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UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION
CASE NUMBER 6:21-md-3006

IN RE:

TASIGNA (NILETINIB) PRODUCTS LIABILITY LITIGATION

| | | |
|--------------------------|---|--------------------|
| ROBERT MERCED, ET AL., | : | |
| | : | |
| Plaintiffs, | : | |
| | : | Orlando, Florida |
| v. | : | April 22, 2022 |
| | : | 10:06 - 10:30 a.m. |
| NOVARTIS PHARMACEUTICALS | : | |
| CORPORATION, | : | |
| | : | |
| Defendant. | : | |
| | : | |

TRANSCRIPT OF DISCOVERY CONFERENCE
BEFORE THE HONORABLE DAVID A. BAKER
UNITED STATES MAGISTRATE JUDGE
AND
THE HONORABLE RACHELLE L. HARZ
NEW JERSEY SUPERIOR COURT JUDGE

Court Reporter: Amie R. First, RDR, CRR, CRC, CPE
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Proceedings recorded by Realtime Stenography.

Transcript produced by Computer-Aided Transcription.

1 APPEARANCES VIA VIDEOCONFERENCE:

2

3 Counsel for Plaintiffs:

4 Raymond C. Silverman

5 Christopher C. Oxx

6 Harrison M. Biggs

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8 Counsel for Defendant:

9 Andrew L. Reissaus

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P R O C E E D I N G S

THE DEPUTY CLERK: Case Number 6:21-md-3006,
In Re: Tassigna Products Liability Litigation.

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

MR. SILVERMAN: Good morning. Raymond Silverman
of Parker Waichman on behalf of the plaintiffs.

MR. OXX: Good morning, Judge. Chris Oxx of
Parker Waichman on behalf of the plaintiffs.

MR. BIGGS: Good morning. Harrison Biggs,
Parker Waichman, on behalf of the plaintiffs.

MR. REISSAUS: Andrew Reissaus for Novartis
Pharmaceuticals Corporation.

JUDGE BAKER: I'll note we've got Judge Harz on
the line as well.

JUDGE HARZ: I'm here. Thank you.

JUDGE BAKER: And I'll leave you to your own
devices, but as far as I'm concerned we don't need this
many attorneys for resolving little discovery disputes.

But anyway, I scheduled this because, in part,
I've noticed that there was an issue. And we gave you some
pretty stern warnings at the last status conference about
keeping things moving, and I didn't want whatever this
little problem is to slow things down.

1 So who wants to speak on behalf of the plaintiff?
2 And tell me what the problem is.

3 MR. OXX: Good morning, Judge. I'll speak on
4 behalf of the plaintiffs, Chris Oxx.

5 So, Judge, we previewed this issue for you a bit
6 at the end of the last conference. We're here regarding
7 your March 15th order that compelled production of
8 documents from eight new Novartis employees.

9 And, in particular, four of those employees were
10 executive-level employees that were involved in the
11 important labeling decisions and the decision not to send a
12 Dear Health Care Provider letter in 2013, 2014. Based on
13 this, you restricted the production from those custodians
14 to only 2013-2014.

15 But your order also contains language stating,
16 quote, the search protocol should be modified to combine
17 results to Tasigna-related materials and not other oncology
18 products.

19 Novartis has latched onto this language to suggest
20 that the current search terms that have been used for every
21 other custodian should for some reason be modified here.

22 Judge, the search terms at issue here, some of
23 which were agreed upon and some of which were court
24 ordered, are already anchored to Tasigna-related terms.
25 What this means is that if the document doesn't have both a

1 Tassigna term and one of the search terms, it's not going to
2 hit. So these terms are already crafted to confine the
3 results to Tassigna-related material.

4 NPC's proposal and what they have proposed to
5 plaintiffs is to only use CVE terms here. That would
6 eliminate terms like label, safety, warning, risk. And,
7 Judge, this issue has already been litigated.

8 NPC took this same position in its original
9 briefing submitted to this Court relating to the search
10 terms for the broader production. That argument was shot
11 down by the Court, and the search terms that we're left
12 with are the ones that were ordered.

13 NPC has made no showing as to why different search
14 terms should be applied to these four custodians than were
15 applied to every other custodian in this litigation,
16 especially given that these custodians only are being
17 ordered to produce from a two-year period.

18 In addition, Judge, to the extent any
19 non-Tassigna-related materials are picked up in conjunction
20 with the agreed-upon search terms, Novartis can continue
21 its current practice that is agreed upon in our ESI
22 protocol to redact any non-Tassigna-related material that
23 appears in those documents.

24 So there really is no issue here. We are of the
25 opinion that the search terms that are currently in place

1 already comply with the language that was in your order.
2 We did not ignore the language that was in your order like
3 NPC has accused us of. We are of the position that we are
4 already in compliance with it.

5 And, you know, if we don't include the terms that
6 are currently agreed upon and we only use CVE terms like
7 Novartis suggests, we're going to miss emails that could
8 say something like, you know, We need to do everything we
9 can to keep these warnings out of the Tasigna label because
10 it will negatively impact our sales.

11 If we go with just CVE terms, we're not going to
12 get that dump.

13 JUDGE BAKER: Who wants to respond?

14 MR. REISSAUS: I'll respond, Judge Baker. This is
15 Andrew Reissaus for Novartis.

16 To start off with, this comes down to an issue of
17 proportionality here. We did litigate search terms with
18 the initial custodians. The Court ordered and agreed to
19 36 at the start. We're now at 48 custodians.

20 The additional custodian order is adding things at
21 the margin based on what documents plaintiffs' submitted to
22 you and you allowed. You recognized that they should have
23 some documents from these four custodians, but then there
24 were considerations to take into account with these
25 high-level executives, particular to the fact that they are

1 high-level executives, and their involvement would be
2 indirect and through people who are already custodians.

3 The fact that this is limited to a single issue
4 that plaintiffs identified which was an allegation that a
5 Dear Doctor letter was not sent as a result of some conduct
6 or choice or decision by these four individuals, which, of
7 course, we dispute, but you said that plaintiff should be
8 entitled to some discovery from their emails to see if
9 there's anything more there.

10 Your order was clear that proportionality plays
11 into the scope of production for these four, and you
12 recognized that by limiting the time period to 2013 and
13 2014. That's actually very broad.

14 The label change that's involved here was approved
15 in January; January 22nd, 2014. And the decision about
16 whether or not to send a Dear Doctor letter based on new
17 FDA guidance happened in February. Yet we have two years
18 of discovery for a decision that's in a very tight period
19 of time. And, in fact, a letter did go out in April to
20 treating physicians. So two years of discovery for
21 something over three or four months, that seems plenty
22 broad.

23 And your order then recognized that there should
24 be -- the parties should modify the search terms. We took
25 that at its word to mean that we should consider and talk

1 with plaintiffs about whether the search terms could be
2 narrowed in an appropriate way to get at what plaintiffs
3 have identified as what they think they need.

4 We made a proposal. And the timing here, it took
5 a little extra time because we didn't receive a copy of the
6 order, of course; but we were doing things as soon as we
7 found out about the order to make sure that we were moving
8 along.

9 So we're plugging ahead, including having the
10 documents that hit on the search terms that we agreed to --
11 agree to use, the CVE terms. Those are in the review queue
12 now. So we are working.

13 The question is whether we should use a narrowed
14 search terms set. Plaintiffs have declined to make any
15 narrowing at all or stick with what they currently are.

16 As a practical matter, how that plays out here,
17 for these four custodians, using the full search term set,
18 we would have 54,674 documents to review. The narrowed
19 search terms that we propose, which are actually still
20 pretty broad, bring in 34,440 documents.

21 So it is a -- there is a reduction. But it's not
22 like we're saying we only want to review 10 percent of the
23 potential hits under what plaintiffs want. It's still
24 sizable. It's just tightening it some to decrease the
25 incremental cost.

1 And the reason --

2 JUDGE BAKER: Are those numbers, those are
3 documents that haven't been produced by anybody else?

4 MR. REISSAUS: Correct. These are deduplicated
5 totals against the existing custodians already.

6 So these are -- if any of these four individuals
7 already emailed with the team and it hit on a search term,
8 that's in because of the other custodians that have already
9 been --

10 JUDGE BAKER: Okay. Why wouldn't these documents
11 be pertinent --

12 MR. REISSAUS: Because --

13 JUDGE BAKER: -- at least potentially?

14 MR. REISSAUS: Any email in their emails could be
15 potentially relevant. The question -- the plaintiffs are
16 not entitled to all documents. They're entitled to what's
17 reasonable and proportionate to produce here.

18 And we've moved heaven and earth to produce
19 1.57 million documents from employees' emails already. And
20 we're talking about an additional request that came after
21 we really, really -- we hired more than 200 people to work
22 on this in December to get through the first batch. And we
23 have 150 people working now.

24 And every time we cross a threshold, we get a
25 request for more: We want broader. We want more. We

1 refuse to narrow in any way.

2 This is a reasonable narrowing.

3 In fact, the only identified reason for these
4 custodians has to do with a Dear Doctor letter, but
5 plaintiffs want every aspect of marketing.

6 And let me give you a few examples of search terms
7 that play in here. So --

8 JUDGE BAKER: Well, what is it that you're hoping
9 to eliminate in your modification of the terms that would
10 reduce the burden on you without excluding things that
11 might be pertinent?

12 MR. REISSAUS: We are not -- the question is, can
13 we eliminate things that are marginally or not relevant?

14 So in the December status conference, in response
15 to Judge Dalton asking Mr. Elias about what plaintiffs were
16 finding in the documents, Mr. Elias told the Court that
17 what I can tell you is that when you get a database in
18 documents as large as we have, there are a number of
19 documents that are not relevant or marginally relevant.

20 And that's after the human review has to happen
21 and they culled 50 percent of the documents out, and
22 there's still pools of marginally relevant or irrelevant
23 documents by plaintiffs own admission.

24 Specifically, there's terms like Lucentis in the
25 search terms, which we've always opposed. Plaintiffs --

1 that's a whole -- that's another product. And plaintiffs
2 have not explained why that search term -- at any time have
3 they explained why they need that search term. We still
4 have these types of things in there.

5 And another example is the term "launch." Tassigna
6 was launched in 2007 for second line CML, meaning patients
7 who had failed prior treatment with Gleevec, and in 2009
8 for a first line treatment. But there's no launch in 2013
9 or 2014. There's a labeling.

10 But the plaintiffs' proposal unnecessarily
11 increases the burden for Novartis to review additional
12 documents that are unlikely to net additional probative,
13 important documents.

14 JUDGE HARZ: Well, in terms of the emails, those
15 really weren't how the arguments started. You were arguing
16 about the words "warnings" and "safety." I mean, you're
17 talking about "Lucentis" and "launch."

18 But from what I'm reading from the -- I asked to
19 see what the issue was. You were arguing you wanted to
20 take out the words "warning" and "safety." And that's why
21 we're here. Maybe if you were talking about "Lucentis" and
22 "launch," we wouldn't be.

23 Isn't that really what happened?

24 MR. REISSAUS: No, Your Honor. That's not what
25 happened.

1 What we did was we made a proposal to plaintiffs
2 of a targeted search term set, and their response was, We
3 will change nothing. If they said there's one or two
4 additional terms that we think were in the search term set
5 that would be appropriate, that's something to discuss; but
6 that's not what happened here.

7 We had, You're trying to relitigate an issue. But
8 it is not true. Proportionality is request-by-request. It
9 must be assessed. It's not a determination across the
10 board for all time.

11 JUDGE BAKER: Let me make an observation and then
12 get a response from Mr. Oxx.

13 You have to understand when these things get
14 presented to the Court and we have arguments at hearings or
15 I review your documents and issue an order, I've got a
16 fuzzy snapshot of what you all have been up to. And I do
17 my best to understand your arguments and evaluate it and
18 give you directions that's proportional, relying on you to
19 implement that.

20 And when I used the language "modified and exclude
21 other products," I thought -- I mean, those aren't terms of
22 art. I thought, based on something that somebody said at
23 the argument, that that meant that you had some way to take
24 out other products, because obviously these executives had
25 more than one responsibility.

1 But it's not as if I've got some great insight in
2 how to do search terms that relate to your database or
3 how -- what these -- all the different activities these
4 individuals had.

5 And I cut down the number of additional
6 individuals whose records are being searched and the dates.
7 And if you didn't like the dates, you could get a little
8 more precise in your argument.

9 So let me hear from Mr. Oxx about "launch" and
10 "Lucentis."

11 JUDGE HARZ: And "label," and "publication,"
12 "risk," "safety," and "warning."

13 I'm looking at the April 14th letter from
14 Hollingsworth, second paragraph. Those seems to be the
15 words everyone is discussing: "Label," "launch,"
16 "publication," "risk," "safety" and "warning."

17 MR. OXX: Sure, Judge.

18 And we've heard a lot of argument from
19 Mr. Reissaus, and we've been back and forth with him a
20 number of times.

21 The one thing, the one question that we've never
22 gotten an answer to is how the search terms that are
23 currently in existence are not structured such that they
24 can find the results to Tasigna-related materials. As I
25 stated at the beginning, everything is anchored to Tasigna.

1 Now, as far as Lucentis goes, Judge, that's a red
2 herring. They've latched onto one example of a term that
3 was included because it had some relation to some failure
4 to report adverse events.

5 And, quite frankly, Judge, if they had come to us
6 and said, Hey, we don't want to use Lucentis here, that
7 would have been a different story.

8 To Judge Harz's point, we probably could have
9 reached an agreement there. They came to us and said, The
10 only thing we want to use here are CVE terms.

11 JUDGE HARZ: Medical terms.

12 MR. OXX: Correct. When I say "CVE terms," I mean
13 terms that would capture things like heart attack, stroke,
14 atherosclerosis, cardiovascular disease, things of that
15 nature.

16 If this issue was one of Lucentis, we wouldn't be
17 in front of you right now.

18 JUDGE HARZ: The whole purpose of this exercise is
19 you want to find out if these marketing people were
20 involved in decision-making pertaining to this Dear Doctor
21 letter as it relates to profits in the company. That's the
22 whole purpose of the exercise.

23 So your point is having medical terms -- CVE, as
24 you call it -- is not going to generate any of the
25 documents that would lead, you know, to discovery if they

1 were concerned about profits, if they were concerned about
2 warning, if they were concerned about the issues having to
3 do with marketing.

4 MR. OXX: Yes.

5 JUDGE HARZ: Okay.

6 MR. OXX: And the fact that they are trying to
7 exclude what sounds like 12,000 documents after having
8 produced 1.5 million makes me concerned that there's some
9 really good documents in there that they don't want us to
10 see.

11 MR. REISSAUS: Your Honor, can I respond quickly
12 to that?

13 JUDGE BAKER: All right.

14 MR. REISSAUS: That's -- frankly, that's one of
15 those allegations that's just not fair or appropriate to
16 make here.

17 This is about burden to review. Humans look
18 through each document that's on these search terms before
19 they're produced. And it's cost. And I'm here to seek a
20 ruling that establishes a reasonable boundary for discovery
21 here.

22 Now, if the CVE terms are not, in plaintiffs'
23 view, are not going to return the documents they need on
24 this issue, we should exclude those. I'll take the 34,000
25 out and I'll --

1 JUDGE HARZ: No, that doesn't make sense.

2 MR. REISSAUS: -- whatever comes in on the other
3 ones.

4 JUDGE HARZ: That doesn't make sense, because
5 those terms are going to be used in the context of safety
6 and warning and risk. They're going to come in under the
7 same paragraph.

8 MR. REISSAUS: Right. Yes, Your Honor.

9 And if they hit on those generic terms of "safety"
10 and "warning," then they will be in the pool to review.

11 But the problem with these custodians, which is
12 true of all custodians but especially true here, is that
13 they work on multiple products. And so they have documents
14 that have 10, 12 products in a PowerPoint, let's say.

15 And so if one slide happens to mention "heart" in
16 it, "have heart team," and has a slide about Tassigna that
17 says, you know, "it was approved in 2011" -- or 2009; but
18 then it has "heart" in another slide and then 55 slides
19 about other products and proprietary things about the sales
20 of those, that document is pulled in by these search terms.
21 And that's the problem.

22 It's not that the Tassigna anchor term doesn't
23 solve that problem. And there is burden associated with
24 pulling in general company documents that don't really have
25 to do with CVEs or this Dear Doctor letter or the issues in

1 the case, and so we looked for a way to narrow this down.

2 You will see that I did not ask the Court or
3 plaintiffs to exclude every document that contains another
4 product mentioned because that could be too broad. That
5 would be a reasonable way to go about this and that would
6 have cut out 30 percent of the hits, but we haven't asked
7 for that. We were trying to find something appropriate as
8 a comprised position.

9 And the established search terms are extremely
10 broad and it's just adding work -- work when we should be
11 wrapping up things and we should be focusing on what's most
12 likely to contain the relevant information.

13 JUDGE BAKER: Here's how I'm viewing what I'm
14 hearing. Pardon the mixed sensory overload.

15 I'm not terribly impressed with the burden
16 argument here. It's been a long time since I was in
17 practice and dealt with clients, but it has astounded me
18 over the last 25 years, let's say, as business practices
19 have changed how many documents people create.

20 I remember searching through hundred-year-old file
21 cabinets that had been inundated with floodwaters in Pine
22 Bluff, Arkansas, and thought that was burdensome because of
23 the mouse droppings. Now we've got a different kind of
24 mouse, different kinds of droppings.

25 But the whole point of this is to give plaintiffs

1 pertinent and potentially pertinent documents that do it in
2 a way that doesn't -- this is in lieu of the defendant
3 having the burden to search through everything and respond
4 to a document request. This is using electronic techniques
5 to narrow things down.

6 I, frankly, don't know that I agree with the
7 practice of having to put an attorney's eyes on every
8 document that's produced when you're pretty confident that
9 they're not very important, but I'll leave that to you.

10 But it doesn't -- given how businesses have chosen
11 how to maintain -- create and then maintain their records
12 knowing that litigation is a significant possibility,
13 you've got to live with what you've done.

14 That said, if you want to take out "Lucentis," if
15 that saves you a few documents, go ahead; but given that
16 we've narrowed this down in terms of the number of people's
17 records being searched in the time period, I didn't hear
18 anything that suggests I need to narrow that any further.

19 You may believe that, but it hasn't been
20 presented. So other than perhaps taking out "Lucentis,"
21 just go ahead and produce them and review them.

22 I guess what we're trying to avoid is you take
23 depositions of these people and it turns out, oh, yeah, we
24 talked about that. And it wasn't produced. And then I'm
25 going to have a motion to require the witness be redeposed

1 and it not count against the time limits. And it's going
2 to screw up our schedule. This is all intended to avoid
3 that.

4 And maybe I was unrealistically optimistic at the
5 beginning because things seemed to go smoothly between
6 status conferences and we weren't hearing a lot of disputes
7 from you, but now we're getting down to the end of it, at
8 least in terms of these electronic document reviews, and
9 we're getting a lot of friction.

10 And maybe you're tired of talking to each other.
11 And I scolded you at the last conference in front of
12 Judge Dalton. Judge Harz may have jumped in on that, too.
13 I don't remember. We're of like mind about it.

14 You need to take a deep breath and refresh
15 yourselves and continue to debate these things quickly, but
16 don't get exasperated with each other because that's very
17 quickly going to lead to us being exasperated with both
18 sides.

19 So in terms of what's been presented to the Court,
20 as far as I'm concerned, you can take out the term
21 "Lucentis" but go through and get the others and get them
22 produced and let plaintiff get ready for their depositions.

23 Do you need a formal order on this, or is this
24 enough guidance for you to go forward?

25 MR. OXX: I don't think we need a formal order.

1 MR. REISSAUS: We can move forward with this
2 guidance.

3 Thank you, Judge Baker.

4 JUDGE BAKER: All right. Are you planning to file
5 something Monday?

6 MR. REISSAUS: Your Honor, the Court, Judge Dalton
7 entered an order asking for a joint submission today. We
8 were working on track to do that today with plaintiffs; but
9 if Monday is better, we are more than happy to do that
10 then.

11 JUDGE HARZ: I think he had asked for ten days.
12 So you're asking for seven days basically?

13 MR. OXX: The order -- in court, it was ten days,
14 but then an order came out saying it was due today on the
15 docket.

16 JUDGE HARZ: Oh.

17 JUDGE BAKER: Well, if today is rough for you, I
18 can give you until Monday, if that helps.

19 MR. REISSAUS: I'm sorry. It cut out there. But
20 I think if you were suggesting Monday, if it would help, it
21 would work. That would be fine with us.

22 MR. OXX: Yes, I think that would help.

23 JUDGE BAKER: All right. Let's do that because
24 that will give you time to absorb what we just talked
25 about.

1 And I can tell you, Judge Dalton is out of the
2 courthouse at an investiture at one of our other divisions.
3 So he's not going to be worried about it too much, although
4 he does work Saturdays sometimes.

5 So that requirement was posted for my benefit. As
6 I said, given that we're getting down to crunch time, I'm
7 going to be keeping a closer eye, and Judge Harz is as
8 well. And she and I are talking, exchanging book lists.

9 Okay. All right. We'll leave it there, unless
10 there's something else we need to take up.

11 MR. REISSAUS: There's one other small thing. And
12 I haven't had a chance to speak with plaintiffs about this
13 yet, but it has to do with the seven depositions that we
14 now have on the schedule.

15 The pretrial order number two talks about how all
16 depositions should be noticed for both the MCL and the MDL.
17 And I think this is just sort of a logistical question.

18 So far the notices that plaintiffs have sent have
19 been for the MDL specifically.

20 JUDGE HARZ: They are also for the MCL.
21 Absolutely.

22 MR. REISSAUS: And I think I was going to propose
23 that we just have the notices put the caption with the MCL
24 in them rather than going through some additional
25 cross-notice kind of thing, but I did not have a chance to

1 ask Mr. Oxx if that was okay with him.

2 JUDGE HARZ: It's an easy solution.

3 MR. OXX: That's fine, Judge.

4 JUDGE BAKER: All right. We are in recess.

5 JUDGE HARZ: Thank you. Everyone have a good
6 Friday.

7 MR. SILVERMAN: Thank you. You too, Your Honors.

8 (Proceedings adjourned at 10:30 a.m.)

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11 C E R T I F I C A T E

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

16

17 April 26, 2022

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19 s\ Amie R. First
20 Amie R. First, RDR, CRR, CRC, CPE
21 Federal Official Court Reporter
United States District Court
Middle District of Florida

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