UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

In Re: Tasigna (Nilotinib) Products Liability Litigation	:	
	:	Case No.:
ROBERT MERCED, ROBERT WITT, TERESA GUSTIN, PAMELA GUSTIN, CHARLOTTE DEAN, RANDY POITRA, DOUGLAS ISAACSON, JEFFREY GIANCASPRO, RONALD HURD, ALLEN GARLAND, ANNETTE SCHIMMING, ESTATE OF GERALD MIELKE, DEBRA CRAIG, CURTIS PEDERSON, BRUCE BECKER, SHEILA COLELLA, RONALD TONGE, STEPHEN LALLY, ROBIN DAVIS, ROGER BURKE, BILLY MILLER, LISA PINSON, EMILY RILEY, MARY ELLEN GALE, POLLY HARRIS, and GREGORY FITCH,	:	6:21-md-3006-RBD-DAB
	:	Orlando, Florida
	:	March 3, 2022
	:	9:31 a.m.
Plaintiffs,	:	
vs.	:	
NOVARTIS PHARMACEUTICALS CORPORATION,	:	
Defendant.	:	

TRANSCRIPT OF MOTION HEARING VIA VIDEOCONFERENCE
BEFORE THE HONORABLE DAVID A. BAKER
UNITED STATES MAGISTRATE JUDGE
AND THE HONORABLE JUDGE RACHELLE L. HARZ
NEW JERSEY SUPERIOR COURT JUDGE

Proceedings recorded by digital recording.
Transcript produced by computer-aided transcription.

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P R O C E E D I N G S

THE COURT: All right. This is Magistrate Judge Baker. I'll ask the clerk to call the case.

THE COURTROOM DEPUTY: Good morning. Case No. 6:21-md-3006-RBD-DAB, in re Tasigna products liability litigation.

Counsel, please state your appearances for the record, beginning with the Plaintiff.

MR. ELIAS: Richard Elias for the Plaintiffs.

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

MS. WICHMANN: Lawana Wichmann with OnderLaw on behalf of Plaintiffs.

MR. OXX: Chris Oxx with Parker Waichman on behalf of Plaintiffs.

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

JUDGE BAKER: Defendants?

MR. JOHNSTON: Good morning, Your Honor. Robert Johnston for Defendant Novartis.

MR. REISSAUS: Andrew Reissaus, also for Novartis.

MS. HOWELL: Kelly Howell for Novartis.

MR. JOHNSTON: And, Your Honor, there are three people who are on video: Charna Gerstenhaber, Jennifer La Mont, and Eric Meyer who are in-house counsel at my client who wanted to

observe today's proceedings.

JUDGE BAKER: All right. And for the record, we've also got Judge Harz from the New Jersey --

JUDGE HARZ: Good morning.

JUDGE BAKER: -- who's here. And I will turn to her and ask any questions that she has and whenever she feels like it.

Let's go ahead and start. I'd like to take up the motion that was docketed at No. 84, the noncustodial sources, first. Who's going to argue that, Mr. Elias? Mr. Silverman?

MR. SILVERMAN: I am, Your Honor, Mr. Silverman.

JUDGE BAKER: All right. Any change since the filings?

MR. SILVERMAN: No, Your Honor. There's been no change. There haven't been any further discussions with Novartis regarding this topic or those two topics.

JUDGE BAKER: I didn't necessarily expect there would be, but I thought I'd ask. Go ahead.

MR. SILVERMAN: Thank you, Your Honor. Your Honor, at issue on this motion are two discrete sets of documents and data which are highly relevant, not duplicative or cumulative of anything which has been produced to date. They are unique in that regard. And frankly and potentially, one of the most important lead issues here is that there is little to no burden to Novartis to produce these documents from these centralized

sources.

I think at the outset, it's important to note two things regarding the specific documents and data being requested. One, these -- the information here involves clinical trials involving the drug Tasigna, and clinical trials are an important piece in any pharmaceutical -- in this pharmaceutical industry as well as in pharmaceutical litigation. They provide high quality evidence of the safety and efficacy of the drug at issue. And as I mentioned a moment ago, in particular, and with respect to the request being made by Plaintiffs here, we are talking about information which is stored by Novartis in non-custodial, centralized sources, meaning that the documents and data are neatly packaged in a finite source and able to be produced with little to no burden.

The two particular sets of information we are requesting here -- are the issue here are, first, documents pertaining to the clinical trials which involved indication other than CML, the non-CML clinical trials which are stored in the CREDI database on behalf of NPC. These particular documents are the core documents which helped to define and summarize the conduct of the clinical trials. By way of examples, they consist of things like study protocols, statistical analysis plans, interim and final study reports, amongst other documents.

There can be no disputes here, Your Honor, that these documents are relevant to the issues in this case. Novartis has

agreed to produce these very documents for the trials involving CML from this very database without the use of any search terms and to just produce them to the Plaintiffs. And whether or not -- the issue of the indication, whether or not something is -- Tasigna is being used in one of these trials for CML versus non-CML, that is of no moment here, Your Honor.

JUDGE BAKER: Do you want to comment on Novartis's position that there's different kinds of studies involved here -- some are ongoing, some are foreign, and some are third parties?

MR. SILVERMAN: Your Honor, that is more -- that argument by Novartis is more directly addressed to the issue of the clinical trial data, the second set of documents. And I'm happy to address that as well.

First and foremost, most of these issues have been raised for the first time on this motion by Novartis. That being said, these are all red herrings as well, Your Honor, or have not in any way been laid out by Novartis. First, the fact that some of these trials may be ongoing does not prevent them being able to produce data which was locked into data sets and then part of interim analyses. There's nothing which precludes them from producing that data. Once it is locked, there is an interim analysis. And then, if they go back and gather additional data, they will then re-blind the individuals for it.

Second, whether or not these trials took place in a foreign

country, I am aware of nothing which -- nothing in any way which changes how this drug works in the person's body based upon whether they --

JUDGE BAKER: Well, there are varying foreign privacy laws.

MR. SILVERMAN: To which Novartis has done nothing to explain what laws they think could be involved, which country they're talking about, which particular data sets could be involved. Their motion is entirely silent on that, other than to say a bunch of maybes and mights.

And to the extent that we have foreign data privacy issues here, we have a protective order in place in this case which prevents any further third-party dissemination of that information. And, in fact, one of the cases cited by Novartis on this particular issue which ultimately was overturned on appeal, a case involving DES, referenced the very fact -- and that was a third-party disclosure, by the way, not a party to the case -- referenced the fact that the underlying court didn't take into account the fact that they could have fashioned a protective order to deal with certain issues. Well, we have one here in this particular case. And Novartis cites no cases on point for any of the propositions that ongoing trials, that foreign data privacy laws preclude the raw data turnover in a pharmaceutical litigation such as this, which is, frankly, a very routine part of discovery based upon the numerous cases

cited by Plaintiffs in which that raw data and Plaintiffs' expert was provided by companies like Novartis.

JUDGE BAKER: What about the third-party studies?

MR. SILVERMAN: Well, this is an interesting point, Your Honor. I don't really -- can't really tell whether these are third-party studies or not. Every study we listed in here we took off of clinicaltrials.gov as being industry funded. We did so for the purpose of that.

Novartis conveniently only says they don't have possession of the data. Well, the Eleventh Circuit says that control, which is the issue here also -- control, could also be implicated if Novartis has the right to request that data and receive it. So to the extent that that is the issue here, Novartis's motion papers are woefully deficient in terms of explaining that particular issue. I find it hard to believe that if Novartis funded these particular studies and then turned around and they don't have the right to their own data. And if they didn't fund the studies, then they should have told us during the meet and confer because I told them straight out on January 4th of this year that if there were studies that they did not have possession, custody, or control of the data, to let me know, and I would take it under advisement. Instead, Novartis just told me they're not producing anything and didn't take me up on my offer.

JUDGE BAKER: All right. I interrupted you. Anything

else you wanted to cover?

MR. SILVERMAN: No, Your Honor. I think our papers address all of the various issues. And I'm happy to answer any other questions you may have at any point in time. Thank you, Your Honor.

JUDGE BAKER: Judge Harz, any questions for Mr. Silverman? You're muted, Judge.

JUDGE HARZ: Thank you. It was all covered. Thank you.

MR. SILVERMAN: Thank you, Your Honor.

JUDGE BAKER: Okay. Who's going to respond for Defendant, Mr. Johnston?

MR. JOHNSTON: I'm going to speak about this motion, and Mr. Reissaus will handle the other motion.

It's important in our view to set the table a little bit here, Your Honor. Novartis has produced almost 15 million documents to the Plaintiffs, from 36 custodians and 11 custodial sources. 308,000-plus are from 11 different custodial sources. And those documents, contrary to Mr. Silverman's representations, include information on CML clinical trials, including study protocols, clinical study reports, statistical analysis plans, and data specification information on CML clinical trials, including study protocols, clinical study reports, statistical analysis plans, and data specifications with CSRs or patient-level data. Those are produced for the CML

cases.

We've then produced the entire regulatory file for Tasigna, including all INBs and NBAs, which includes all studies relied upon by the company to support registration of the drug for CML, which is the only indication for which it has been registered in the United States.

We've produced to the clients ARGUS data runs that is from the safety database, which include not only post-marketing events but clinical trial adverse events. And those, contrary to the suggestion in their briefing, those runs include the ability to search by clinical trial number. Column C tells whether or not it's a clinical trial case or a post-marketing case in what we gave them. Column T tells you the study number. And Column V gives the project code.

So they already have the ability to sort adverse event data based on clinical trials. We've given them preclinical trial information. We've given them post-marketing analyses; in that, we've given them the global program team's SharePoint site. We've given final approval promotional materials. We're in the process of dealing with some hard copies, but those will be forthcoming. We've given Plaintiff and prescriber specific information, organizational charts, standard operating procedures.

There are a couple of items still in play. There's the Excel spreadsheets that we have to redact that we agreed to, and

there's four Swiss custodians that Novartis voluntarily agreed to produce in light of the Court's orders that have to go through a Swiss privacy review before we can produce, and that is underway.

The fact of the matter is that discovery has to stop at some point. There has to be some limit. They're not entitled to every document that theoretically might be relevant. They're entitled to documents that are relevant, reasonably accessible without undue burden and expense and proportional to the needs of the case.

We're there, Your Honor. But with respect to these specific sets, I can -- I will now address those specifically. Plaintiffs are not entitled to discovery regarding non-CML indications and project codes from the CREDI database. We've already given them everything in that database related to CML. Plaintiffs' position -- and by the way, that's 84 million documents, almost 75 gigabytes of data from 11 different sources including CREDI, REDI, and ARGUS. And we've agreed to produce documents from CREDI without using the court ordered search terms in an effort to move this forward to resolution.

The Plaintiffs' position is that any safety data stemming from any trial is relevant to this case, and we don't disagree with that, but we've given that to them. They have it in ARGUS. They have it in ARGUS by clinical trial, and they have it in the hard copy submissions that they've been given from CREDI for

CML. They have it in the summaries of safety and efficacy that are submitted to FDA and the periodic safety reports that were submitted annually for a decade by Novartis to the FDA, which they have been given.

There is some suggestion about sanitizing data that they need these other -- well, let me save that for a second.

One of the things that I think the Court needs to know is that the non-CML files involve 125 cases -- people, patients in one instance; 55 cases in another instance; 629 cases in one instance; 18 patients in another instance. These are not huge numbers of patients, and it's unlikely that those -- reanalyzing whether or not we captured adverse events in ARGUS from those trials correctly is not likely to move the needle on their ability to prove or not their failure-to-warn claims.

JUDGE BAKER: What burden is there to producing those?

MR. JOHNSTON: Your Honor, at some point, any burden is undue and any burden is not proportional where they have cumulative and duplicative evidence that satisfies their needs. And they have that here.

The burden is to collect and produce it. I mean, it's burdensome, but it is -- I'm not -- what I'm saying is they've got what they need to litigate this case, and we need to be done with this litigation with discovery of Novartis. It has to stop at some point. And they've got the safety data, so they don't need these other files. And it's just a speculative fishing

expedition that they're going to find something in those files that they would argue changes the analysis here.

ARGUS provides them all of the safety data from all of the clinical trials. So there's really no reason to get these other files for CML because -- look, Your Honor, we understand why they would want the CMLs. They would want to understand the efficacy -- the risk-benefit calculation and the efficacy of data in those trials. They don't need the efficacy data from a trial on multiple myeloma or GIS, all they need is whether or not there were CVE adverse events, and they've got that, Your Honor. So that's our main argument as to the CREDI.

As to the SAS data, essentially, Plaintiff's expert gives a list of what he says he needs, which is -- let me see where I have that in my notes. Data protocol --

JUDGE HARZ: You're talking about the raw SAS data, right?

MR. JOHNSTON: Yes, yes, Your Honor.

JUDGE HARZ: Okay. Thank you.

MR. JOHNSTON: He says he needs protocols, data analysis plan, clinical study reports, data dictionaries, and patient-level trial data.

As to the CML studies, they have that from CREDI. They have patient-level data. They have CSRs of adverse events, they have data dictionaries, they have the reports, and they have the protocols. He has it. What he doesn't have is it in

computerized electronic form that he can manipulate in a way that we can't verify what he's done and which, you know, he could do 30,000 analyses that don't come up in their favor and find one, disclose the one and not the ones that aren't in their favor. And it's subject to great manipulation, but the fact --

JUDGE BAKER: I bet you can ask him about that somewhere.

MR. JOHNSTON: The fact of the matter is, Your Honor, they have the data already, just not in computerized format. And to the extent the theory here is that the quote/unquote sanitized data hid from the FDA in approving this drug for sale adverse events that would have changed the FDA's decision, that is absolutely and clearly preempted under the *Buckman* line of cases starting at the Supreme Court, including the Eleventh Circuit in the -- give me one moment, Your Honor -- in the *Mink v. Smith & Nephew* case which we cited in our *Colella* briefing at 860 F.3d 1319. The failure to report and failure to warn claims based on pre-approval submissions to the FDA and claiming that somehow the FDA should have been told something different, that's preempted by *Buckman*. The idea --

By the way, they say this is regularly done. I've been doing this for 20 years, I've never produced SAS data. The *Jones* case in which -- that they cite in their favor, I was trial -- I was counsel in that case. We didn't produce SAS data in that case. They didn't even ask for SAS data in that case.

In fact, this is the first time in my experience litigating for Novartis that someone has asked for clinical trial underlying SAS data. So the idea that this is a usual thing in litigation is simply not true.

They have the clinical trial reports; they have the patient-specific data. This is simply their continued effort at a scorched earth, get my hands on everything so I can conduct a fishing expedition in the hopes of finding some difference that they can exploit where they have no evidence that there's been anything improperly reported in the clinical study outcome -- output. It's just a fishing expedition.

And let me -- I need to address the specific categories that you asked about. The reason we weren't able to tell Mr. Silverman whether we had data or not is because we were trying to figure it out. It wasn't an easy task because the client is not used to delving into these databases for purposes of litigation because they've never done it before. It was not an easy task to get answers to the questions. But the studies that we list as not being ours are comparative studies that were done by other pharmaceutical companies. So they were done by industry, but they weren't done by us, and we don't have those data sets. And that's supported by the declaration that we submitted with our papers, Your Honor.

As to -- one second. As to ongoing trials, Your Honor, I've actually litigated this before. Ongoing trials -- interim

results of ongoing trials have no meaning because the trial's not done. Okay. So it's only -- it's likely to change, and it is prejudicial to the client. First of all, no one gets that except the FDA. That's clearly protected commercial information as to how they've conducted their trials and how they're evaluating them until they're -- until the trial is finished.

It is potentially misleading because the interim results may bare very little relationship to the final results, and there are cases that I believe we cited in our brief that say you don't get ongoing trials. When the trial is over, you can have them, but not in an interim basis. So those trials should not be produced, even if the Court were considering something further.

And there is a burden of complying with foreign privacy laws. I mean, the law is the -- the GDPR covers -- governs our trials.

What is that?

MS. HOWELL: It's the European standard.

MR. JOHNSTON: It's the European standard -- because you have to apply the highest standard, so if they want me to identify the standard, it's going to be the European GDPR standard that has to be applied to redact personal information in these trials, which has not been done if they haven't been submitted to the FDA already. So there is a burden associated with that, and there's a burden associated in the statistical

data of collecting that data in a way to turn it over. It's not just sitting there in some -- if it wasn't a trial that was given to the FDA for registration, it is not sitting there in a package as Mr. Silverman suggests. That package would have to be created. So there is a burden associated with transmitting -- finalizing and transmitting statistical data for non FDA-submitted studies.

But the bottom line is that they already have all this stuff. They already have all this stuff, and the reason -- the only reason they offer is speculation for looking at it, is that maybe there was sanitization of the data that they somehow can exploit.

And by the way, if this Court is inclined to rely on Dr. Madigan's or Professor Madigan's statement that he's received this data in other cases, I don't know whether that's true or not. I have reason to think it's not true, at least in some of the cases he cited. We cited those in our papers. We were involved in some of those cases, and we're not aware that he got statistical outputs from clinical trials in those cases. More importantly, in those cases, his expert reports don't rely on clinical trial statistical data. They tend to rely on FAERS data available from the FDA for the analyzing of adverse events.

But if the Court's inclined to give any credence to that declaration, we ask for a deposition of Madigan. I'm not sure how that's going to go because I presume he's going to invoke

all sorts of confidentiality obligations he has in those cases where he testified and reviewed data. So I don't think the Court can give any weight to the statement that he got that information. More importantly, the Plaintiffs haven't cited opinions in those cases where he got that information over objection from the other side. Maybe somebody gave it to him in those cases voluntarily, in an effort to avoid a discovery dispute. But the Plaintiffs don't cite a bunch of cases dealing with statistical data, electronic statistical data that are turned over. All of the cases they cite are just generalized clinical trial data, and we've given them that.

So, Your Honor, in our view there is no adequate relevance for any burden, given the -- what has gone before, given what the Plaintiffs already have. And by the way, this is not unique. None of this is unique because they already have the safety data from all of these trials. So we would ask the Court to deny their request for these materials at this time.

JUDGE BAKER: Judge Harz, anything you want to weigh in on?

JUDGE HARZ: No, thank you.

MR. SILVERMAN: Your Honor, may I --

JUDGE BAKER: I'll give you three minutes for rebuttal.

MR. SILVERMAN: Your Honor, I need about a minute. I think that Mr. Johnston's rambling wildly inaccurate,

accusatorial argument with respect to these particular pieces of documents and data speak very loudly. I would probably need about an hour to respond to each individual inaccurate statement that Mr. Johnston just said as well as his completely ridiculous statement as to what this data is to be used for. Dr. Madigan's declaration speaks for itself.

I would say two particular points that I'd like to raise.

Regarding the interim analyses that he mentioned, the case that Mr. Johnston referred to was a case involving a subpoena, an administrative subpoena being served in the early 1980s against a chemical company who was fighting back against the United States government, and they wanted to subpoena some analyses being done by a third party, the University of Wisconsin. That is obviously the best he could do in that regard. His statements regarding interim analyses and how he's precluded and something about the FDA is just -- I'm not aware of any of that.

The other thing I'd like to say regarding the idea that we have these documents and data, we don't. And that's just a plain and simple fact. And, importantly, with respect to the idea that there are data points included in a PDF in clinical study reports: One, we don't know whether that data is complete; two, it certainly doesn't represent every trial we've requested here; and third, most importantly, the *Sedona Principles* with respect to ESI say that if a party is

keeping it in a form which is searchable and able to done so in electronic form, they don't get a right to turn it over in a degraded format, which is exactly what that was. It's incomplete in the first place.

What we should all be doing here, we should have the data that we requested that they have in the form that we want it that they have it, and then we can all be singing off of the same hymn sheet. Thank you.

JUDGE BAKER: All right. I've heard enough on that one.

Let's turn to the motion that was filed at docket No. 83 in a redacted form and sealed filing docket No. 85.

Who's going to argue that for the Plaintiffs?

MR. ELIAS: I am, Your Honor.

MR. JOHNSTON: Your Honor, may I just ask indulgence? I need to change a technological setting in our room in order for Mr. Reissaus to argue that. So let me do that real quick before you get started if you don't mind.

JUDGE BAKER: Let me know when you're ready.

MR. ELIAS: And, Your Honor, Richard Elias will be arguing that for the Plaintiff.

MR. JOHNSTON: Thank you, Your Honor.

JUDGE BAKER: Go ahead, Mr. Elias.

MR. ELIAS: Thank you, Your Honor. At issue in our motion is a request for documents from 13 additional custodial

files. Ten of these custodians were previously requested in the areas of strategic and the --

JUDGE BAKER: Before you get into it, can you in this context, explain to me what you mean by "custodial files"? I mean, we've been bandying that term around, but these individuals, they're not custodians. They may be document custodians in a technical sense, but I'm a little [indiscernible audio] what we're talking about here. Some of these people don't work there. I mean, we're talking about searching servers, aren't we, that are associated with people? So I'm not sure the custodial term helps us.

MR. ELIAS: Your Honor, I appreciate that, and I think that that's an accurate observation. I think we use the word "custodial files" as a -- as kind of a shorthand for the files associated with these individuals. So, primarily, I think, in these cases, it's on whatever server, the e-mail file associated with these particular individuals. So it's not like something in their office. As you noted, many of these individuals don't work there. So that's what -- that's what we are requesting, similar to what has been requested and produced with the other what we'll call custodians or employees or former employees of the company.

JUDGE BAKER: We may need to explore that some more, but before we leave the subject completely, how many -- I mean, is it primarily the e-mails that you're looking for? I mean,

are there meeting notes? Are there -- you've attached a lot of sales material as exhibits in your filing. I mean, is it that kind of stuff, or is it really the e-mail chains back and forth --

MR. ELIAS: Your Honor --

THE COURT: -- to figure out what the process was?

MR. ELIAS: Your Honor, I think from our perspective the priority is the e-mail, and that -- the reason being is that many of the other documents such as meeting notes, such as brochures, et cetera, are usually attached to e-mails. So when we -- when we use our, you know, search methodology with search terms, et cetera, we're able to pick up a lot of that material by the e-mails. So the e-mails are what we're primarily looking for.

JUDGE BAKER: And have you given any thought to casting this not in a custodial search terminology, but just an old fashioned document demand that focuses on what you describe in your memorandum as the big issue which is the -- who had what connection to the Dear Doctor letter not being sent, right? I mean, there are other issues, but that seems like the biggie.

MR. ELIAS: Yes, Your Honor, that's a very big issue. I guess from our perspective, it's not clear how, you know, how we would formulate the document request, other than a request for the e-mail files from those individuals employing search terms. You know, other than that, we don't have, I think, a

really convenient way to capture the e-mails themselves, although I'm not an expert on the technical side of it. And, you know, if that's something that the Court wants us to explore, we can give that some more thought.

JUDGE BAKER: All right. I wanted that clarification. Go ahead with your argument.

MR. ELIAS: Okay, Your Honor. Thank you very much.

So, with respect to the -- we'll just call them the files of the individuals and, primarily, the e-mail files that we're seeking, as we've stated in our papers, four of them -- well, three we have not previously requested. And at issue are four high-level leaders at Novartis: Alessandro Riva, who was the global head of oncology; Christi Shaw, who was the U.S. president; Phillippe Drouet, who was the vice president of hematology business franchise; and Hugh O'Dowd, who was the global chief commercial officer. These are former employees.

JUDGE BAKER: So they're all former employees?

MR. ELIAS: Yes, they're all former employees.

So the decision to request documents from these individuals is, as you know -- as we noted, three of them we didn't request documents in the first instance. So it comes after careful consideration of the documents that have been produced so far that we've been able to review. And what those documents have revealed and as Your Honor mentioned, one of the big issues is this Dear Doctor letter that was drafted but not sent. What the

documents frankly have shown so far is that there was a collapse at Novartis of the wall between safety and profit motive. And, you know, the evidence which we did not know until we got their recent productions in this case, was that the company actually mapped financially the financial and market share loss, dollar for dollar, that specific warning actions, namely, sending out Dear Doctor letters had on the company.

In Canada, after they sent the letter, they did a financial analysis and estimated that that letter, in and of itself, caused an $8 million loss. They also, based on the decision in the United States, when they were contemplating sending a Dear Doctor letter, they anticipated a much larger loss because the United States is a much larger market. They literally contemplated and anticipated in their budget a $25 million loss associated with sending a Dear Doctor letter.

JUDGE BAKER: I understand that this was important to them, but how does that show that these people who were concerned about money were part of the decision-making process?

MR. ELIAS: Great question, Your Honor.

JUDGE BAKER: Yeah, just as consistent with they need to know what they need to do if things outside their control happen.

MR. ELIAS: Well, Your Honor, so, I think the documents that we set forth -- and, again, we don't have the whole picture here, right, because we don't have the documents

from the individuals that are responsible for, you know, making these decisions. But what we're -- what we have been able to show is that there was a decision to send a Dear Doctor letter. The Dear Doctor letter was drafted; a letter to the FDA was drafted. That decision needed to be ratified by a senior committee in Novartis called FDLT, and the head of that committee was Alessandro Riva, okay, the global head of oncology. And then, once that was -- once that was confirmed or ratified by the committee, it was also going to be ratified by O'Dowd and Shaw as well as Riva who also -- who, of course, stood as not only the committee leader but the head of the oncology franchise.

So in that committee, what we now know is that Riva and his underlings decided not to send the letter. They decided instead to call the FDA, have one of their underlings call a representative at the FDA and leave a voicemail message confirming that they weren't requested to have sent out the letter. And the FDA said, no, we didn't request that, and then they killed the decision.

Importantly, to answer your question, Your Honor, what we -- what we do have is an e-mail from Drouet upon announcing of that decision. And Drouet is the person that was associated with the financial analysis. And his subordinate said, It seems our assumptions were correct. Okay. And that assumption being that they -- the FDA did not request the letter. And it's clear

that this is an input, in terms of their assumptions that they weren't requested to send the letter, that they communicated to the decision makers.

So, Your Honor, it is clear that there is a link that this financial analysis was, in fact, influencing the safety decision making because the safety decision making ultimately was being decided by the people who were also responsible for finances. And we, unfortunately, don't have the complete story because we don't have the e-mails from Riva, from O'Dowd, from Drouet.

Now, Novartis says, Yes, you do -- because they're caught in the e-mails of the custodians that we do have.

But that's wholly inadequate because what we don't have are the horizontal communications between the senior level executives who were pulling the strings and making the ultimate decisions as to whether or not to make warning decisions based on finances. And so, it is our position that we cannot and do not have the full picture of what actually happened and what drove this without the custodial files of these individuals. And we're talking about -- and, yes, our motion is broader, and I'll talk about the other custodians in a minute. But we're talking about four additional custodians who don't work there. There's no incrementally burden -- the incremental burden on Novartis for those custodians is marginal, and we have already made a showing, which is in my opinion, Your Honor, doing these cases for a while, pretty extraordinary evidence. I've never

seen in a products liability case in this day and age, whether it be a Pharma case, whether it be any industry, where a company actually maps the dollar loss not of a safety hazard, but of a warning action, which goes to the very heart of what this claim is, a failure to warn.

So, Your Honor, I think we have made the threshold showing that we need to make in order to get the files from those additional custodians.

JUDGE BAKER: What time frame are you talking about --

MR. ELIAS: Your Honor, the time frame that --

JUDGE BAKER: -- as to scope?

MR. ELIAS: Your Honor, I would -- the scope would be the identical scope that we have set out in the prior order. Now, I will say, in terms of the scope going -- the end date, the end date's going to be governed by their termination of employment. These individuals, I think -- and Mr. Johnston or Mr. Reissaus can confirm -- have been gone from the company since, probably, 2016 and before. Maybe some were there after 2016, maybe, 2017, 2018. I don't know their exact departure dates, but given the fact that they are former employees, these are -- these are fairly limited scope and in time.

JUDGE BAKER: Well, but isn't it also limited by when decision making occurred?

MR. ELIAS: Well, Your Honor, yes, but I think the decision making, we don't know when the decision making

occurred. I mean, I think we know the time frame of a Dear Doctor letter, but I think what this opens and shows is that the decision making, all along, was occurring at these levels. And so the decision -- we should have been entitled to the custodial files, you know, in the dates that we set forth in terms of the start dates in the prior order or per agreement. And I forget exactly what date that is.

Your Honor, if you don't have any more questions about that, I'll briefly address the other custodians. The other custodians as we set out in our papers, and I don't think we need to go into great detail into each of the individuals, but I think the overarching message here on the marketing, the strategic marketing, the global marketing, and the sales, is that these departments, okay, weren't just, you know, printing brochures. They weren't just, you know, even deciding what language would go into a particular advertising piece. What's clear from the testimony of their representative Mr. Fosko and the documents that we've revealed to the Court is that these individuals were involved in key strategic decisions that had to do with sending Dear Doctor letters, had to do with messaging to physicians. And, Your Honor, one document in particular that I would like to point the Court's attention to is the document -- is Exhibit 1 in this case. And that's the exhibit that we cited. That's the exhibit where they mapped the financial loss of the Dear Doctor letter in Canada. And on page 6, there's

kind of a timeline, a map of what actions they had taken and were going to take. And one of the actions says, A comprehensive plan of action to establish confidence in Tasigna as the standard of care for CML patients, okay, which included sales force training and meetings with physicians. Okay.

So we have shown that the financial decision and the impact of that warning and how they were going -- in Canada, the Dear Doctor letter and how they were going to address it involved marketing and sales. It involved a comprehensive plan of action to train the sales force and have meetings with physicians to train them and message what -- their view of the world of the cardiovascular risk. And, Your Honor, the documents reveal that when they talked to physicians, they were told to basically tell physicians that cardiovascular risks are a class wide effect, every other TKI has a cardiovascular risk -- which isn't true -- and that Tasigna was the most efficacious. And it is our position and we will show that that is misleading and it's false. But what we are able to show here is that marketing, sales had a direct tie to the company's financial concerns that warning decisions had on the company.

And, Your Honor, unless you have any other questions, I don't think we need to go through all the individuals that we have -- that we've listed. The only thing I will say is that we didn't want to burden the Court with a hundred additional exhibits which we could have done. We have multiple documents

for all of these individuals. We were trying to give the Court a flavor of their involvement, but I think that we've made the appropriate case for these specific individuals in our papers.

JUDGE BAKER: Judge Harz, anything you want to interject to Mr. Elias at this point?

JUDGE HARZ: Not at this point. Thank you.

MR. ELIAS: Thank you.

JUDGE BAKER: All right. Mr. Reissaus, are you going to respond?

MR. REISSAUS: Yes, Your Honor, thank you.

I'll start with Mr. Elias's last comment that they have hundreds of additional documents that would somehow support this motion. They've got 46 that they grouped into eight exhibits. Looking at those, that must be the best that they can show for these folks, and it does not meet the burden to expand production beyond what they already have.

Their characterization of the documents is not correct. And they've deposed witnesses about these issues, and they don't -- the testimony does not line up with what they've said here and the documents do not. And you're hearing their speculation, and they're asking for you to allow them to go on another fishing expedition.

They want 13 additional custodians. They say three of those are new; however, those have -- the three that are new are ones that they asked for in the prior litigation years ago, and

the Court denied those there. There was no showing then; there's no showing now.

Two reasons you know this is a fishing expedition. Mr. Elias -- you asked Mr. Elias what time frame is appropriate here. And he said, well, the time frame for discovery in this case. Which, the Court has allowed some discovery pre approval of Tasigna in 2007, all the way through present. And so, for these 13 custodians, it is their entire time in role working on Tasigna, or overseeing Tasigna for these six high-level executives. These are folks that are in different positions, from vice president of hematology and further up in the company, who receive documents about a plethora of products, dozens of products and when they're --

JUDGE BAKER: Don't the search terms --

MR. REISSAUS: No --

JUDGE BAKER: Aren't they going to limited it just to Tasigna?

MR. REISSAUS: That's a good question. You would think so, but that's not how it works in reality. As Mr. Elias told you in a previous conference when you asked him how Plaintiffs' review of documents are going, they said many of the documents they're looking at have little relevance if any and suggested that put a burden on them. Well, that's the result of the search terms that we have which are extremely broad and include terms that were added over our objection.

THE COURT: Well, but can't you experienced, sophisticated litigators figure out how -- a way to narrow this down so you only get the things that are related to what's been argued in the materials that have been submitted to the Court?

MR. REISSAUS: We asked Plaintiffs that. As part of this meet and confer, we said, Can you tailor your request? Can you focus in on particular time frames or search terms that hit the issues you seem to care about on these custodians?

They declined to do that. I will tell you, the executives that Plaintiffs allege were involved with the Dear Doctor letter decision in the U.S. -- which, they've mischaracterized that record -- they've worked at the company for years, and this decision is a three-month period from January of 2014.

And an important fact that you did not hear in the argument just a moment ago. FDA released a brand-new guidance at the same exact time they approved this label update for Tasigna in January, 2014. And it is entirely reasonable to ask FDA how that new guidance applies, especially when that guidance says that FDA will give you a direction if a Dear Doctor letter is required in response to a label change. And it also is appropriate, where the FDA required a Dear Doctor letter for a competitor product just a few months earlier, to ask that question and get an answer to it is a reasonable thing. And the documents that Plaintiffs cite do not show that it was -- this was a decision that was contemplated and driven, and the strings

were pulled from up on high. The U.S. team, Katie Chon, who is a custodian is on these e-mails, the global program team members for Tasigna who are custodians are included on these e-mails. Plaintiffs have the communications up and down and with the people who had to implement any decision. There's no need for additional discovery there.

JUDGE BAKER: I wanted to ask you that. How much more -- how many more documents do you estimate would this retrieve if we narrowed it down to, let's call it, a more pertinent time frame?

MR. REISSAUS: I couldn't tell you because I don't know what the pertinent time frame in Plaintiffs' view would be on this Dear Doctor letter. Are you --

JUDGE BAKER: I'm not talking about the Plaintiffs' view. I'm talking about the view of the Court.

MR. REISSAUS: So we would have to go look. And my concern is that we have extremely broad search terms here. And we've also, at Plaintiffs' insistence, we've not been able to take advantage of e-mail threading. So as a result, every time an e-mail gets forwarded on to someone else, you get an earlier copy of that communication over and over again, which has expanded the scope of what we've had to do and will apply here as well.

JUDGE BAKER: But you've got some de-duping technology that you can use to strain that stuff out, can't you?

MR. REISSAUS: So, we can -- we -- de-duping is one aspect, which is, if ten people are on the same exact e-mail, we can usually narrow that down to just one copy. The issue with e-mail threading is, if Joe sends ten people an e-mail, and then one of those people forwards it to another person, they'll get that original e-mail once and then the next one, and each time it gets forwarded on, even if the original e-mail is not changed, we're producing that original e-mail each time it gets forwarded on, rather than just the last in time that captures everything that was unchanged before. It increases the volume. I point that out because this is part of a pattern of asking for everything and not tailoring requests. And at this point, they have what they need. They have the U.S. marketing teams, and they have the -- they have the Tasigna product team that actually was implementing things.

The burden for Novartis here goes back to human review. If the search terms -- no matter what the scope with search terms or time frames -- every document, we are looking at it with a human reviewer prior to production. And as you know, that has come at great expense and great burden and under a very tight schedule. And we've hired more than 200 attorneys who worked dedicated to document review here, and we should not have to reopen that now. The documents that Plaintiffs cite, 70 percent of them come from things that they had years ago. The additional documents are more of the same. They are not opening

new issues here. This is -- this is a rehash in an attempt to just relitigate the fact that they want closer to 50 custodians instead of 36. I think I've addressed the executives, that and the Dear Health Care Provider letter issue here.

Moving into the marketing folks, we fundamentally disagree with Plaintiff's characterization of what strategic and global marketing are. And the testimony of Mr. Fosko, which the Court has seen on prior occasions, does not reflect that. Plaintiffs have six U.S. marketing custodians already that cover all time frames involved with this case. And that is the team that is involved with the strategies as they are implemented in the U.S., and if there are global or strategic marketing people who are in meetings or communicating with the broader team or communicating with the U.S. marketing team that would have to implement any of these allegations that Mr. Elias has made, those are captured in what Plaintiffs already have. And that's why they've been able to identify these issues. And they've asked about them in prior deposition.

There's no need to expand an additional six -- or, excuse me, seven strategic and global marketing team members on that basis.

The last thing I'll say here is that notably missing from Plaintiffs' briefing was the idea of proportionality, and that really is what we have to focus on in here. There has to be a spot to draw a line on discovery, and 13 more custodians is not

the place to do that.

This is not Novartis's burden to prove proportionality here. Plaintiffs have an affirmative duty to make a showing of proportionality when they make the request, and the case law that we cite in our brief talks about that fact, that Plaintiffs bear that burden.

It is not enough to show that additional individuals may have some connection to the events at issue. The issue is whether the burden of expanding production beyond what it already has is justified because they have some uniquely relevant information, not necessarily another version of the same document. Is there something unique out there that they haven't gotten yet? Is there marginal utility, I think, as you put it previously, to expanding discovery beyond what Plaintiffs have? It's not the case here, and we ask that you deny Plaintiffs' motion.

I'm happy to answer any questions you or Judge Harz may have.

JUDGE BAKER: Judge Harz, anything else from you?

JUDGE HARZ: I just want to -- am I on mute?

JUDGE BAKER: No.

JUDGE HARZ: No, I'm not on mute.

I look at, like, on page 18 and 19 of Plaintiffs' submission on this issue, and they give examples like, for example, James Campbell and Jane Vesotsky and why those

individuals are important to them and why their custodial files would be important. Like, "James Campbell...key role in developing the messaging for...Tasigna global brand and marketing team related to PAOD risks and multiple documents demonstrate...he was involved in determining how" -- Novartis -- "employees should 'reactively respond'" -- and that's in quotes -- "to such risks." "Part of Plaintiffs' contention in this matter is that" -- Novartis -- "downplayed the cardiovascular risks of Tasigna in order to promote the drug over its predecessor...." "Documents that address the messaging surrounding these risks and, by extension, the custodians who were involved in creating those documents and messaging, are critically important to this claim."

How do you say that it's not?

MR. REISSAUS: So the --

JUDGE HARZ: I just picked one.

MR. REISSAUS: Uh-huh, yeah. So the marketing of Tasigna and the plans for Tasigna, they have six custodians that already are doing that. And the fact that there's someone else that has a role in the global part of the organization that is dealing with non-U.S. markets, the fact that someone was doing that focused on the worldwide markets is not -- there's not marginal utility to expanding discovery on those folks.

I will note, some of the folks that they've included in this section, for example, Richard D'Addabbo, that's someone

whose involvement predates the events at issue here. He's not a -- he wasn't around when cardiovascular events were identified as a signal. This request is not targeted, and it's not an attempt to get things that they don't already have. This is an attempt to impose additional burden here.

JUDGE HARZ: It says, "...in 2014, D'Addabbo was involved" -- in -- "...creating a 'Customer Challenge tool' which appeared to develop messaging to establish Tasigna as the recognized standard of care in CML, including by switching 'appropriate' -- I can't -- 'imatinib-treated patients to TAS.'" "The latter issue is something Plaintiffs specifically allege in their complaints and goes" -- on -- "and goes to assertions that" -- Novartis -- "...improperly persuaded physicians to prescribe Tasigna over Gleevec, the safer alternative, in an effort to increase profits and maintain market share."

I mean, what I'm saying is there's been a showing for each of these individuals in the papers as to why it's relevant to their claims and a reasonable basis to seek the documents. You're just saying they already have it. It's too much. It's too burdensome.

And then I look at Jane Vesotsky, that's Canada and the U.S. Her involvement includes direct comments regarding CVE messages for the CVE work group. She developed -- she had a "role in developing language to address the severe risks associated with Tasigna, especially where she...allegedly in a

'marketing' position, goes to Plaintiffs' contention that these 'commercial-side' individuals extended well beyond their titles in a cross-functional way that impacted the messaging about...risk-benefit profile of the drug."

What the Plaintiffs are saying -- this goes to their claim that the company put profits over safety, and the people who were involved in profit making were involved in safety.

So are you saying you disagree, they haven't shown a causal -- a reasonable need? Because, for each one they show a reasonable need.

MR. REISSAUS: Your Honor, yes. I do not believe that they have made that showing. I will tell you, with the first person you mentioned, Richard D'Addabbo --

JUDGE HARZ: Right.

MR. REISSAUS: -- the switch that they're talking about, that is not something related to cardiovascular events. And, again, global versus U.S., and they have this document already. They have the U.S. team. They have other members of the global program team. They don't need to expand to him.

Now, with regard to Jane Vesotsky, I will admit that is a more difficult call there. She was a member of the cardiovascular working group internally at Novartis. The reason her -- including her as a custodian is burdensome here is because Plaintiffs already have numerous other members of that working group. They do not need the e-mails of every single

member of that group. That's scorched earth litigation that's done with the purpose to impose costs. There's no evidence --

JUDGE HARZ: Okay. Let me hear from Mr. Silverman as to the last or whoever is going to respond. Could you respond, you know --

MR. ELIAS: Yes. Yes, Your Honor. So let me, let me say this. And I guess my response is, I'll -- I will respond to the last thing that Mr. Reissaus said.

Jane Vesotsky, who is senior product director, global product strategy, was a member of the cardiovascular working group at Novartis. Okay. That's a working group that was set up to analyze the safety signal, okay, and form a strategic plan of action, supposedly, for safety in terms of what they received. She is in -- she's a strategic marketer. Okay. So what we have shown and what the documents show is that there was no wall between marketing and safety. And so, what we're asking for here, we have not received from -- we have made a showing for all of these custodians. And for these custodians in these functional areas, strategic marketing and global marketing and sales, we have not received one custodian. So we have shown that there are multiple custodians. And it goes beyond this list, okay, but we're trying to reduce it to be as reasonable as we can that these individuals were all involved in the key safety issue of cardiovascular.

JUDGE HARZ: And on October 26, 2021, it was basically

said that the issues having to do with these types of individuals would be -- those related to marketing could be deferred until we were further advanced so we could understand what significance, if anything, there was with regard to these particular custodians, right?

MR. ELIAS: Correct, Your Honor. That's why -- that's what we're doing here. We believe we've made the showings.

MR. REISSAUS: Your Honor, I would note, the pieces you read from Plaintiffs' brief, those are their advocacy statements. And it's necessary to look at the documents for what they actually say behind them, and they don't say what Plaintiffs say they say.

The fact that there are additional people that worked on Tasigna is not a reason to add 13 more now. The question is, do they have what they need? And they do. They have the documents on all of the issues that they've identified here in their brief, and they're able to ask witnesses about those now.

The Court deferred ruling on additional marketing custodians beyond what Novartis already agreed to do. We agreed to provide U.S. marketing, and there are multiple members of the global program team. They have the core of the people who worked on the issues that are involved with this litigation, and the fact that other people may have touched it at isolated moments in time is not a basis to further expand discovery beyond what it is. Thank you.

JUDGE HARZ: Had you given them any strategic marketing custodians prior or just U.S. marketing?

MR. REISSAUS: It's been U.S. marketing, and there was one global marketing custodian in the prior litigation, Rebecca Jolley.

JUDGE HARZ: Right. Okay. Thank you.

JUDGE BAKER: All right. Judge Harz, you don't have any corresponding motions that are pending in front of you, correct?

JUDGE HARZ: No.

JUDGE BAKER: All right. Obviously, this affects your litigation. That's why we certainly appreciate your taking the time to join us and make pointed inquiries. I will be taking these motions under advisement and preparing an order resolving them. We do have a further hearing set for April 13th with Judge Dalton and me and Judge Harz, probably, as well if it suits her schedule. We'll have this resolved before then, and you'll be able to report to us.

And without indicating any rulings on anything, as you may anticipate, as is frequent here, the -- there's a substantial likelihood that Plaintiffs will get something but not everything. So I don't think either side's going to be thoroughly happy with whatever ruling I make, and if there's some lingering issues on that, either I'll take them up, or we can take care of them in April. But we are -- as counsel have

indicated from both sides, the clock is running. We're running out of time here, and although there will be a time change in a week or so, it's not going to help you much. You should get this thing ready for trial and other proceedings.

So having said that, before I conclude the hearing, I'll go back and forth between, first from the Plaintiff, anything to add at this point?

MR. ELIAS: Nothing from the Plaintiffs, Your Honor. Thank you for your time this morning.

Thank you, Judge Harz.

JUDGE BAKER: Mr. Johnston, anything from you?

MR. REISSAUS: No, Your Honor. I'm on mic, but Mr. Johnston says no too.

JUDGE BAKER: All right. And, Judge Harz, anything you want to add for good of the order?

JUDGE HARZ: No. Thank you. Thank you.

JUDGE BAKER: All right. We will be in touch.

MR. ELIAS: Thanks, Judge.

MR. REISSAUS: Thank you.

(WHEREUPON, this matter was concluded at 10:37 a.m.)

* * *

CERTIFICATE OF REPORTER

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

/s/ Suzanne L. Trimble 3/8/22

Suzanne L. Trimble, CCR, CRR, RPR
Official Court Reporter

Date