovery after that. The reality is that

1 discovery isn't going to show anything. The real focus in this
2 case is going to be between the discovery or the -- the first
3 reports in about 2010 of vascular events and the warnings and
4 precautions that the FDA approved in 2014. That's where the
5 fire and the -- and the interesting stuff in this case is --
6 lies. And they've already got that. So I would suggest that
7 maybe you don't dock them the 60 hours but you prorate that
8 somehow or you give me 160 hours.

9 The problem with giving me 160 hours is that I --
10 the -- the idea that I'm hearing is that I don't really need to
11 take depositions. And so that's not really a fair outcome
12 either. If I'm not going to do anything but take an hour- or
13 two-hour deposition of the prescriber, you giving me 160 so
14 that they can have their 160 doesn't seem to do justice either.

15 So I don't know that I have an answer, but I do think
16 that some credit must be given for the depositions that we've
17 already agreed that they can use and that they've already
18 taken.

19 **JUDGE DALTON:** Okay.

20 **MR. ELIAS:** Your Honor, can I respond?

21 **JUDGE DALTON:** I got all the information I need.

22 Thanks, Mr. Elias.

23 Okay. What I'm going to do is I'm going to give you
24 all 140 hours each in terms of discovery time -- deposition
25 time, I mean. I'm not going to divide it between fact and

1 expert witnesses. You-all can make those allocations whatever
2 way you think is the most efficient way to do it. I'm not
3 going to make any accommodation or adjustment for any discovery
4 that was taken previously. If you-all want to -- if you choose
5 to waste your time plowing old ground, then it's just going to
6 be time off of your clock.

7 So I'm going to enter a scheduling order later on
8 this week that will set fact discovery closing sometime
9 probably in mid-July, with plaintiffs' expert disclosures due a
10 month thereafter, with defense expert disclosures due a month
11 after that, with expert discovery closing sometime in
12 September, and then with a date for -- I'm sorry -- with the
13 expert disclosure discovery, that is, cutting off sometime in
14 November of 2022. So all discovery will be over sometime in
15 November of 2022.

16 And then, I've already given you the date for your
17 Rule 26 disclosures. And I'm going to look for Mr. Johnston's
18 preemption filing and your response.

19 I'm going to wait after your meet and confer, your
20 proposals on DFS. And by the end of this week I'm going to get
21 your positions with respect to the custodial terms. That's
22 also after a meet and confer for your custodian list and the
23 search terms.

24 And then Judge Baker and Judge Harz and I will confer
25 once we've looked at those submissions and give you some

1 direction as to whether or not we think we have what we need in
2 order to make a decision for you in terms of the scope of your
3 ESI. And I think that's one of the things that needs to be
4 done the most critically on the front end.

5 And then we're going to get together. I'm not sure
6 if my initial order set dates or not. But we're going to get
7 together once a month.

8 And I am going to designate the lawyers that you
9 asked me to designate in your submissions in terms of lead and
10 liaison. I want to make sure that the liaison lawyer
11 especially understands his or her importance in terms of
12 maintaining dialogue and communications between the state court
13 and this court in terms of not only filings but ways that we
14 can use our time more efficiently.

15 I know that you're going to have issues there that
16 Judge Harz will have to address that are more case specific
17 than I will have here, but I'm not sure what she's going to do
18 in terms of restricting your ability to do case-specific
19 discovery until some of our work is done here. I'm going to,
20 hopefully, encourage her to put as much of that off as
21 possible. But I think, between us, unless she has an
22 objection, anything that you do in this case -- anything that
23 you do in her case will count in this case. So, in other
24 words, the time that I just gave you for deposition time,
25 that's going to include state court time on these common

1 issues. So there's not going to be any double dipping there.
2 You're not going to be able to do some discovery in the state
3 court and not count it against your clock here. All right?

4 So I wouldn't expect there to be any litigation about
5 that, but if you-all have any disagreements about that, of
6 course, I'll sort that out. But you should appreciate the fact
7 that if you notice a deposition in the state court proceeding,
8 I would expect you to notice it here as well.

9 I also want to just remind you of your obligation
10 with respect to production of documents from third parties.
11 One of you mentioned that. If you issue a subpoena, I know you
12 know that you have an obligation to give the other side notice.
13 Sometimes I find in the course of the lawyers' busy days that
14 that slips through the cracks. That always causes problems
15 down the road when one lawyer has used his subpoena power to
16 accumulate documents or information from a third party and the
17 other side doesn't know about it or find out about it until
18 later on. I take a dim view of that. So please be mindful of
19 your obligation to provide notice of document production
20 requests or subpoenas that are issued to third parties.

21 Let me check with Judge Baker, and then I'm going to
22 check with Judge Harz and see if there's some things that they
23 want me to raise that I haven't raised to this point. But
24 we've had a pretty productive morning.

25 Judge Baker.

1 **JUDGE BAKER:** Let me just alert you to -- let me just
2 say the culture of at least the Orlando division of the Middle
3 District of Florida, which is, once we set a schedule, we mean
4 it. It doesn't say that it can't be changed, but it's not
5 likely to be changed. And it won't be changed based on
6 unnecessary disagreements between counsel or lack of diligence
7 by counsel.

8 Also, with -- if there is motion practice on
9 something, don't necessarily count on having a hearing or oral
10 argument. Sometimes we do; sometimes we don't. We do plan to
11 have conferences with you on a regular basis, but that may or
12 may not -- it will be mostly checking in, making sure things
13 are moving, not necessarily hearing argument on anything that's
14 in dispute.

15 And I may be going beyond my remit here, but -- and I
16 don't know what your experience has been elsewhere in the
17 country about magistrate judges. I've been doing this a long
18 time. Judge Dalton has been doing this a long time. We've
19 been doing it together for a long time. I've been working with
20 a lot of other district judges over the 30 years I've been on
21 the bench. And we work well together. Let me just put it that
22 way.

23 **JUDGE DALTON:** One other thing about Rule 26, which
24 you-all know, but it's worth reminding you, is that when we get
25 to that point that you are producing your experts' reports,

1 there's no daylight between the testimony at trial and what's
2 included in the report. So, again, I know you-all are
3 professionals. You've dealt with this issue many times.
4 Sometimes your witnesses are less proficient, at least in terms
5 of their understanding of the need for comprehensive disclosure
6 of their opinions and the basis for their opinions. But I
7 don't want anybody to be surprised later on. There's not going
8 to be any flexibility or daylight between what's in the report
9 and the testimony that's permitted at trial. So just be
10 mindful of that going forward.

11 Judge Harz, thank you for your patience on the
12 telephone from New Jersey.

13 **JUDGE HARZ:** Thank you.

14 **JUDGE DALTON:** I want to give you an opportunity to
15 add anything that you want to add before I let these folks go.

16 **JUDGE HARZ:** I would just ask everyone, you know,
17 please realize everything that they send to you and your team,
18 your whole staff, please, of course, include myself and my law
19 clerk -- everyone has the emails -- on everything that goes to
20 you so that you and I all have the same documentation to
21 review.

22 Thank you.

23 **JUDGE DALTON:** I will. And I'm going to include in
24 my order appointing the lead and liaison lawyers that the
25 liaison lawyer has a responsibility to make sure that there is

1 a duplication in any submission, whether it's a filing or it's
2 an informal submission. I know I asked you to send me the
3 PFS's in Word form so that I could look at those. But that's a
4 rare exception. I almost never receive something off the
5 docket. So the liaison lawyer, just be on the lookout for
6 that. It will be in there, and you'll be required to make sure
7 that anything that's filed here is brought to the attention of
8 Judge Harz and vice versa.

9 All right. If there's anything else that either of
10 you have on your mind that you think I could take up that might
11 be helpful, I'm happy to do it before I turn you loose.

12 Mr. Johnston.

13 **MR. JOHNSTON:** Just one quick question. Mr. Elias's
14 clients have made a disclosure about litigation financing,
15 but -- or maybe it's that Mr. Silverman's clients have done
16 that, but Mr. Elias's clients have not pursuant to the local
17 rule. Can I get you to instruct everyone to follow that local
18 rule also, please?

19 **JUDGE DALTON:** Well, the Certificate of Interested
20 Persons would require that you disclose anybody that's got an
21 interest, potentially, in the outcome of the case. And so I'll
22 be sending out --

23 Did we -- Lauren, are we going to send out an initial
24 order or not?

25 **LAW CLERK:** I don't believe so, Judge.

1 **JUDGE DALTON:** You'll be getting an initial order
2 from me that requires the filing of a Certificate of Interested
3 Persons which will -- should obviate the need to look into that
4 any further, Mr. Johnston. I didn't do it automatically
5 because the case didn't come in in the ordinary course, but I
6 will send out those initial orders. And there may be a couple
7 of other housekeeping orders that come out.

8 Anything else? Anything else?

9 All right. Well, thank you-all. I'm hopeful that
10 when we see each other again, we'll be in better shape
11 COVID-wise. We got to a point where -- in fact, when I tried
12 the Coloplast/Boston Scientific case, we were at a pretty good
13 spot. I was able to allow the vaccinated personnel to remove
14 their masks. And we had lots of lawyers, more than we have
15 here. Obviously, our numbers went south in a hurry very
16 shortly thereafter, but we seem to be moving back in a positive
17 direction. So, you know, I'm hopeful that we won't have to
18 continue with the COVID precautions indefinitely. We might.

19 But in any event, I appreciate you-all making the
20 trip. I know that travel is much more onerous than it is
21 ordinarily. And so I appreciate you being here.

22 I will tell you that I'm not -- I'm old school. I
23 like to have the lawyers in front of me. I'm not a fan of
24 Zoom. I'm not a fan of virtual court proceedings. I recognize
25 that we have a responsibility to do it when people's health or

1 safety is jeopardized. And so I don't mean to suggest that I
2 won't do it. But I just very much appreciate having the
3 lawyers here because it's much more productive. I appreciate
4 the fact that all of you took some personal risk in traveling
5 here in light of our health situation in Florida. So I'm
6 mindful of that, and I appreciate you being here.

7 I do want you to know that if you have a personal
8 circumstance that you think makes it unhealthy or unsafe for
9 you to travel, I'm open to that. But you need to file a motion
10 and let me know what your circumstances are. And if I can
11 accommodate you in any way, I will. Just know that my
12 preference is -- my own experience with Zoom and virtual
13 connections has been not particularly good. So I don't like to
14 do it, but I will do it if it's necessary.

15 So, with that, I'll excuse you-all. Thank you for
16 your travel and your time here. I hope you-all stay healthy
17 and well, and I'll see you next go-around.

18 We'll be in recess.

19 (Proceedings adjourned at 12:43 p.m.)
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C E R T I F I C A T E

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

October 4, 2021

s\ Nikki L. Peters
Nikki L. Peters, RPR, CRR, CRC
Federal Official Court Reporter
United States District Court
Middle District of Florida