

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXELIXIS, INC.,)
)
Plaintiff,)
) C.A. No. 22-228-RGA
v.)
) Trial Volume IV
MSN LABORATORIES PRIVATE)
LIMITED, et al.,)
)
Defendants.)

J. Caleb Boggs Courthouse
844 North King Street
Wilmington, Delaware

Thursday, October 26, 2023
9:28 a.m.
Bench Trial

BEFORE: THE HONORABLE RICHARD G. ANDREWS, U.S.D.C.J.

APPEARANCES:

MORRIS NICHOLS ARSHT & TUNNELL LLP
BY: ANTHONY D. RAUCCI, ESQUIRE
BY: JACK B. BLUMENFELD, ESQUIRE

-and-

WILMERHALE
BY: KEVIN S. PRUSSIA, ESQUIRE
BY: LISA J. PIROZZOLO, ESQUIRE
BY: AMY KREIGER WIGMORE, ESQUIRE
BY: JONATHAN A. COX, ESQUIRE
BY: KEVIN M. YURKERWICH, Ph.D.

For the Plaintiff

1 APPEARANCES CONTINUED:

2 HEYMAN ENERIO GATTUSO & HIRZEL LLP
3 BY: DOMINICK GATTUSO, ESQUIRE

4 -and-

5 WINSTON & STRAWN LLP
6 BY: GEORGE LOMBARDI, ESQUIRE
7 BY: BRYCE COOPER, ESQUIRE
8 BY: KURT A. MATHAS, ESQUIRE
9 BY: KEVIN BOYLE, ESQUIRE
10 BY: ELIZABETH GRDEN, ESQUIRE

For the Defendants

Also Present:

09:21:33 Dr. Kondal Reddy Bairy

09:21:33 *** PROCEEDINGS ***

09:21:33
09:28:01 DEPUTY CLERK: All rise. Court is now in
09:28:01 session. The Honorable Richard G. Andrews presiding.

09:28:16 THE COURT: All right. Good morning everyone,
09:30:21 please be seated. So I guess we're ready to begin.

09:30:25 MR. PRUSSIA: Some housekeeping, Your Honor, on
09:30:26 the post-trial briefing. Is it okay that if we start there
09:30:29 or...

09:30:29 THE COURT: Okay. Sure.

09:30:30 MR. PRUSSIA: Okay. We've already agreed on a
09:30:34 schedule for post-trial briefing, if it suits the Court.
09:30:37 Opening briefs would be filed on Tuesday, December 12th.
09:30:41 Responsive briefs would be filed on Tuesday, January 23rd.
09:30:47 And on February 20th, there will be reply briefs, that reply

09:30:51 1 briefing will be limited to infringement by Exelixis and for
09:30:55 2 MSN invalidity including secondary considerations.

09:31:00 3 The we have proposed pages, if it suits the
09:31:03 4 Court.

09:31:04 5 THE COURT: Well, so on December 12th, you are
09:31:08 6 going to be filing an infringement brief and they're going
09:31:11 7 to be filing an invalidity brief; right?

09:31:13 8 MR. PRUSSIA: That's correct.

09:31:13 9 THE COURT: Okay. All right. Yeah. So, what
09:31:16 10 are your proposed pages?

09:31:18 11 MR. PRUSSIA: Each side would have a total of
09:31:20 12 80 pages for their three briefs to be allocated however they
09:31:23 13 see fit between the three briefs.

09:31:25 14 THE COURT: Okay. So on infringement, you'd get
09:31:28 15 80 pages and they'd get 80 pages.

09:31:30 16 MR. PRUSSIA: No, No. 80 pages throughout the
09:31:34 17 three briefs that are being filed.

09:31:35 18 THE COURT: Oh, right. Right. I was doing the
09:31:37 19 math wrong.

09:31:37 20 MR. PRUSSIA: Yeah, that would be a little
09:31:39 21 excessive maybe just on infringement.

09:31:41 22 THE COURT: That was the reason I was asking. I
09:31:43 23 mean, so that's a reasonable way to approach the issue
09:31:48 24 because I thought the amount of pages that would be dealt
09:31:51 25 with -- devoted to infringement would be a lot less than the

09:31:56 1 amount of pages devoted to invalidity, so the way you're
09:32:01 2 doing that would take that into account, so...

09:32:04 3 MR. PRUSSIA: And then in addition to the
09:32:05 4 briefing, there would be 40 pages of findings of fact.

09:32:08 5 THE COURT: All right. And how are they going
09:32:10 6 to be.

09:32:11 7 MR. PRUSSIA: Again, that would be allocated
09:32:13 8 between infringement and invalidity as the parties see fit.

09:32:17 9 THE COURT: But they'd file them with the
09:32:19 10 December 12th brief or they'd dribble in over time?

09:32:22 11 MR. PRUSSIA: I think there would be two
09:32:24 12 filings, one on the 12th and then one on the 23rd because
09:32:27 13 there would be responsive findings of fact.

09:32:31 14 THE COURT: Okay. And so, the 40 pages would be
09:32:34 15 devoted -- divided up as each side saw fit?

09:32:38 16 MR. PRUSSIA: That's correct.

09:32:40 17 THE COURT: All right. And you're agreeable
09:32:44 18 with it?

09:32:44 19 MR. COOPER: Yes, we are.

09:32:47 20 THE COURT: That seems -- wait. Let me just
09:32:59 21 think about this for a second.

09:33:20 22 All right. That's fine. Why don't you submit a
09:33:24 23 piece of paper in due course that memorializes it and I will
09:33:28 24 sign it.

09:33:31 25 Okay. So now are we ready to begin?

09:33:34 1 MR. PRUSSIA: Yes. Ms. Pirozzolo will begin for
09:33:36 2 us. And just for the Court, Ms. Pirozzolo will be handling
09:33:38 3 the '349 patent issues. I will be handling the malate salt
09:33:42 4 patent issues.

09:33:43 5 THE COURT: Okay. But you're going to be doing
09:33:45 6 all of your argument up front; right?

09:33:47 7 MR. PRUSSIA: Thank you for that -- thank you
09:33:49 8 for that question, Your Honor.

09:33:50 9 We have proposed for the Court, if it suits the
09:33:53 10 Court, that we would -- Exelixis would start with
09:33:56 11 infringement on the '349 patent. MSN would then respond to
09:34:01 12 that and present their closing statement with respect to the
09:34:05 13 invalidity issues. We would then respond to those
09:34:08 14 invalidity arguments and then MSN would have a brief
09:34:11 15 rebuttal to that as well. We would allocate --

09:34:14 16 THE COURT: So anyway, you're good with that?

09:34:17 17 MR. LOMBARDI: Yes.

09:34:17 18 THE COURT: Okay. Well, we'll be trying to
09:34:19 19 count up the time so that -- all right. So, good. Let's
09:34:22 20 go.

09:34:24 21 MS. PIROZZOLO: Thank you, Your Honor. Good
09:34:29 22 morning. Lisa Pirozzolo for Exelixis.

09:34:33 23 And before I begin, Plaintiffs would say like to
09:34:35 24 thank the Court for its time and attention. The Court and
09:34:38 25 its staff for the time and attention during this trial.

09:34:41 1 The infringement dispute focuses on one issue:
09:34:48 2 Does MSN's ANDA product contain a glidant? And I'd like to
09:34:52 3 talk through three key questions: What is a glidant? How
09:34:58 4 is GRASTAR being used in MSN's ANDA product? And can a
09:35:03 5 diluent, which is what MSN says GRASTAR is in its ANDA
09:35:08 6 product, be used -- be also a glidant?

09:35:12 7 So on the first question, what is a glidant, all
09:35:16 8 the witnesses who testified on this point consistently
09:35:21 9 testified that a glidant is a substance that improves the
09:35:24 10 flow of powder mixture.

09:35:26 11 If we could call up PDX-2 by MSN's scientists
09:35:32 12 Dr. Ravi Nithiyanandam testified that a glidant is a
09:35:38 13 chemical that improves the flow characteristics of a powder
09:35:42 14 mixture. Dr. Donovan testified that a glidant is a
09:35:48 15 substance which improves the flow characteristics of a
09:35:53 16 powder mixture.

09:35:54 17 If we'd pull up -- and that is PDX-3.

09:35:58 18 If we'd pull up PDX-4.

09:36:01 19 Dr. Koleng testified that the plain and ordinary
09:36:08 20 meaning of a glidant is a powder -- something that's added
09:36:12 21 to a powder blend to improve flow. This testimony is
09:36:15 22 consistent with the two references cited in the
09:36:20 23 specification of the '349 patent, the Swarbrick reference,
09:36:25 24 which is Plaintiff's Exhibit 394, and the Remington
09:36:30 25 reference, which is Plaintiff's Exhibit 572A.

09:36:34 1 Now, Dr. Donovan has discussed various
09:36:39 2 mechanisms by which a glidant may operate, but there's no
09:36:44 3 support for the assertion that a particular mechanism is
09:36:50 4 required under the '349 patent: First, Dr. Donovan'
09:36:55 5 definition of a glidant does not include any mechanism.
09:36:59 6 Secondly, the Claim 3 -- the asserted Claim 3 of the
09:37:03 7 '349 patent does not include any mechanism. And third, the
09:37:08 8 specification of the '349 patent does not contain any
09:37:12 9 reference to the mechanism by which a glidant operates.

09:37:18 10 So going to the second point, how is GRASTAR
09:37:22 11 used in MSN's ANDA product?

09:37:24 12 So what we know is that there is no dispute that
09:37:30 13 cabozantinib (L)-malate is a poorly flowing drug
09:37:34 14 substance -- drug product -- or drug substance, sorry. That
09:37:37 15 is clearly stated on Page 34 of MSN's pharmaceutical
09:37:42 16 development report, which is Defendants' Exhibit 215, and it
09:37:47 17 is when an API is poorly flowing that you use a glidant.

09:37:53 18 There's also no dispute that as to when and in
09:37:59 19 what amount GRASTAR is added to MSN's ANDA product. So,
09:38:04 20 MSN's ANDA products have an intergranular layer and an
09:38:08 21 extragranular layer. MSN makes the granules containing the
09:38:13 22 API and then adds GRASTAR at the pre-lubrication step just
09:38:19 23 before the products are formed into tablets. That is
09:38:22 24 precisely where a glidant is typically added in the
09:38:26 25 pharmaceutical manufacturing process.

09:38:30 1 Dr. Koleng testified to that at Page 84 of the
09:38:33 2 transcript and Dr. Donovan testified to that at Page 228 of
09:38:39 3 the transcript.

09:38:39 4 And Dr. Shah, a coinventor on the '349 patent,
09:38:45 5 testified that's, in fact, when Exelixis adds a glidant in
09:38:48 6 its process.

09:38:50 7 It's also clear from MSN's ANDA submission that
09:38:55 8 the GRASTAR is added in an amount of 9.71 percent of the
09:39:00 9 product. And as we saw when we looked during the trial at
09:39:05 10 both the Swarbrick and Lachman references, when starch is
09:39:12 11 used as a glidant, it's typically added in a range of
09:39:16 12 .1 percent up to 10 percent.

09:39:19 13 So, the -- the GRASTAR in MSN's ANDA product is
09:39:25 14 being added to the product at the time a glidant is
09:39:28 15 typically added and it's being used in an amount typical of
09:39:32 16 a starch glidant.

09:39:33 17 So, we also have, importantly, what MSN told the
09:39:37 18 FDA about its ANDA products. MSN repeatedly and without
09:39:44 19 qualifications said that the granulated corn starch in its
09:39:49 20 ANDA product improved flow and MSN's statements to the FDA
09:39:56 21 proved infringement.

09:39:57 22 Let's call up Plaintiff's Demonstrative
09:40:01 23 Exhibit 9. This is the initial risk assessment in the
09:40:06 24 pharmaceutical development report in MSN's ANDA. And what
09:40:13 25 this says is that granulated corn starch is used as a

09:40:19 1 diluent in minimal concentration and it enhances the
09:40:22 2 flowability of the granules.

09:40:26 3 And when asked about this section of MSN's
09:40:30 4 pharmaceutical development report, Dr. Donovan testified
09:40:34 5 about granulated corn starch.

09:40:37 6 And if we call up Plaintiff's Demonstrative 7,
09:40:41 7 I'll read what she said about this.

09:40:44 8 What she said was that the ANDA would be
09:40:49 9 expected -- if we can highlight the bottom. I won't read
09:40:52 10 the whole thing -- but she's talking about the initial risk
09:40:56 11 assessment report and its reference to GRASTAR. "And it
09:41:00 12 would be expected, even before experiments, to -- to
09:41:04 13 potentially enhance the flowability of the granules."

09:41:07 14 So Dr. Donovan admits that the GRASTAR would be
09:41:12 15 expected to improve the flowability of the granules.

09:41:18 16 So, let's also call up -- MSN again discussed
09:41:29 17 granulated corn starch in its microbial method validation
09:41:34 18 submitted to the FDA. And if we put up Plaintiff's
09:41:39 19 Demonstrative Exhibit 11, this is the validation report.
09:41:44 20 And in that, MSN assessed the quality of various grades of
09:41:50 21 corn starch and said: Starch are used in the pharmaceutical
09:41:55 22 industry -- this is the last sentence -- for a wide variety
09:41:58 23 of reason, such as an excipient in a tablet and capsule, as
09:42:02 24 a diluent, glidant, or as a binder.

09:42:10 25 Now, MSN argues that this statement is not about

09:42:12 1 granulated corn starch, but that's not right. If you look
09:42:15 2 at the document in its entirety and you look above this
09:42:21 3 statement -- and we can call up Slide 12 -- what you see is
09:42:28 4 that MSN was discussing the different types of starch used
09:42:34 5 in its product and they were -- explicitly referenced
09:42:40 6 granulated corn starch. So, the statement about starch
09:42:42 7 being used as a glidant applied to the GRASTAR corn starch.

09:42:49 8 Now, I'd also like to go to -- Dr. Nithiyanandam
09:43:07 9 said that all these statements were true and correct. But
09:43:13 10 actually I realized I skipped one of the statements. If we
09:43:16 11 go to Slide 10. This is the section of the pharmaceutical
09:43:19 12 development report discussing the optimization of the corn
09:43:24 13 starch. This is where MSN actually conducted experiments on
09:43:29 14 the granulated corn starch in its product and it was varying
09:43:35 15 the amount of granulated corn starch ranging from 6.7 to
09:43:40 16 12.7 percent. And right -- and this cannot be dismissed as
09:43:46 17 just summarizing the literature, as MSN's witnesses have
09:43:51 18 testified.

09:43:52 19 In this section of the pharmaceutical
09:43:54 20 development report, MSN stated in no uncertain terms that
09:44:01 21 "granulated corn starch plays an important role in flow
09:44:03 22 characteristics."

09:44:07 23 So, on the third question: Can a diluent, which
09:44:11 24 is what MSN says GRASTAR is, also be a glidant? So, the
09:44:20 25 fact that a diluent -- that an excipient is a diluent does

09:44:25 1 not mean it is not a glidant. All the experts agree that
09:44:31 2 excipients can perform multiple functions. Dr. Donovan
09:44:36 3 admitted diluents can improve flow. Glidants can improve
09:44:42 4 flow. And, in fact, if we put up PDX-14, Dr. Donovan
09:44:50 5 testified that both, referring to diluents and glidants,
09:44:58 6 "both are known to be able to improve the flow properties of
09:45:01 7 a powder blend."

09:45:03 8 For these reasons, the evidence demonstrates
09:45:07 9 that the GRASTAR in MSN's ANDA product is a glidant.

09:45:11 10 THE COURT: Can't basically every excipient be
09:45:14 11 called a diluent?

09:45:16 12 MS. PIROZZOLO: I mean, I'm not an expert in
09:45:20 13 excipients, but certainly there are many diluents that when
09:45:27 14 you add something, you are diluting the powder --

09:45:31 15 THE COURT: Right.

09:45:32 16 MS. PIROZZOLO: -- to a certain extent.

09:45:34 17 THE COURT: Right. And excipients are added.

09:45:37 18 MS. PIROZZOLO: Yes. Yes.

09:45:37 19 THE COURT: All right. Thank you.

09:45:40 20 MR. LOMBARDI: Good morning, Your Honor. For
09:45:46 21 the record, George Lombardi on behalf of MSN. And I will
09:45:50 22 start there with the formulation patent and infringement.

09:45:55 23 And I agree that the question there is whether
09:45:58 24 granulated corn starch serves as a glidant in the MSN
09:46:02 25 formulation. So, what is a glidant? I guess the right way

09:46:06 1 to phrase this is I partially agree with what they said.

09:46:10 2 A glidant is something that improves the flow,
09:46:13 3 but it does so by acting on the formulation in
09:46:18 4 scientifically specific ways. And that's what Dr. Donovan
09:46:22 5 testified about, and I'm going to talk about that in a
09:46:25 6 little bit more detail as we go through this, Your Honor.
09:46:28 7 But that's generally what it is.

09:46:30 8 There are three reasons why Plaintiffs have not
09:46:34 9 proved infringement. And it's well to keep in mind,
09:46:37 10 Your Honor, as I know everybody's aware of this, but they do
09:46:41 11 have the burden on this. They have to come forward with
09:46:44 12 proof. So, the three reasons.

09:46:46 13 One is there is experimental evidence that the
09:46:51 14 granulated corn starch in MSN's formulation does not act as
09:46:57 15 a glidant.

09:46:58 16 Number two, it did not work. The granulated
09:47:03 17 corn starch did not work the way a glidant works. We'll
09:47:09 18 talk about that about that.

09:47:11 19 And the third one is MSN treated this as a
09:47:14 20 diluent. That's how they reported it to the FDA. And
09:47:18 21 that's what it was. So I'm' going to talk through each of
09:47:21 22 the three steps.

09:47:22 23 The first is that there is testing that shows
09:47:25 24 that there was no infringement, actual testing, Your Honor.
09:47:30 25 And this came out of MSN's lab notebooks. And I'm going to

09:47:34 1 put up a table that was in evidence before you.

09:47:38 2 Slide 3, please.

09:47:39 3 This is a table that came out of MSN and,
09:47:44 4 Your Honor, in the build-up to this table, to presenting
09:47:48 5 this table, we showed you the lab notebook excerpts where
09:47:52 6 the work was done and then translated to this table. So,
09:47:55 7 you've seen the lab notebooks, and then you've seen this.

09:47:59 8 What was going on in this testing, on the left
09:48:02 9 is one batch. On the right is another batch. And they are
09:48:06 10 identical with the exception of the corn starch and the
09:48:10 11 granulated corn starch as you see there.

09:48:13 12 So, on the left is a formulation that has corn
09:48:18 13 starch. On the right is one that has granulated corn
09:48:20 14 starch.

09:48:20 15 And what they were doing was determining flow,
09:48:25 16 determining how the flow went when you change between corn
09:48:29 17 starch and granulated corn starch. And down at the bottom
09:48:32 18 where it says "Carr index" and "HR," that's Hausner
09:48:38 19 ratio and the Carr index are ways of determining flow. And
09:48:43 20 when the flow -- when the numbers there go down, that
09:48:49 21 indicates that the flow is actually better. When the
09:48:51 22 numbers go up, it means the flow is worse.

09:48:54 23 Now, everybody thinks that -- thought that this
09:48:57 24 was an important table. In fact, Plaintiff's expert,
09:49:02 25 Dr. Koleng relied on it, and he called it -- I think he

09:49:04 1 called it at the time, his most important -- one of his --
09:49:07 2 the most important things he relied on in his infringement
09:49:10 3 opinion.

09:49:11 4 But what we found out during the evidence is
09:49:14 5 that there was a simple arithmetic error in the table. And
09:49:19 6 the error -- if we could just go to Slide 6, please.

09:49:25 7 The error -- and when I say arithmetic,
09:49:28 8 Your Honor, it's just a matter of the bulk density number
09:49:31 9 and the tapped density number. There's some multiplication,
09:49:35 10 some division. It wasn't done properly.

09:49:38 11 Everybody agrees, Dr. Koleng, Plaintiffs,
09:49:41 12 everybody agrees that the correct numbers are actually what
09:49:45 13 I put up there, 34.42 and 1.52 which indicates that when the
09:49:51 14 granulated corn starch was tested, it didn't improve the
09:49:56 15 flow properties. Actually, according to these numbers, it
09:49:59 16 made it worse.

09:50:01 17 THE COURT: Corn starch is a glidant, isn't it?

09:50:05 18 MR. LOMBARDI: Corn starch is a glidant, yes.

09:50:07 19 No, I'm sorry. I'm sorry. Corn starch is not a
09:50:09 20 glidant. Granulated corn starch is not typically a glidant,
09:50:13 21 either. Corn starch is not a glidant.

09:50:21 22 THE COURT: All right.

09:50:22 23 MR. LOMBARDI: I think I may -- I'm saying --
09:50:23 24 I'm talking about in this table, it's not a glidant.

09:50:26 25 THE COURT: No. No. I mean, just generally.

09:50:27 1 Corn starch is a glidant.

09:50:29 2 MR. LOMBARDI: It can be a glidant, yes. Yeah.

09:50:31 3 THE COURT: So comparing the flow of one
09:50:33 4 purported glidant to another purported glidant, the
09:50:38 5 difference -- what difference does it make? It just
09:50:41 6 presumably shows that corn starch is better at this than
09:50:45 7 granulated corn starch; right?

09:50:46 8 MR. LOMBARDI: It -- well, in this testing, it
09:50:50 9 shows that. You still don't know whether they're actually
09:50:53 10 acting as glidants based on this testing, but this gets you
09:50:56 11 to the bottom line testing about whether the granulated corn
09:51:00 12 starch improves the flow property. And the testing, the
09:51:04 13 actual testing shows that it does not improve the flow
09:51:08 14 properties and everybody agrees --

09:51:10 15 THE COURT: But isn't the relevant testing not
09:51:12 16 granulated corn starch versus corn starch, but batch number
09:51:16 17 252/044 with and without granulated corn starch?

09:51:21 18 MR. LOMBARDI: Well, but isn't that the same
09:51:23 19 thing, Your Honor? I mean, what we're trying to figure out
09:51:25 20 is what the effect is of granulated corn starch on the flow
09:51:29 21 properties. That's what the calculations are at the bottom
09:51:32 22 is to -- that tells you what the effect on the flow
09:51:35 23 properties is. The only difference is the corn starch
09:51:38 24 versus the granulated corn starch. And so you can see the
09:51:42 25 granulated corn starch doesn't have a positive impact.

09:51:46 1 Doesn't have a positive impact on flow properties.

09:51:53 2 THE COURT: All right.

09:51:54 3 MR. LOMBARDI: It's the only testing we have,
09:51:57 4 Judge. And it -- by the way, remember, except for the
09:52:01 5 result, it's testing that Dr. Koleng relied on, Plaintiff's
09:52:04 6 expert relied on. And he only changed his mind about
09:52:07 7 relying on it when he realized that there had been a
09:52:10 8 mathematical error and that the mathematical error changed
09:52:14 9 the result. So this is test that experts on both sides have
09:52:17 10 relied on in this case to show infringement.

09:52:20 11 And the important thing -- now, Dr. Koleng
09:52:23 12 eventually says, "I rejected this study because of the
09:52:27 13 mathematical errors," but there's been no showing that
09:52:30 14 there's any lack of reliability in any of the other numbers
09:52:34 15 and any of the data that was collected. There's been no
09:52:37 16 showing that there's been any problem with the data
09:52:40 17 otherwise.

09:52:40 18 And so, this is the table that both sides agreed
09:52:46 19 shows -- shows whether there is improvement in flow
09:52:52 20 properties and it does not show that. And it's important
09:52:54 21 Your Honor, because this is the only testing -- this is the
09:52:58 22 only testing. The Plaintiffs didn't do any testing at all.
09:53:02 23 They have the burden in this case. And so that's why this
09:53:08 24 is so important, I think.

09:53:10 25 It was reliable until they found out that the

09:53:12 1 math error existed.

09:53:15 2 Now, number two, granulated corn starch does not
09:53:20 3 work the way a glidant works. That was Dr. Donovan who put
09:53:27 4 up a document, an article, and I'm not going to put it up
09:53:32 5 for you right now, Judge, but it had about five different
09:53:35 6 ways, mechanisms of action in which glidants were -- and she
09:53:38 7 went through each of them and I'm not going to go through
09:53:41 8 each, but in a general sense, the question that you're
09:53:44 9 asking is: Did granulated corn starch or could granulated
09:53:49 10 corn starch work in any of those five ways to affect the
09:53:55 11 formulations' properties, flow properties?

09:53:58 12 And she went through each of them and she
09:54:01 13 specified, but I think in a general sense you could say that
09:54:05 14 the problem is that the size of the granulated corn
09:54:11 15 starch -- corn starch particles was not of a type that was
09:54:15 16 going to work as a glidant in the formula. She went through
09:54:19 17 each of those and showed that according to the scientific
09:54:22 18 literature, this is not working as a glidant.

09:54:25 19 Third point I was going to make, Your Honor, is
09:54:28 20 that it acted as a diluent. That is what they said to the
09:54:33 21 FDA. And the literature for the product described it that
09:54:37 22 way. And we showed you other testing from within MSN,
09:54:44 23 disintegration testing that showed that they were concerned
09:54:48 24 with the effect that this had on disintegration and that's
09:54:52 25 what they were looking at when they were looking at using

09:54:54 1 the granulated corn starch. That's what they were looking
09:54:57 2 at.

09:54:57 3 So, let me talk a little bit about Plaintiff's
09:55:01 4 arguments, Your Honor, if I may. I would characterize
09:55:06 5 Plaintiff's arguments as taking snippets from one document,
09:55:10 6 combining it with a snippet from another document and trying
09:55:13 7 to come up with something that makes it look like granulated
09:55:19 8 corn starch would act -- was actually acting as a glidant in
09:55:21 9 this case. And that's not true. They use general
09:55:26 10 statements in handbooks that say that a glidant has the
09:55:30 11 proper -- has -- improves flow properties. And they combine
09:55:34 12 it with MSN documents that indicate that granulated corn
09:55:39 13 starch has good flowability properties. So, let me pause on
09:55:44 14 that for just a moment, Your Honor.

09:55:46 15 This idea that granulated corn starch has good
09:55:51 16 flowability is not something that means it's a glidant. And
09:55:55 17 you've heard testimony to that effect. But if I could try
09:55:59 18 to describe it this way. Granulated corn starch is -- is a
09:56:02 19 substance itself. Obviously. It's a powder. And so, it
09:56:06 20 has its own properties about whether it's good for flow, bad
09:56:11 21 for flow, whether it flows well or doesn't. Granulated corn
09:56:14 22 starch can be poured down tubes in the laboratory, and
09:56:19 23 that's when you need -- or the manufacturing process and
09:56:21 24 that's when you need to know its individual flow properties.

09:56:26 25 And so, you have indications that granulated

09:56:32 1 corn starch has good flow properties. That's fine. By
09:56:35 2 itself, that can be true without meaning that it's actually
09:56:39 3 operating as a glidant. To operate as a glidant, it has to
09:56:43 4 improve the flow properties of the actual formulation. It
09:56:50 5 can't be that it alone -- that it alone has good flow
09:56:55 6 properties. It has to be shown that it improves the flow
09:56:58 7 properties of the formulation. And there's been no showing
09:57:00 8 of that. The table is evidence against that. And
09:57:05 9 Dr. Donovan' testimony about the methods of action is
09:57:08 10 testimony against that.

09:57:10 11 Diluents can have good flowability without being
09:57:16 12 glidants. And to be a glidant, you have to operate on the
09:57:20 13 formulation. And there is no evidence that it happened that
09:57:25 14 way. So Plaintiff's evidence is pulling a quote from here,
09:57:30 15 pulling a quote from there, putting them together, but that
09:57:34 16 doesn't satisfy their burden of proof here which is to show
09:57:39 17 that the granulated corn starch in this instance, the
09:57:46 18 granulated corn starch in this instance is operating on the
09:57:50 19 formulation as a glidant. We had the evidence in this -- on
09:57:58 20 this point. I'm just going to grab a drink real fast.

09:58:01 21 THE COURT: Sure. Yeah.

09:58:02 22 MR. LOMBARDI: Thank you, Your Honor. So, with
09:58:13 23 that, unless Your Honor had any more questions on that
09:58:17 24 point, I'm going to move to the obviousness --

09:58:19 25 THE COURT: Sure.

09:58:19 1 MR. LOMBARDI: -- point. And I'll just put up
09:58:22 2 Claim 7 -- Slide 78, which is the claim, Judge, just so that
09:58:26 3 it's up there before us. I know you have seen a lot of this
09:58:28 4 the last few days.

09:58:30 5 This is -- we've called the formulation patent.
09:58:34 6 I think the issue here comes down to inherency. It comes
09:58:39 7 down to the last phrase there, whether it's a -- wherein the
09:58:44 8 pharmaceutical composition is essentially free of the 1-1
09:58:49 9 impurity, and you've of course heard that essentially free
09:58:52 10 means less than 200 parts per million. And so that's the
09:58:56 11 standard that everybody agrees we're working with.

09:58:59 12 I'm not going to spend a lot of time on the rest
09:59:02 13 of it, but I do want to mention, obviously the entire claim
09:59:05 14 has to be obvious. And I think we've established -- I don't
09:59:10 15 think there's any real dispute that the claim, the
09:59:15 16 excipients, the pharmaceutical composition was obvious. We
09:59:19 17 used the Brown reference, which was that patent application,
09:59:23 18 which is in the prior art. It disclosed the pharmaceutical
09:59:26 19 composition. It disclosed the chemical compound. It
09:59:30 20 disclosed the crystalline. And it disclosed fillers and
09:59:35 21 disintegrants and lubricant. It didn't literally disclose
09:59:39 22 glidants, Your Honor. It did disclose some things that are
09:59:43 23 used as glidants in the list of excipients, but didn't
09:59:46 24 disclose glidants.

09:59:47 25 Dr. Myerson testified, I think it was yesterday,

that it was within the level of skill in the art for somebody who had a chemical compound like this to come up with the excipients that would work. It was routine, scientific work. And that's also reflected in the patent itself. There's no claim that there was anything novel or unique or that they determined about -- about these excipients that couldn't have been determined by somebody operating through routine skill in the art. And so, we read you excerpts from the patent which specifically talk about it can be -- leaving the composition, the pharmaceutical composition steps to a person of skill in the art, it's within known techniques. It's within their skill. So, I don't think there's any dispute about -- going to be any dispute about the rest of it.

But I do want to talk about inherency, Your Honor, because we spent a lot of time at trial talking about inherency. And you heard about batches that were created by Regis -- a company called Regis, and you know there were three batches out there. And they -- the evidence was that they precisely followed the steps in the Brown example for making the compound. Precisely followed those steps.

And that's not in dispute. I believe Dr. Myerson confirmed that from the witness stand and obviously our experts said the same thing.

10:01:32 1 So, when you perform -- when Regis performed
10:01:36 2 that testing, according to the method of Brown, Regis always
10:01:40 3 got a composition that was essentially pure -- that was
10:01:45 4 essentially free of the 1-1 impurity. Always got that.
10:01:51 5 Now, in some the testing was less precise and it said it
10:01:56 6 detected up to 200 parts per million. Found --

10:01:59 7 THE COURT: One of the experts for the Plaintiff
10:02:02 8 agreed, it was under 200 for each. I don't think that's
10:02:07 9 a --

10:02:08 10 MR. LOMBARDI: Yeah. Okay. I think -- and --
10:02:09 11 but one point I did want to make, Your Honor, it's
10:02:12 12 significantly below 200. There was a kind of testing called
10:02:16 13 GTI that we talked about where they really got more specific
10:02:21 14 in their ability to test for the presence of the impurity.
10:02:26 15 And under that method, it was substantially under 200. It
10:02:30 16 was between 20 and 40 parts per million, which I think is
10:02:35 17 important.

10:02:35 18 So, that's the testing that was done. Actual
10:02:39 19 testing that was done that shows that when you perform it
10:02:42 20 according to the method in the Brown example, you get
10:02:47 21 something that is essentially free of the 1-1 impurity.

10:02:51 22 Now, so, what do Plaintiffs say? And, again,
10:02:55 23 Your Honor, I feel like this is, again, an instance of trial
10:02:58 24 by snippet. They take a snippet from a document, a snippet
10:03:03 25 from another document. There is an absence of proof and a

10:03:06 1 lot of speculation that goes on.

10:03:08 2 So, let me show you Slide 96, which is one of
10:03:12 3 the documents that they, I think, showed multiple times with
10:03:16 4 multiple witnesses. Your Honor, Process A-2 refers to the
10:03:20 5 Brown example and they said, Well, look, this is our client
10:03:27 6 reporting to the FDA that the range is 35 to 411, that shows
10:03:32 7 that there's variability.

10:03:35 8 Now, I think -- I think we understand that it
10:03:39 9 right that this is probably referring to Girindus testing at
10:03:42 10 the top end. But the fact is --

10:03:44 11 THE COURT: Aren't we just kind of guessing
10:03:46 12 because those numbers, neither the low end nor the top
10:03:50 13 end -- the top end doesn't match Girindus. The bottom end
10:03:55 14 doesn't match the bottom end of the Regis, either. Does it?

10:04:00 15 MR. LOMBARDI: And that was exactly the point I
10:04:01 16 was going to make, Your Honor.

10:04:03 17 While I think it's -- there's a good chance that
10:04:05 18 it's Girindus, something to do with Girindus, we don't have
10:04:08 19 this testing. We've asked Plaintiffs for this testing.
10:04:11 20 They have haven't provided it. They're the ones that have
10:04:14 21 it. We can't come to any conclusions about what 35 to 411
10:04:19 22 means unless you know the process that's used to come to
10:04:23 23 those results.

10:04:24 24 So, they continued to put this up on the screen
10:04:28 25 and put it up before witnesses, but it doesn't tell you

10:04:32 1 anything about whether there's inherency in this case. So,
10:04:36 2 that document is one of the ones that Plaintiffs cite.

10:04:40 3 Now, the other that we heard a lot about is
10:04:43 4 Girindus and as you heard, Your Honor, it's a company that
10:04:46 5 also made a batch and that batch got -- got tested. And
10:04:52 6 what was significant about Girindus is that it deviated from
10:04:57 7 Brown. Literally deviated from and expressly deviated from
10:05:02 8 Brown. This was not something where we hunted up
10:05:06 9 differences and put them up on the screen for Your Honor.
10:05:10 10 These were what were called planned deviations by Girindus,
10:05:14 11 and I'll just put up.

10:05:15 12 Slide 91, please.

10:05:17 13 And this is just an example, this is --
10:05:24 14 Dr. Lepore ran through this for you, but that's the word,
10:05:28 15 "planned deviation." It appears a number of times.

10:05:30 16 Dr. Lepore also pointed out a step that was
10:05:33 17 completely different in the Girindus approach. And so,
10:05:37 18 Girindus doesn't use the Brown example. Doesn't use the
10:05:43 19 Brown example. And so, what you get then when Girindus ends
10:05:47 20 up with different results is not a surprise.

10:05:50 21 If we could put up Slide 83.

10:05:53 22 This was another table, Your Honor, that you saw
10:05:58 23 a lot of at the trial. The green is the Girindus testing,
10:06:03 24 which you see is 200 or less. And then the Girindus was the
10:06:08 25 one that was .06, which we learned is 600 parts per million.

10:06:13 1 And so the logical conclusion is that when you do the
10:06:17 2 testing, according to Brown, as Regis did, you're below
10:06:22 3 200 parts per million. And when you do the testing with
10:06:25 4 deviations, planned deviations, as Girindus did, you get a
10:06:32 5 different result.

10:06:33 6 So, Girindus is not relevant to the
10:06:36 7 determination of whether there's inherency here because they
10:06:40 8 didn't perform the test that was at issue. And that's what
10:06:45 9 the evidence is on Girindus.

10:06:47 10 THE COURT: So, one of the things that was not
10:06:49 11 addressed at trial, and I imagine you have the burden on
10:06:52 12 this, was assuming that the GTI were a correct measurements,
10:06:59 13 if you're normally going to take some experimental results
10:07:03 14 and say that will happen 100 percent of the time, you'd like
10:07:09 15 to have a statistician or some sort of person like that
10:07:12 16 telling you that three samples with this spread is
10:07:19 17 sufficient to mean it will occur 100 percent of the time.
10:07:23 18 Wouldn't you?

10:07:23 19 MR. LOMBARDI: Well, I don't think that that's
10:07:25 20 required by the case law, Your Honor. What's required is
10:07:30 21 that you show you're going to get the same -- I'm talking in
10:07:32 22 lay terms, but that you're going to get, basically, the same
10:07:35 23 thing every time. And the difference you're referring to
10:07:38 24 under the GTI, the -- is 20 to 40. And what's significant
10:07:42 25 about that is the context here is 200. It's 200. So, it is

10:07:49 1 dramatically below what the relevant level is for our
10:07:53 2 consideration.

10:07:53 3 Now, I could understand what Your Honor's saying
10:07:57 4 in a circumstance, say, where it was -- you know, you had
10:07:59 5 one that was 196 and another was 150 or and maybe another
10:08:06 6 was similarly high, that would raise some questions about
10:08:09 7 that. But this -- the genotox testing, which is the most
10:08:14 8 specific, is so far below that I think that provides the
10:08:18 9 Court with the assurance that if you follow the Brown
10:08:22 10 method, you will -- you will inherently get the result.

10:08:26 11 Your Honor, there were other arguments that
10:08:30 12 Plaintiffs made about this. They talked about the use of
10:08:35 13 the word "approximately" in the -- the formulation
10:08:40 14 instructions for Brown and that somehow that introduced
10:08:44 15 variability. Approximately is something that's used in --
10:08:48 16 and, again, Doctor Myerson talked about this. It's
10:08:52 17 something that's used when you don't need precision for a
10:08:55 18 specific element of a formulation. You know, approximately
10:08:58 19 five minutes perhaps. You don't need it to be precise.

10:09:02 20 When the Brown procedure needed to be precise,
10:09:05 21 it said so. It was very precise in terms of grams or other
10:09:11 22 factors. But if you don't need to be precise, approximately
10:09:15 23 comes in and that's normal.

10:09:17 24 But more importantly, Judge, there's absolutely
10:09:19 25 no proof that the use of the word approximately somehow led

10:09:24 1 to a variation that affected the level of impurities.

10:09:28 2 There's nothing. Nothing. And so, that's just Plaintiffs
10:09:33 3 speculating without any proof to back it up.

10:09:37 4 And so, Your Honor, I guess I'll conclude there
10:09:43 5 on the -- the obviousness of the formulation patent.

10:09:48 6 If you go back and you look at the -- I'll go
10:09:50 7 ahead and put 78 back up, just so we have the claim there.

10:09:55 8 All of the elements -- and I agree, one of the
10:09:58 9 witnesses said, you know, you have to consider all of the
10:10:01 10 elements, and you do.

10:10:02 11 All of the elements were there in Brown from the
10:10:07 12 pharmaceutical composition through the chemical compound,
10:10:11 13 through the excipients, with the exception of a glidant and
10:10:14 14 the essentially free of. But the addition of glidant is
10:10:20 15 something that was well within the skill of the art.

10:10:22 16 One other observation I meant to make,
10:10:24 17 Your Honor, about these claims is sometimes you'll see
10:10:29 18 pharmaceutical composition claims that are very specific
10:10:34 19 excipients, like you'll have Filler A and there will be, you
10:10:40 20 know, .5 or something like that. And the same for each of
10:10:43 21 the others. And the argument is made that, well, we figured
10:10:47 22 out the exact way these worked together. We're not talking
10:10:51 23 about a claim like that. We're much broader. And we're
10:10:53 24 talking about just the idea of using any of these
10:10:57 25 excipients, which I don't think is inventive and I think we

10:11:01 1 have shown is obvious under the -- under the law.

10:11:07 2 And, Your Honor, as you know, under our
10:11:09 3 procedure here, I'm going to continue and I'll talk now
10:11:12 4 about the crystalline (L)-malate salts and I'll just put
10:11:18 5 Claim 150 -- Slide 150, I'm sorry -- which is the claim just
10:11:24 6 so we have it up in front of us.

10:11:26 7 And I won't read through all this, but
10:11:29 8 Your Honor the basic idea is that it's a compound that's a
10:11:35 9 malate salt and the salt is crystalline and that flows
10:11:37 10 through -- I'm using this as a representative -- but that
10:11:40 11 basically flows through all of the claims.

10:11:43 12 THE COURT: Is it your position that the three
10:11:46 13 patents rise or fall together?

10:11:48 14 MR. LOMBARDI: I think they do. There are some
10:11:51 15 differences on some of the issues. On written description,
10:11:54 16 for instance, yes, definitely. On obviousness-type double
10:11:58 17 patenting there are a few differences in the claims. I
10:12:01 18 don't think they're significant differences and I can talk
10:12:03 19 about that when we get to that.

10:12:05 20 But I think that they don't change the result, I
10:12:08 21 think the result is they will rise and fall together. And I
10:12:12 22 think that's the way the case was tried. I didn't -- I'm
10:12:16 23 not -- I don't believe I heard any arguments or testimony to
10:12:19 24 the effect that one of these would withstand challenge if
10:12:23 25 the others have gone down.

10:12:25 1 So, I'll talk first about written description,
10:12:30 2 Your Honor. As you know, the basic watch word for -- not
10:12:36 3 watch word -- I guess the basic phrase for written
10:12:39 4 description is you're trying to see if the inventor has
10:12:44 5 possession of the full scope of the claims and our position
10:12:49 6 is that they clearly -- Plaintiffs' clearly didn't have
10:12:53 7 possession of the full scope of the claims.

10:12:54 8 And so what are the basics of a written
10:13:00 9 description analysis? You look at the specification and
10:13:03 10 what does it describe? And you look at claims to see
10:13:07 11 whether the specification supports the claims, whether the
10:13:11 12 specification shows that the Plaintiff has in its possession
10:13:17 13 the -- what is being claimed.

10:13:19 14 And here, the specification addresses two
10:13:23 15 forms -- two crystalline forms N-1 and N-2. And you heard a
10:13:28 16 lot about this, Your Honor, so I'm not going to repeat a lot
10:13:31 17 of it, but the basic idea is the only forms disclosed in the
10:13:37 18 patents are the N-1 and the N-2, and they do that in
10:13:43 19 substantial detail and they do lots of different things to
10:13:47 20 characterize and identify them.

10:13:49 21 And the fact that they only do that with respect
10:13:52 22 to the N-1 and the N-2, I think, shows you how deficient the
10:13:58 23 specification is for other forms because they only do it for
10:14:03 24 the N-1 and the N-2.

10:14:05 25 So, in the claims -- we got the specification

10:14:09 1 that's just N-1 and N-2. The claims cover all crystalline
10:14:13 2 forms and there are more than two crystalline forms.
10:14:21 3 There -- you heard Dr. Steed testify that there are 11
10:14:25 4 currently known. He told you that that is not a firm
10:14:33 5 number, there could be more. You just don't know because
10:14:36 6 you can't predict how many polymorphs they are. That has to
10:14:40 7 do with the way polymorphs come about. Different polymorphs
10:14:44 8 can be formed by small differences in the manufacturing
10:14:48 9 techniques that are used. And so, you don't know how many
10:14:52 10 there are. But the proof is, in this case, that there are
10:14:56 11 11 that are currently known.

10:14:59 12 Dr. Trout made some comment about he thinks it's
10:15:01 13 three, but he didn't show you any of his analysis of that.
10:15:05 14 He said, "Yeah, I thought about this carefully and I came to
10:15:08 15 this conclusion," but that's not proof, Your Honor. That's
10:15:12 16 just hand waving. It didn't provide you with any evidence
10:15:17 17 on that point.

10:15:18 18 So, there are 11 out there. There could be many
10:15:23 19 more. We don't know. We know that with polymorphs there
10:15:27 20 have been as many -- I think the testimony was 70 polymorphs
10:15:32 21 out there for one compound in one instance. And so we don't
10:15:37 22 know what it could be.

10:15:39 23 So, it's very clear that the Plaintiff doesn't
10:15:43 24 have the full scope of the invention, does not possess the
10:15:46 25 full scope of the invention and does not disclose it. And

10:15:50 1 that's factually true, also, Your Honor, because you know
10:15:54 2 that Plaintiff, from the evidence, Plaintiff did not create
10:16:00 3 MSN's form which is form S or any of the 11 other forms.
10:16:05 4 They didn't do that. That's admitted.

10:16:08 5 And so as a factual matter they didn't have
10:16:11 6 possession. And also as a legal matter, they don't have
10:16:14 7 possession.

10:16:14 8 Now, there are cases, as Your Honor is fully
10:16:18 9 aware, where a disclosure can be said to be representative
10:16:24 10 on -- and so, you make a disclosure, and that's
10:16:26 11 representative of the fact that you have the full scope of
10:16:29 12 the invention.

10:16:30 13 But that's not the case here.
10:16:33 14 Representativeness has not been established because
10:16:37 15 polymorphs are inherently unpredictable. Dr. Trout agreed
10:16:43 16 that just because you have a polymorph like the N-1 or N-2,
10:16:47 17 it doesn't give you any ability to predict what other
10:16:50 18 polymorphs might be or what their characteristics might be.
10:16:54 19 They're all different. They all have different
10:16:57 20 crystalline -- different crystalline structures.

10:16:59 21 So it's unpredictable how many are out there.
10:17:03 22 It's also the fact that differences in polymorphs make for
10:17:07 23 differences in properties of the compound. And you heard a
10:17:10 24 lot about that. I won't -- I won't repeat all that. But
10:17:15 25 everything from densities and melting points to solubility

10:17:19 1 to potency to activity, all can vary as properties of the
10:17:25 2 polymorphs. All can vary as properties.

10:17:28 3 We know that form S from MSN is different than
10:17:33 4 N-2. We know that N-1 is different than N-2. We heard
10:17:38 5 stories about Norvir where one polymorph of a compound was
10:17:42 6 successful in treatment and another one was not. And so,
10:17:47 7 there is nothing representative about the disclosure in this
10:17:51 8 case.

10:17:52 9 Plaintiff's arguments seem to be - I guess I'll
10:18:00 10 wait and respond, but I didn't see any -- any rebuttal of
10:18:05 11 the fact that they just didn't have possession here. They
10:18:09 12 just didn't have possession of the invention here.

10:18:12 13 One thing Plaintiffs did do -- and maybe we can
10:18:15 14 put the claim up, 150 here.

10:18:23 15 You remember they said, well, the problem here
10:18:25 16 for you, Mr. Lombardi is that the word "form" is not in the
10:18:29 17 claim which I think is a word game, even for those of us who
10:18:38 18 deal with words, Your Honor, because if you have a form in
10:18:42 19 the claim or out of the claim, it's still -- the scope of
10:18:44 20 the claim is to cover all the crystalline forms that are out
10:18:49 21 there.

10:18:49 22 I did want to just, I guess, alert, Your Honor,
10:18:55 23 that -- I think there's some case law that is very similar
10:19:01 24 to what we're talking about here, and we will obviously talk
10:19:04 25 about that in great detail. But one case I just wanted to

10:19:08 1 mention is the ICU medical case which was a case that
10:19:14 2 involved spiked valves in a medical device.

10:19:18 3 THE COURT: Yeah, so, I mean, the case that I'm
10:19:20 4 looking for from either side here, and I just can't believe
10:19:24 5 that it hasn't come up in the Federal Circuit before, though
10:19:27 6 I think it hasn't, is, you know, the one that says if you
10:19:34 7 discover one polymorph, you can claim them all.

10:19:38 8 And, you know, this issue has at least been on
10:19:48 9 the fringe of a number of different things that I've done
10:19:50 10 over the last few years, and I'm just surprised that there
10:19:55 11 isn't an answer. You know, it seems like more a question of
10:19:58 12 law to me than a factual question.

10:20:01 13 MR. LOMBARDI: Yeah. Well, and, Your Honor,
10:20:03 14 you're right. Neither side has cited you a case that deals
10:20:07 15 with that point directly. But I think that this is
10:20:12 16 consistent with things like the ICU medical case. And the
10:20:17 17 reason I say that is in ICU medical, there was a
10:20:21 18 specification that supported spiked valves. There were
10:20:25 19 claims initially in the first patent that supported spiked
10:20:28 20 valves. They did it in another patent that took the spiked
10:20:31 21 out, and so you had claims to all valves and a specification
10:20:36 22 that was just to spiked valves.

10:20:38 23 Here, you had a specification that was just to
10:20:40 24 N-1 and N-2. Prior patent, you had claims to N-1 and N-2.
10:20:45 25 Now they take out the N-1 and N-2 and make it all

10:20:49 1 crystalline forms, but the specification is still just N-1
10:20:53 2 and N-2.

10:20:53 3 So, I think it fits into that kind of case. And
10:20:58 4 obviously, Your Honor, we'll argue the law fully, but those
10:21:02 5 are the -- that kind of case, I think, provides some
10:21:05 6 guidance for what to do in the polymorph situation.

10:21:10 7 So, our bottom line on that one, Your Honor, is
10:21:14 8 that they did not have possession of the full scope of the
10:21:17 9 invention and that we have established that there's no
10:21:22 10 written description here.

10:21:23 11 And let me switch now, same patent, but
10:21:29 12 obviousness-type double patenting. As you know, Your Honor,
10:21:32 13 the whole purpose of obviousness-type double patenting is to
10:21:39 14 create -- is to prevent an unjustified time-wise extension
10:21:45 15 of the patent. I won't put the timeline up because we've
10:21:48 16 already done it for you here, Your Honor, but the -- the
10:21:52 17 reference patent expires in two -- 2026. And it covers the
10:21:59 18 compound and salts of the compound. And then the malate
10:22:05 19 salt patents which are at issue here extend to 2030. So it
10:22:10 20 extends the protection for this kind of salt from the prior
10:22:15 21 patent term all the way into the new patent term which is an
10:22:18 22 additional four years. And that's the time-wise extension
10:22:22 23 that we're concerned about here.

10:22:26 24 And I think that the issue here -- and maybe we
10:22:29 25 should -- did I put 150 up? Yeah.

10:22:39 1 The issue -- the issue that we're concerned
10:22:40 2 about here is primarily the malate salt, the malate salt
10:22:46 3 aspect of the claims. We got claims to the salt in the
10:22:49 4 reference patent, and is the selection of malate salt
10:22:54 5 somehow inventive?

10:22:56 6 Now, I mentioned to Your Honor there are other
10:22:58 7 elements that theoretically could be at issue in the
10:23:01 8 obviousness analysis here with different claims. There's a
10:23:07 9 crystalline aspect of this, but I think the evidence is that
10:23:12 10 of salts used in pharmaceutical products, 90 percent of
10:23:17 11 salts used are crystalline. It's routine to use crystalline
10:23:21 12 salts. There's also a treatment of cancer aspect to these
10:23:27 13 claims. And the treatment of cancer was also taught by the
10:23:31 14 '928 application. So, I don't think those are going to be
10:23:35 15 substantial issues.

10:23:36 16 So, let me talk about malate salt which I think
10:23:39 17 is where the issue actually is. And what we did was at
10:23:45 18 trial was to present you with evidence that malate salts
10:23:50 19 were within -- were the type of salts that a person of
10:23:55 20 ordinary skill in the art would consider and use. They
10:24:01 21 are -- there's evidence that they're not toxic. They come
10:24:04 22 from natural ingredients. I believe it was apples. They
10:24:07 23 have been used with tyrosine kinase inhibitors which is the
10:24:13 24 kind of drug that we have at issue in this -- in this case.
10:24:18 25 And it's -- you heard a lot about the Rule-of-2. I am not

10:24:24 1 going to repeat it.

10:24:25 2 But it satisfies the Rule-of-2 when used with
10:24:28 3 cabozantinib. It satisfies GRAS, generally recognized as
10:24:33 4 safe. And so, it would be a good candidate to put into a
10:24:38 5 salt screen. The testimony was that a salt screen is
10:24:41 6 routine and nothing to indicate that it wasn't routine. And
10:24:46 7 when you put something in a salt screen, you're going to
10:24:49 8 find out its properties. And then it's the exercise of
10:24:52 9 ordinary skill to learn what would be acceptable.

10:24:55 10 And as Your Honor knows, we don't have to prove
10:24:58 11 that malate salt would have been the number one selection of
10:25:01 12 every person of skill in the art. We have to show that it
10:25:05 13 would be suitable for this use and it would be obvious that
10:25:07 14 it could be suitable for this use and I think that we've
10:25:12 15 done that.

10:25:12 16 I want to -- in opening I made reference to a
10:25:16 17 case, a *Pfizer* case, which we'll talk about in our briefs,
10:25:19 18 but that was a situation where there was pharmaceutical
10:25:27 19 salts in prior art and then a very specific salt that was
10:25:30 20 not a popular salt, not a popular salt for you called
10:25:35 21 besylate, kind of in the range of how often the malate salt
10:25:40 22 is used. And the Federal Circuit there said that it's
10:25:44 23 routine to select the salt in that instance. And so we'll
10:25:47 24 be relying on that case. With that, Your Honor, I'll save
10:25:52 25 whatever I have for rebuttal.

10:25:54 1 Thank you very much.

10:25:55 2 THE COURT: All right. Thank you.

10:25:56 3 MS. PIROZZOLO: Thank you, Your Honor. I'd like
10:26:04 4 to just briefly touch on a point with that Mr. Lombardi made
10:26:08 5 with regard to infringement. He put up the MSN lab notebook
10:26:13 6 data with the bulk density, tapped density, Carr index and
10:26:18 7 Hausner ratio numbers and said there was an agreement that
10:26:23 8 that experiment improved flow.

10:26:26 9 In fact, bulk density and tapped density are
10:26:29 10 used to calculate the Carr ratio and the Hausner index.
10:26:33 11 There is a discrepancy in the lab notebook. Those numbers
10:26:37 12 don't match. But as Dr. Koleng explained, he disregarded
10:26:41 13 that data because you can't tell where the error is. It
10:26:45 14 could be that the bulk density and tapped density numbers
10:26:49 15 are wrong so we do not -- everybody does not agree that the
10:26:53 16 data in the lab notebook disproves that GRASTAR improves
10:26:58 17 flow. And Dr. Koleng's testimony is that at Page 182 of the
10:27:02 18 transcript.

10:27:04 19 THE COURT: And so, Dr. Koleng, his testimony
10:27:07 20 was, in so many words, yeah, there's an error, but I'm not
10:27:11 21 sure where?

10:27:12 22 MS. PIROZZOLO: Exactly.

10:27:13 23 THE COURT: Okay. Thank you.

10:27:14 24 MS. PIROZZOLO: Now, I'd like to go on the
10:27:20 25 validity issues with the '349 patent. What is clear is that

10:27:25 1 the process in the Brown patent is very different from the
10:27:30 2 process in the '349 patent. Dr. MacMillan testified about
10:27:35 3 differences in the process. And I'd like to go -- on the
10:27:41 4 issue of whether these three Regis batches are sufficient to
10:27:45 5 prove that the --

10:27:48 6 THE COURT: So, before you go there, talking
10:27:50 7 about the Brown process being different, do you agree that
10:27:55 8 for this really the only question is the disclosure either
10:28:02 9 inherently or otherwise of the essentially free limitation?

10:28:06 10 MS. PIROZZOLO: Well, the essentially free
10:28:09 11 limitation covers the pharmaceutical composition. So we
10:28:13 12 don't agree because really Dr. Myerson explained this gap in
10:28:19 13 their testimony --

10:28:20 14 THE COURT: Yeah. Right.

10:28:20 15 MS. PIROZZOLO: -- that getting to --

10:28:23 16 THE COURT: And so, but essentially, leaving
10:28:28 17 aside the -- that which I'm glad you brought up, the
10:28:35 18 obviousness is still -- focuses on the essentially free part
10:28:38 19 of --

10:28:40 20 MS. PIROZZOLO: That is correct, Your Honor,
10:28:42 21 because the -- this synthetic process that's disclosed in
10:28:47 22 the '349 patent is what allows the pharmaceutical
10:28:50 23 composition to be essentially free of the 1-1 impurity
10:28:54 24 because it -- the numbers that you saw on Table 2 are quite
10:28:59 25 low, 2 to 12. And that means, as Dr. Shah explained, during

10:29:03 1 manufacturing, you can put that API with excipients, expose
10:29:08 2 it to heat and water, and the actual tablets that are taken
10:29:12 3 by cancer patients will remain free of the impurity.

10:29:16 4 Now, if we could pull up Slide 12, which is
10:29:22 5 Plaintiff's Exhibit -- it's Page 2 of Plaintiff's
10:29:25 6 Exhibit 38. This is a table that we reviewed during the
10:29:30 7 trial that has data for the three Regis batches and the one
10:29:36 8 Girindus batch. And what the table shows is that the
10:29:42 9 Girindus batch had .06 which is 600 PPM of the impurity.

10:29:50 10 With the analytical methods used here, no 1-1
10:29:55 11 was detected in the Regis batches. But to the core question
10:30:01 12 of whether these three Regis batches are sufficient to prove
10:30:05 13 that the Brown process inevitably will produce API free of
10:30:11 14 the 1-1 impurity, this chart shows the problems with that
10:30:16 15 argument. MSN's argument is that the three Regis batches
10:30:21 16 were all using the same method, but if you look at this
10:30:25 17 chart, there are wide variations between the purity reported
10:30:29 18 for those three batches in this chart.

10:30:31 19 For example, if you look at the bottom of the
10:30:33 20 chart on the total impurities line, one Regis batch had
10:30:39 21 .87 percent, another had .58 percent, another had .54. And
10:30:46 22 there are similar discrepancies all over the rest of the
10:30:50 23 chart.

10:30:50 24 So, this shows the variability inherent in this
10:30:57 25 process that Dr. Myerson talked about during his

10:31:01 1 examination.

10:31:02 2 And, you know, I think counsel said Dr. Myerson
10:31:08 3 agreed that the -- that Regis exactly followed the Brown
10:31:12 4 method. That's not correct. Dr. Myerson made the point
10:31:17 5 that there's variability inherent in these processes.

10:31:22 6 And we also heard testimony during trial that
10:31:25 7 there was also deviation or process changes for the Regis
10:31:30 8 batches as well. So, it doesn't make sense for MSN to think
10:31:36 9 about process deviations for Girindus but not think about
10:31:40 10 process deviations for Regis. But the bottom line is the
10:31:44 11 inherency standard is very high and MSN hasn't presented
10:31:49 12 evidence to show that every time you practice the Brown
10:31:53 13 process you'd get API essentially free of the 1-1 impurity.

10:31:58 14 In fact, MSN's argument really flies in the face
10:32:01 15 of all the facts in this case. You know, you heard
10:32:05 16 testimony from Dr. Wilson, Dr. Shah that Exelixis has spent
10:32:09 17 eight years developing this new synthetic process. You
10:32:13 18 heard testimony from Dr. MacMillan that the B-2 process was
10:32:18 19 very different. The A-2 process, that they're saying
10:32:23 20 inherently produces API essentially free of the 1-1
10:32:27 21 impurity, has the steps that Exelixis discovered would
10:32:32 22 result in degradation and formation of the impurity during
10:32:37 23 synthesis. So it simply doesn't make sense to say every
10:32:41 24 time you follow that process that Exelixis had to change to
10:32:46 25 get this truly pure API that it would produce the -- the API

10:32:51 1 desired.

10:32:51 2 So, I will now -- unless Your Honor has
10:32:54 3 questions, I will yield to Mr. Prussia.

10:32:57 4 THE COURT: All right.

10:33:00 5 MR. PRUSSIA: Thank you, Your Honor. If it
10:33:11 6 suits the Court, I'll start with double patenting and then
10:33:13 7 move to written description. Or I can take it the other way
10:33:18 8 if you like.

10:33:18 9 THE COURT: Yeah. Why don't you do it the other
10:33:20 10 way.

10:33:20 11 MR. PRUSSIA: Sure. And I just want to level
10:33:23 12 set for the Court. As Your Honor knows, none of these
10:33:25 13 claims involve functional limitations. We're talking about
10:33:28 14 what everyone agrees are structural elements of the claim.
10:33:33 15 There was no rejection during prosecution. The examiner
10:33:36 16 never said your claims do not support a genus of crystalline
10:33:40 17 salts. This is the first time this issue is coming up in
10:33:44 18 this litigation.

10:33:45 19 Another important point, Your Honor, is that
10:33:48 20 there is an agreed upon plain meaning. Now, Mr. Lombardi
10:33:52 21 says that we're playing word games, but the experts agree on
10:33:55 22 what the plain meaning is and that plain meaning does not
10:33:58 23 include the word "forms."

10:33:59 24 Now, they -- they are trying to make this into a
10:34:03 25 genus case. It's not a genus case. If there is any -- if

there is a genus here, it's the genus of crystalline malate salts that Dr. Trout showed you in the specification are the three salts that are identified at Column 6; the (L)-malate salt, the (D)-malate salt, and the (DL)-malate salts.

You only get to this genus of forms if you do with -- if you do what -- do to the claim that Mr. Lombardi did with his hypothetical with Dr. Trout. You remember he asked Dr. Trout to assume -- to write in the words -- if you go to -- where is it guys -- 43.

He asked Dr. Trout to assume that the word "forms" was at the end of the claims. That's the only way you get to their genus of forms is if you do what Mr. Lombardi is asking you to do, which is literally rewrite the claims to write in the word forms. That's entirely improper when we have a plain and ordinary meaning of the claims. And let's go to that plain and ordinary meaning.

That plain and ordinary meaning, if you go to Slide 38 --

THE COURT: But just in that point, the practical effect of crystalline, as opposed to crystal forms, is -- the scope of the patent is the same; isn't it?

MR. PRUSSIA: Well, the scope -- well, in the sense that crystalline only requires repeated long range order. Forms requires that long range order to be arranged in a particular arrangement. And so it is correct,

10:35:42 1 Your Honor, that -- as Dr. Trout testified, that the claims
10:35:45 2 will cover additional forms, but the claim doesn't require
10:35:48 3 that. All the claim requires is crystalline material and
10:35:53 4 the testimony from both sides is that a person of skill
10:35:56 5 could identify that crystalline material without the need to
10:36:01 6 further identify the forms. It's two separate things.

10:36:04 7 And as we walked the Court through the
10:36:05 8 specification, that's how the inventors set out their
10:36:08 9 invention. They explain the crystalline salts. They
10:36:12 10 explain the beneficial properties of those crystalline
10:36:16 11 malate salts; the stability, the suitable characteristics
10:36:20 12 for a pharmaceutical development.

10:36:22 13 And then underneath Table 1, we focused on that
10:36:25 14 paragraph that then went on to describe the separate aspect
10:36:30 15 of the disclosure, which they specifically called out as
10:36:33 16 distinct and different from the malate salts. And that's
10:36:35 17 the first time in the whole patent where they introduced the
10:36:39 18 concepts of crystalline forms.

10:36:41 19 So it's set out as two separates inventions and
10:36:44 20 rightly so because the malate salts impart properties --
10:36:49 21 general properties of stability, pure crystallinity, and you
10:36:55 22 heard testimony from Dr. Shah as to what those benefits --
10:36:59 23 what those benefits translate to in terms of providing rapid
10:37:03 24 dissolution, which was the basis of his declaration that he
10:37:07 25 submitted to the Patent Office and how that relates

10:37:09 1 bioavailability of Cabometyx. The crystalline forms is a
10:37:15 2 separate -- is a separate invention here.

10:37:17 3 THE COURT: Well, so the crystalline is actually
10:37:22 4 not exactly the same scope as if it was crystalline forms,
10:37:24 5 it's got a broader scope.

10:37:26 6 MR. PRUSSIA: It does, yes. That is true.

10:37:28 7 But let's talk about the genus here. What is
10:37:32 8 the genus? Mr. Lombardi said that -- I think he put it
10:37:36 9 there was hand waving on our side. It's their burden by
10:37:40 10 clear and convincing evidence to establish whatever this
10:37:43 11 genus is that they say it is. And all you heard -- all you
10:37:47 12 saw was a list that Dr. Steed put up in front of you of 11
10:37:52 13 purported forms. He didn't actually walk you through his
10:37:56 14 analysis to show you how he identified what those supposed
10:38:00 15 forms were. And, in fact, when we were here last year, he
10:38:04 16 told Your Honor that the only way in which you can
10:38:08 17 differentiate, distinguish, identify forms is to identify
10:38:12 18 ten peaks, ten reflection points in the XRPD. He didn't do
10:38:15 19 that.

10:38:15 20 If we pull up DDX Steed 20.

10:38:18 21 This is what he put in front of Your Honor. He
10:38:20 22 put up -- he put up a list of four forms. Remember we
10:38:25 23 walked through to count the number of peaks that he
10:38:28 24 identified for each form. There aren't ten peaks. His
10:38:32 25 testimony under oath in this Court before was you need ten

10:38:35 1 peaks. He doesn't identify ten peaks.

10:38:37 2 So this idea that there's this genus of 11
10:38:40 3 forms, where is the evidence of that? It's just simple
10:38:43 4 say-so from Dr. Steed. I submit that doesn't meet their
10:38:46 5 burden of clear and convincing evidence.

10:38:47 6 At the end of the day what they're asking the
10:38:50 7 Court to do is to say -- is to look at -- look at written
10:38:54 8 description through the lens of the accused product. And
10:38:56 9 we'll cite case law to Your Honor in our post-trial briefing
10:38:59 10 that suggests that's improper. That's not the analysis for
10:39:03 11 written description. We're not supposed to be looking at
10:39:05 12 the accused product for purposes of written description.

10:39:08 13 All we're asking is whether -- whether the four
10:39:11 14 corners of the specification discloses to a skilled artisan
10:39:14 15 that the inventors had possession of what's claimed. And
10:39:17 16 the undisputed testimony from both sides' experts is that a
10:39:23 17 person of skill in the art would look at these claims, they
10:39:26 18 would only be interested in identifying, under their view of
10:39:29 19 the rule that this claim covers forms; right?

10:39:33 20 The person of skill would only be interested in
10:39:35 21 pharmaceutically relevant forms, not far flung embodiments
10:39:39 22 that no one would ever look to develop.

10:39:41 23 Dr. Steed testified that pharmaceutically
10:39:44 24 relevant forms are just the forms that are likely to arise
10:39:47 25 during normal drug development. He said that at 540 of the

10:39:51 1 transcript, 541 of the transcript, 3 -- 3 through 10.

10:39:55 2 And he admitted that N-1 and N-2 are stable
10:39:59 3 forms, they're -- they provide good pharmaceutical
10:40:02 4 properties, and there's no evidence from them that N-1 and
10:40:06 5 N-2 are not representative of whatever genus they say
10:40:10 6 exists. They didn't put on any evidence that suggests that
10:40:13 7 N-1 and N-2 are not representative of these forms. It's
10:40:17 8 their burden.

10:40:18 9 Now, all they did was come up with the, what I
10:40:21 10 would say, is the unremarkable, undisputed, uncontested
10:40:25 11 point that different forms can have different properties.
10:40:28 12 To that I'd say, so what?

10:40:32 13 Dr. Steed admitted to the Court that -- that
10:40:36 14 when you -- when Your Honor asked the question whether his
10:40:39 15 interpretation would result in nothing being representative
10:40:42 16 of anything, that's exactly the result of their argument.
10:40:47 17 Nothing would be representative, if anything. That's --
10:40:50 18 that's not the law. That's not the way we're supposed to
10:40:53 19 look at things.

10:40:53 20 Again, the question is N-1 and N-2, under their
10:40:57 21 version of the world where this claim covers forms, is it
10:41:00 22 representative of what -- what a person of skill in the art
10:41:03 23 would understand to be the invention? And the agreed upon
10:41:08 24 testimony is that a person of -- a person of skill in the
10:41:11 25 art would be interested in pharmaceutically relevant forms.

10:41:15 1 Dr. Trout told you at most it would be three
10:41:17 2 forms, so we're talking N-1 and N-2 and form S.

10:41:23 3 And what do we know about form S? We know that
10:41:27 4 Dr. Steed's not arguing that it's not -- he's not arguing
10:41:30 5 that it's an unstable form. There was some testimony about
10:41:34 6 form S being hygroscopic, but Dr. Steed told Your Honor that
10:41:38 7 he's not offering the opinion that just because it's
10:41:41 8 hygroscopic it's unstable. We know from the first case,
10:41:45 9 they came in and they argued to Your Honor that form S is a
10:41:49 10 stable form. And we know that they have represented to the
10:41:54 11 Food & Drug Administration that their form S is
10:41:56 12 bioequivalent to the same forms that are disclosed in our
10:42:02 13 patent specification.

10:42:03 14 So where is the evidence that N-1 and N-2 are
10:42:06 15 not representative, even under their, what I would say,
10:42:09 16 incorrect, misconstrued version of the claims?

10:42:15 17 Under the proper construction of the claims
10:42:18 18 where you apply the agreed upon plain and ordinary meaning,
10:42:20 19 they didn't even put on a case that there's lack of written
10:42:25 20 description. There is agreement that cabozantinib is
10:42:29 21 disclosed. Agreement that there are methods of preparing
10:42:33 22 crystalline cabozantinib malate disclosed in the
10:42:36 23 specification.

10:42:36 24 So, under what we would say is the proper
10:42:39 25 understanding of these claims, where it simply covers

10:42:43 1 crystalline salts, and all you're looking for -- all you're
10:42:46 2 doing is asking the question whether there's crystalline
10:42:51 3 malate salts disclosed in the specification, the answer to
10:42:54 4 that question is yes and there's no dispute about that.

10:42:56 5 But even if you want to go further and say,
10:42:58 6 okay, maybe, you know, because this covers forms there needs
10:43:02 7 to be some disclosure that the inventors possessed forms, we
10:43:06 8 have disclosure of that as well. And that's supported by
10:43:09 9 the representativeness of N-1 and N-2.

10:43:12 10 And I'm sure there will be some suggestion on
10:43:14 11 the other side that that's not fair because we didn't invent
10:43:17 12 form S, and we never said that we invented form S, but
10:43:21 13 that's not -- that's not the question.

10:43:22 14 We disclosed crystalline salts all the way back
10:43:26 15 in 2009. We disclose the advantageous properties of those
10:43:31 16 salts. We disclosed it to the world. Disclosed it to MSN.
10:43:35 17 They took it. They cited in their patents. They created
10:43:39 18 form S. They got a patent for form S. That's the way it's
10:43:42 19 supposed to work.

10:43:43 20 You disclose an invention. People come along,
10:43:46 21 they try to improve upon the, they get their own patents.
10:43:49 22 Their patent goes out to 2039. So, they have their own
10:43:53 23 benefit that they've attained by our disclosure of the
10:43:57 24 beneficial properties of crystalline salts. There's nothing
10:44:01 25 uncommon, there's nothing unusual about that.

10:44:03 1 As Your Honor knows, these claims of
10:44:07 2 pharmaceutical salts, they're essentially ubiquitous and
10:44:10 3 Your Honor is looking for a case that says, well, under 112,
10:44:13 4 you know, a claim like this would be invalid. The fact that
10:44:16 5 it hasn't existed suggests the uncommon nature of their
10:44:20 6 argument in this case.

10:44:21 7 So I'm happy to answer any questions you have on
10:44:24 8 112, Your Honor.

10:44:26 9 THE COURT: So, just -- you mentioned when I
10:44:30 10 asked Dr. Steed -- I was thinking about asking Dr. Trout,
10:44:34 11 but I didn't -- there was one point where he said, well, N-1
10:44:39 12 and N-2 are -- yes they're representative and he said three
10:44:45 13 things, one of which was they have the same chemical
10:44:49 14 formula. The other two, at least in the moment, didn't
10:44:51 15 strike me as much in the way of differentiation.

10:44:56 16 It strikes me had I asked, but I didn't, that
10:45:00 17 Dr. Trout's opinion would be one polymorph is representative
10:45:04 18 of all polymorphs.

10:45:06 19 MR. PRUSSIA: So I don't think Dr. Trout would
10:45:08 20 say that. What I think he would say, and what our position
10:45:10 21 is, they can be.

10:45:12 22 And so the question here is for N-1 and N-2,
10:45:15 23 where they're highly stable forms, those are the forms that
10:45:18 24 were known as of the priority date. We're talking about
10:45:20 25 after arising forms; right?

10:45:21 1 Is there anything about -- and just to back up,
10:45:27 2 this is a well-studied system. 14 years it's been in the
10:45:30 3 prior art, four different pharmaceutical companies have
10:45:32 4 studied it. And at most, if you just take at face value
10:45:37 5 Dr. Steed's list, which we don't because there's been no
10:45:39 6 rigorous analysis of it, it's at most 11. So this is not --
10:45:42 7 this is not 70 forms. I don't know what the evidence is to
10:45:46 8 support that. We're not talking about hundreds of forms out
10:45:50 9 there.

10:45:50 10 THE COURT: We're talking about two handfuls.

10:45:52 11 MR. PRUSSIA: Two handfuls at most of which we
10:45:55 12 would say, you know, is unsupported. But two handfuls at
10:45:57 13 most and so the question would be: Is there anything about
10:45:59 14 those additional forms that make N-1 and N-2 not
10:46:03 15 representative? And I would say -- submit that we saw no
10:46:06 16 evidence of that. So, I don't think we would go that far.

10:46:10 17 THE COURT: And so, just going back to where we
10:46:13 18 were at the beginning is once -- once the inventors had
10:46:20 19 discovered they could make some crystal, crystalline
10:46:25 20 structure or crystalline amount of the API, they could then
10:46:37 21 patent in effect all crystalline structures of the API
10:46:43 22 whether they were just little bits or, you know,
10:46:48 23 well-defined polymorphs that just hadn't been discovered
10:46:51 24 yet; right?

10:46:52 25 MR. PRUSSIA: Under -- under a strict plain

10:46:56 1 reading of the claim, yes, it's structure. So if someone
10:46:59 2 else incorporates that structure, Your Honor is correct.
10:47:02 3 But there's a limiting principle here, and that's for the
10:47:07 4 person of skill in the art, looking at these sorts of
10:47:09 5 claims, you're interested in the forms that are
10:47:11 6 pharmaceutically developable in the pharmaceutically
10:47:13 7 relevant forms. So these sorts of far-flung embodiments
10:47:16 8 aren't really within the scope of the claims. That's not --
10:47:19 9 that's not something that a person of skill in the art --
10:47:21 10 let me correct that. It is within the scope of the claims,
10:47:25 11 but a person of skill in the art who's looking to -- who is
10:47:28 12 looking to practice the invention is concerned primarily
10:47:33 13 with those forms that are pharmaceutically relevant.

10:47:35 14 THE COURT: But the bioavailability or whatever
10:47:38 15 of the API has already been determined; right?

10:47:42 16 MR. PRUSSIA: Well, the bioavailability of -- in
10:47:45 17 the sense that it -- whether it has good or bad
10:47:48 18 bioavailability, yes. Yeah, that's right.

10:47:50 19 THE COURT: So, I mean, I'm thinking -- you
10:47:53 20 know, there's a famous case or I think there's somebody who
10:47:57 21 patented a drug for its cancer effect even though it would
10:48:00 22 come to you in a different way. So, that's not much of a
10:48:05 23 restraint, I don't think.

10:48:07 24 MR. PRUSSIA: I've lost the thread of Your
10:48:09 25 Honor's question, I apologize.

10:48:10 1 THE COURT: Yeah, yeah. Well, it's not
10:48:11 2 worthwhile. Keep going where you're going.

10:48:13 3 MR. PRUSSIA: I'm hoping to pivot to
10:48:16 4 obviousness-type double patenting.

10:48:18 5 THE COURT: Okay.

10:48:19 6 MR. PRUSSIA: Okay. So, on this, on this,
10:48:21 7 Your Honor, I find it interesting. You and I have had a
10:48:25 8 discussion, and Mr. Lombardi has been having a discussion
10:48:27 9 and --

10:48:29 10 THE COURT: Just on the written description, do
10:48:31 11 you agree that the three patents they clearly just rise and
10:48:36 12 fall together?

10:48:37 13 MR. PRUSSIA: On written description? Yes.
10:48:39 14 Yes.

10:48:40 15 THE COURT: Okay. But how about on obvious-type
10:48:43 16 double patenting, I take it your view, which seems to me to
10:48:47 17 be the right one, would be leaving aside -- theoretically at
10:48:52 18 least there are three different patents.

10:48:54 19 MR. PRUSSIA: That's exactly right, and we
10:48:56 20 disagree that they rise and fall together.

10:48:58 21 Now, Mr. Lombardi is trying to minimize the
10:49:02 22 significance of the additional limitations the
10:49:05 23 pharmaceutical --

10:49:05 24 THE COURT: No. No. I mean, yes. He takes the
10:49:07 25 one that's his best case.

10:49:10 1 MR. PRUSSIA: Right.

10:49:10 2 THE COURT: You presumably would pick a
10:49:12 3 different one as your best case.

10:49:13 4 MR. PRUSSIA: That's exactly right, sir. And
10:49:15 5 the reason why he's minimizing those additional limitations
10:49:17 6 is because he has no evidence on them. So, these additional
10:49:21 7 limitations, the method of treating kidney cancer, the
10:49:24 8 pharmaceutical composition claims, you remember right at the
10:49:26 9 beginning of my cross-examination of Dr. Steed, he admitted
10:49:29 10 he has no expertise. He's not a formulation scientist.
10:49:33 11 He's not a clinician, of course. He has no expertise in
10:49:37 12 those elements of the claim. He doesn't rely on anyone who
10:49:40 13 has expertise for those elements of the claim. So has no
10:49:44 14 competency. He has no ability to offer an opinion with
10:49:47 15 respect to the obviousness of those limitations, and I would
10:49:49 16 suggest that his testimony on that point should be
10:49:53 17 discredited.

10:49:54 18 And that reason alone is -- is what -- they
10:49:58 19 haven't met their burden, I would say, in terms of
10:50:00 20 establishing obviousness for those additional limitations of
10:50:03 21 the claims.

10:50:03 22 And that's part of -- that's part of the
10:50:07 23 analysis here. I mean, as Your Honor knows, we're comparing
10:50:10 24 Claim 5 against all of the additional limitations that are
10:50:13 25 in the crystalline malate salt patents. We have those

10:50:15 1 additional limitations, and we have the limitations for the
10:50:19 2 crystalline and the malate salt limitations that everyone
10:50:22 3 agrees none of that is disclosed in the claim. None of that
10:50:27 4 is disclosed in the underlying specification. So, those are
10:50:32 5 differences, and they are distinct differences.

10:50:34 6 And I would suggest that the discussion that you
10:50:36 7 and I have been having and the discussion that you and
10:50:38 8 Mr. Lombardi had about the nature of the claims of the
10:50:41 9 crystalline malate salt patents -- we've been talking about
10:50:43 10 polymorphs and the like -- that further suggests that these
10:50:46 11 claims are patentably distinct because if that's right, if
10:50:49 12 the crystalline malate salt patents should be considered
10:50:52 13 with respect to the idea that they cover crystalline forms
10:50:55 14 and the like, none of that's disclosed in the '473 patent.

10:50:58 15 There's no discussion of the need for a
10:51:01 16 pharmaceutical salt. There's no discussion for the -- about
10:51:05 17 the -- the problems that a pharmaceutical salt was looking
10:51:08 18 to address with cabozantinib or the beneficial properties
10:51:11 19 that it could impart to the API. None of that's there in
10:51:15 20 the prior art.

10:51:15 21 So, if that's something that should be
10:51:18 22 considered for the crystalline malate salt patents in terms
10:51:20 23 of 112, then it certainly should be considered with respect
10:51:24 24 to obviousness-type double patenting, and I would say by
10:51:26 25 itself is enough to overcome their argument. But if you go

beyond that, if you peel the layer of beyond -- beyond that, you have to remember, just looking at the face of the claim, it doesn't require a pharmaceutically acceptable salt.

There is that "or" in the middle. So, there does need to be a motivation to even try to go with the salt to begin with.

And I'd say we didn't hear much of anything.

THE COURT: Wait, wait. I lost the thread.

MR. PRUSSIA: Mm-hmm.

THE COURT: When you're talking about "or," you're talking about the reference patent; right?

MR. PRUSSIA: That's exactly -- it's the base claim in the '473 patent.

THE COURT: And so why would -- why does the "or" matter?

MR. PRUSSIA: I'd say "or" matters because the claim allows to you move forward with the free base. So there needs to be -- there's multiple layers of motivation here that they need to establish. Number one, motivation to abandon the free base and develop a pharmaceutically acceptable salt. One.

Two, motivation to -- motivation to include malic acid in a salt screen, and then -- and then -- well, before you even get to that, motivation to form a salt to begin with. Then motivation to include malic acid in a salt solution. So there's three layers of motivation that they

10:52:40 1 need to establish. And I'd say on all of them, they fail to
10:52:44 2 meet their burden. I read the Madam Court Reporter's
10:52:48 3 transcript about six or seven times looking for where there
10:52:51 4 was a discussion of motivation in Dr. Steed's direct
10:52:55 5 examination and the only hint of it at the time is when he
10:52:57 6 started talking about testing solubility.

10:53:01 7 The reason that he has to go to testing things
10:53:03 8 is because there was no disclosure of any problems in the
10:53:06 9 prior art with the free base of cabozantinib. Everyone
10:53:10 10 agrees on that. There's no disclosure of any problems with
10:53:13 11 this bioavailability, solubility, dissolution, none of that.
10:53:18 12 So, we have to ask the question: Why would a POSA even want
10:53:22 13 to try a salt to begin with? But even if you skip over that
10:53:25 14 question --

10:53:25 15 THE COURT: I thought there was some
10:53:27 16 testimony -- and maybe it was in a different context -- that
10:53:29 17 a salt was generally a preferable way of delivering a drug
10:53:34 18 product.

10:53:34 19 MR. PRUSSIA: I think he offered some testimony
10:53:36 20 about the general properties of a salt, but even if you just
10:53:39 21 look at the numbers, I -- I showed -- I think it was the
10:53:43 22 Paulekuhn reference that showed that of all the Orange Book
10:53:46 23 listed patents, half of them are not in a salt form.

10:53:49 24 So -- but I don't think even if you were to go
10:53:51 25 based on data that's enough for a motivation. What's this

10:53:54 1 generalized motivation theory the Federal Circuit has told
10:53:57 2 us is not enough? There needs to be some specific
10:54:00 3 motivation in the context of your case to direct a POSA to
10:54:04 4 do what the inventors did to arrive at the invention, and
10:54:08 5 they just haven't come up with that. All they're pointing
10:54:11 6 to is generalized things. So what they do is resort to, oh,
10:54:14 7 well, you make it, you test it, and you'd see it has low
10:54:17 8 water solubility so that would give you motivation.

10:54:19 9 But if you would make it and you test it, then
10:54:22 10 what's the limiting principle? Why wouldn't you test its
10:54:26 11 solubility and biorelevant media? Why wouldn't you test its
10:54:30 12 permeability? Why wouldn't you test its dissolution? And
10:54:33 13 the testimony that we saw from Dr. Trout based on what we
10:54:37 14 know today about cabozantinib, as Dr. Shah explains that, if
10:54:40 15 you did all those things, the POSA would have realized
10:54:44 16 there's no need to form a salt because the solubility in
10:54:47 17 water and the solubility in biorelevant media is the same.
10:54:51 18 They're both poorly soluble in each context.

10:54:54 19 The reason why the inventors formed a salt had
10:54:56 20 nothing to do with solubility. It had to do with stability.
10:54:59 21 And there was nothing about that, of course, in the prior
10:55:02 22 art, and you heard nothing about that from Dr. Steed because
10:55:04 23 it wasn't available to a POSA.

10:55:06 24 But even if you get beyond the motivation to
10:55:09 25 form a salt point, we got to talk about malic acid. Had

10:55:14 1 only been used four times in the history of approved drugs
10:55:17 2 by the time we got to the priority date. 0.26 percent of
10:55:21 3 the time.

10:55:22 4 And the only way that Dr. Steed gets to
10:55:26 5 including malic acid in the salt screen is just through
10:55:29 6 multiple layers of hindsight. He picks the things that he
10:55:33 7 likes that work that include malic acid, like the Rule-of-2
10:55:38 8 as Your Honor showed with my easel. He excluded the
10:55:42 9 Rule-of-3.

10:55:44 10 Why? I would submit because it didn't work for
10:55:46 11 malic acid. He ignored the definition in the specification
10:55:51 12 of the '473 patent. Why? Because malic acid was not one of
10:55:55 13 the 24 listed acids in the specification. And then, we have
10:56:00 14 this genus of 113. That's the genus, at least 113
10:56:06 15 pharmaceutically acceptable salts.

10:56:08 16 And his list that he ultimately showed the Court
10:56:12 17 excludes things like hydrochloric acid which he agrees and
10:56:17 18 everyone knows is well established in the literature is the
10:56:20 19 most commonly used acid. He says a person of skill in the
10:56:24 20 art wouldn't even have included that in a salt screen for
10:56:28 21 cabozantinib. That, I would suggest, just illustrates the
10:56:32 22 level of hindsight that he's applying because he's only
10:56:35 23 applying rules that allows him to arrive at malic acid.

10:56:40 24 And then, with respect to reasonable expectation
10:56:43 25 of success, the testimony that came in from Dr. Koleng, who

as Your Honor heard, is the only expert in this case who's actually done this work. He's the only one that has conducted salt screens, has consulted with a pharmaceutical drug company about identifying the best salt out of a screen. He explained for the Court all of the inputs that go into salt screening, all of the variability and why it's -- there's no expectation of success through the salt screen.

And we heard from Dr. Koleng and Dr. Trout, if we go to Slide 29, about all of the things that have -- would have led a POSA -- I don't want to use the words teaching away. It may be too strong, but the things that were taught in the prior art about the limitations of malic acid. It isn't just, you know, malic acid has only been used four times in the -- as of the priority date. That's not -- doesn't reduce just to that.

There's a reason why it had only been used four times as of the priority date. There were complications as were described in the prior art with malic acid. Dr. Koleng and Dr. Trout described that for the Court. And it helps to explain the reasons why malic acid had been rarely used. And on top of that, both Dr. Trout and Dr. Koleng explained why those concerns would have caused additional concerns specific to cabozantinib, given the fact that it was a weak base.

10:58:17 1 And, finally, with reasonable expectation of
10:58:20 2 success, they are trying to suggest that -- I think what
10:58:26 3 they're arguing to Your Honor, if I heard Mr. Lombardi
10:58:27 4 correctly, that the standard -- that they meet the
10:58:31 5 reasonable expectation of success simply because malic acids
10:58:36 6 were in the prior art, and even though they were not in the
10:58:37 7 prior art with respect to cabozantinib. And if you could
10:58:41 8 form a salt with the malate salt, then that's enough. It's
10:58:45 9 not enough.

10:58:46 10 There needs to be some reason for a POSA to
10:58:50 11 arrive at the invention. There needs to be some --
10:58:54 12 something that would point a POSA to arrive at that
10:58:57 13 particular species of the genus of 113. And there was
10:59:01 14 nothing in the prior art that would have guided the POSA to
10:59:04 15 malic acid.

10:59:05 16 The reason for that is because there was no
10:59:07 17 disclosure in the prior art about any problems. If you
10:59:11 18 don't know the problems that you're looking to solve with
10:59:13 19 the salt, how do you know which salt to pick?

10:59:18 20 And then, finally, unexpected results, which I
10:59:21 21 think are important here in this case. Dr. Shah testified
10:59:26 22 to Your Honor about this. You didn't see any experimental
10:59:29 23 data from them responding to the evidence of unexpected
10:59:34 24 results that were submitted to the Patent Office. And by
10:59:37 25 the way, of course, as we showed Your Honor at the end of

10:59:40 1 Dr. Trout's examination, is what contributed -- is what --
10:59:44 2 it was a contributing factor to the Patent Office allowing
10:59:46 3 the claims over the exact same prior art that Dr. Steed and
10:59:50 4 MSN are relying on in this case.

10:59:53 5 And if I could just take one more minute,
10:59:55 6 Your Honor.

10:59:55 7 THE COURT: Yeah, yeah.

10:59:56 8 MR. PRUSSIA: I'm sure they're going to stand up
10:59:57 9 and talk about the Pfizer case. A couple things about the
11:00:00 10 Pfizer case from almost 20 years ago at this point.

11:00:03 11 When the Federal Circuit wrote that decision,
11:00:05 12 they explicitly said that their decision was limited to the
11:00:08 13 particularized facts of that case. That's their words, it's
11:00:12 14 not mine. It was limited to the particularized facts of
11:00:15 15 that case and since then there have been numerous decisions,
11:00:19 16 including the *Merck versus Mylan* decision in a sister court
11:00:24 17 in West Virginia that, have found claims like this to not be
11:00:31 18 obvious. And in that case there was also an
11:00:33 19 obviousness-type double patenting challenge.

11:00:35 20 And we'll lay out for Your Honor in our briefing
11:00:37 21 how this case maps on directly to cases like *Merck versus*
11:00:41 22 *Mylan*. Just as in this case -- just as in that case where
11:00:46 23 there was testimony that hydrochloric acid was the most
11:00:49 24 preferred salt, the same is true here. Just as in that case
11:00:52 25 where there was no disclosure of any problems with the base

11:00:55 1 compound, the same is true here. Just as in that case where
11:00:59 2 there was testimony that the pK_a delta, whether it's two or
11:01:05 3 three, doesn't provide a reasonable expectation of success,
11:01:08 4 the same is true here. And I would say even more so in this
11:01:12 5 case, we have evidence because of the unexpected results
11:01:16 6 that are essentially unrebutted by -- by the other side.

11:01:23 7 And on top of that, the -- the additional fact
11:01:31 8 that we're dealing with in the case of malic acid, a
11:01:34 9 counterion that had only been used four times in the history
11:01:37 10 of approved salts as of the priority date, and we offer
11:01:41 11 specific reasons in the context of cabozantinib why it would
11:01:44 12 have led to it being even a further complicated choice.

11:01:48 13 So I know I'm over my time, but I'm also happy
11:01:51 14 to answer any questions the Court has.

11:01:53 15 THE COURT: So, the prior trial we had dealt
11:02:01 16 with the reference patent here; right?

11:02:04 17 MR. PRUSSIA: That's correct.

11:02:04 18 THE COURT: And the same ANDA product that we're
11:02:11 19 talking about today -- or I guess products is the right
11:02:16 20 word -- they infringed that patent; right?

11:02:18 21 MR. PRUSSIA: That's right.

11:02:20 22 THE COURT: And so, by -- so, the malate salt
11:02:33 23 claims, they could be thought of as essentially dependent
11:02:38 24 claims from -- or they could at least be made into dependent
11:02:45 25 claims from the reference patent; right?

11:02:48 1 MR. PRUSSIA: I would say no, Your Honor. I
11:02:53 2 would say that -- well, whether they could. I think that --
11:02:57 3 what our position would be is that there's -- there's
11:03:00 4 different supports. There's additional support in the
11:03:02 5 malate salt patents that would support, especially the
11:03:05 6 crystalline and the -- and the malate aspect of the claims
11:03:10 7 that are -- do not appear in the '473 patent.

11:03:13 8 THE COURT: Right. But the -- if you think of
11:03:19 9 the reference patent in the Venn diagram sense --

11:03:23 10 MR. PRUSSIA: Yeah, yeah.

11:03:24 11 THE COURT: -- the patents that we're talking
11:03:27 12 about here are within the Venn diagram. They're little
11:03:31 13 pinpoints somewhere in that diagram; right?

11:03:35 14 MR. PRUSSIA: I see what you're saying,
11:03:36 15 Your Honor. I just want to clarify one thing, that is if
11:03:37 16 they're different -- they're totally different families;
11:03:39 17 right? I just want to make that point.

11:03:41 18 But, yes, with that caveat. I understand what
11:03:43 19 you are saying but it was -- the suggestion sort of is that,
11:03:46 20 you know, this is a improper extension of essentially the
11:03:50 21 same invention and it's not that. It came it came off an
11:03:54 22 entirely different lineage with an entirely different
11:03:55 23 disclosure.

11:03:57 24 THE COURT: All right. So, as -- in the real
11:04:05 25 world, they could not have been dependent claims --

11:04:07 1 MR. PRUSSIA: Right.

11:04:08 2 THE COURT: -- because --

11:04:09 3 MR. PRUSSIA: That's right.

11:04:09 4 THE COURT: -- they didn't -- because the
11:04:13 5 independent claim was from somebody else.

11:04:14 6 MR. PRUSSIA: That's exactly right. Yeah.

11:04:27 7 THE COURT: And the phrase that's kind of the
11:04:35 8 guidepost for this analysis, patentably distinct.
11:04:44 9 Sometimes -- sometimes two words is enough. What would you
11:04:48 10 say -- what is the Federal Circuit's sort of further
11:04:54 11 explanation of what patentably distinct means?

11:04:57 12 MR. PRUSSIA: Your guess is as good as mine,
11:04:59 13 Your Honor. I think what they've said is the regular
11:05:03 14 obviousness analysis applies, except for you cannot use the
11:05:07 15 patentee' disclosure in the base reference against her in
11:05:12 16 the obviousness-type double patenting analysis.

11:05:14 17 You can look to it to help understand the
11:05:16 18 meaning of the claim, so that's why I pointed Your Honor to
11:05:19 19 that definition because it informs the meaning of the
11:05:23 20 claims. But, otherwise, what the Federal Circuit has told
11:05:26 21 us is that the analysis isn't the same.

11:05:29 22 THE COURT: And the --

11:05:40 23 MR. PRUSSIA: Which is why -- I hate to
11:05:42 24 interrupt your thought.

11:05:43 25 Which is why I was pointing to the motivation at

11:05:45 1 the beginning of my presentation on this because I think
11:05:47 2 they've skimmed over that and I think it's an important part
11:05:50 3 of the analysis.

11:05:51 4 THE COURT: And that's why when we started on
11:05:54 5 Monday maybe you had some issue and it was a surprise to me
11:05:59 6 that secondary considerations applied, that's the reason why
11:06:05 7 is because the Court has said it's essentially like
11:06:08 8 obviousness analysis.

11:06:10 9 MR. PRUSSIA: That's exactly right. Yes. I
11:06:14 10 believe it's the *Pfizer/Teva* case or something. We'll cite
11:06:16 11 it to you.

11:06:17 12 THE COURT: It seems like that's not in dispute.

11:06:18 13 MR. PRUSSIA: Yeah.

11:06:19 14 THE COURT: Okay. Thank you, Mr. Prussia.

11:06:21 15 MR. PRUSSIA: Thank you, sir.

11:06:25 16 MR. LOMBARDI: Your Honor, I'll just make a
11:06:28 17 couple points here.

11:06:30 18 Slide 83, please.

11:06:31 19 I'm going back to the '349 patent and the
11:06:34 20 inherency issue, Your Honor, and this is the table that
11:06:37 21 you've seen a number of times today already.

11:06:40 22 And counsel pointed to variation in other
11:06:45 23 impurities as an indication that somehow -- I think the
11:06:50 24 argument was that somehow the -- the experiment was,
11:06:50 25 Your Honor --

11:06:59 1 THE COURT: So the three things were not
11:07:01 2 identical.

11:07:02 3 MR. LOMBARDI: No, and -- but that's -- that's
11:07:04 4 not accurate, Your Honor. And they didn't get any testimony
11:07:07 5 on this, but obviously -- so take -- take the 1-1 impurity,
11:07:12 6 for instance. Under the GTI you get variation in test
11:07:17 7 results, that's normal in science. You got 20 in one
11:07:22 8 instance and 40 in another. That happens. That doesn't
11:07:25 9 mean there's a variation in the procedure that was used.

11:07:29 10 So, to point out a variation in some other
11:07:32 11 impurities and say, well, that means that it was performed
11:07:36 12 differently is not accurate because you have variations when
11:07:40 13 you do that kind of testing. And I just wanted to make that
11:07:43 14 point because what -- when you get down to it and drill down
11:07:47 15 to what the evidence actually was, you have Dr. Myerson just
11:07:51 16 looking and saying, yeah, I think there's variation. But
11:07:54 17 there's no proof that any variation came from an actual --
11:08:00 18 any variation in the 1-1 impurity, which is what we're
11:08:02 19 looking at. Variation above 200 parts per million, which is
11:08:06 20 the standard, there's no evidence that there was any
11:08:10 21 difference in the performance of the procedure that led to a
11:08:15 22 variation. And so that -- I wanted to make that -- that
11:08:18 23 point, Your Honor.

11:08:18 24 On the obviousness-type double patenting,
11:08:22 25 counsel tries to limit what the scope of the claims are and

11:08:27 1 talks a lot about it's -- what would be most
11:08:31 2 pharmaceutically relevant and things like that. That's just
11:08:34 3 not what the scope of the claim says. The scope of the
11:08:37 4 claim says all crystalline salts -- all crystalline --
11:08:40 5 excuse me. I'm sorry, Your Honor -- all crystalline salts.
11:08:44 6 That's the scope of the claims.

11:08:46 7 They did not describe or support the full scope
11:08:50 8 of the claims. He made a couple of comments about Dr. Steed
11:08:54 9 and what Dr. Steed said, which are not accurate. I -- and
11:08:59 10 I'll just tell you, first of all, Dr. Steed -- with those
11:09:02 11 peaks, Dr. Steed did look at all the peaks. He said have
11:09:06 12 you to look at the entire diffractogram. He put up a
11:09:10 13 limited view and he put that up to show you that there are,
11:09:14 14 in fact, differences in the structures. There are
11:09:17 15 differences in the structures. So, he showed you.

11:09:21 16 Now, Dr. Trout didn't show you anything, but he
11:09:24 17 showed you there are differences and he also told you that
11:09:27 18 the differences lead to different properties. Now, counsel
11:09:31 19 says, well, it doesn't matter because it's not -- it doesn't
11:09:35 20 affect pharmaceutical acceptability, the differences in
11:09:38 21 properties. That's not the issue. The claim is the full
11:09:42 22 scope. The full scope of the polymorphs under the -- under
11:09:47 23 the malate salt heading. The full scope.

11:09:51 24 And the properties are different across that
11:09:55 25 scope. They have to show they have description of the

entire scope of that, not what's pharmaceutically acceptable. And we talked about differences between form S, N-1 and N-2.

We talked about differences between N-1 and N-2 just as an example to show you that there are differences in the -- in the way the crystalline structures of the malate salt perform.

And finally, Judge, on the obviousness-type double patenting. They -- obviousness-type double patenting takes the reference claim and compares it to the patent-in-suit. And with the reference claimed here, pharmaceutical salt is disclosed. We don't have to prove any motivation. That's not part of it. It's disclosed.

Now there are other things we have to prove motivation about for sure, but not about the salt. That's right there in the reference claim, that's what we're comparing to the patents-in-suit.

And as to the additional issues, Your Honor, I did address -- I think counsel maybe said I didn't or maybe I misheard him, but I did address the other two elements that we need to address; one is crystalline salts and one is treatment of cancer.

And I told you that Dr. Steed, I believe it was, testified that 90 percent of all pharmaceutically acceptable salts that are sold are crystalline and that that would be a

11:11:28 1 motivation for a person of skill in the art to use that.

11:11:31 2 And the treatment of cancer actually appears in the

11:11:38 3 '928 application, which is the parent application to the

11:11:43 4 '473 patent. It's right there. It says use this for the

11:11:45 5 treatment of cancer.

11:11:47 6 So the motivation was there for those additional
11:11:50 7 points and if I gave that short shift the one the first
11:11:54 8 time, it wasn't my intention but I wanted to make sure I got
11:11:57 9 that.

11:11:57 10 And with that, Your Honor, I thank you for your
11:12:01 11 time and your staff for their time this week.

11:12:04 12 THE COURT: All right. Well, thank you,
11:12:08 13 Mr. Lombardi.

11:12:10 14 All right. Well, the argument has been helpful
11:12:14 15 this morning and so I will take this under advisement and
11:12:23 16 look forward to dealing with you again in the spring of
11:12:29 17 2024.

11:12:31 18 Okay. We'll be in recess. Thank you everyone
11:12:34 19 for your cooperation in this trial.

11:12:38 20 DEPUTY CLERK: All rise.

11:27:48 21 (Court was recessed at 11:27 a.m.)

22 I hereby certify the foregoing is a true and
23 accurate transcript from my stenographic notes in the
24 proceeding. /s/ Heather M. Triozzi
25 Certified Merit and Real-Time Reporter
U.S. District Court

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