

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

IN RE: OZEMPIC (SEMAGLUTIDE)) MDL NO. 22-MD-3038 (CFC)
PATENT LITIGATION) ANDA CASE

NOVO NORDISK INC. and NOVO)
NORDISK A/S,)

Plaintiffs,)

v.)

RIO BIOPHARMACEUTICALS)
INC., et al.,)

Defendants.)

NOVO NORDISK INC. and NOVO)
NOVO NORDISK A/S,)

Plaintiffs,)

v.)

MYLAN PHARMACEUTICALS INC.,)
)

Defendant.)

C.A. No. 22-294 (CFC)

C.A. No. 22-1040 (CFC)

Thursday, July 13, 2023

9:00 a.m.

Markman Hearing

844 King Street
Wilmington, Delaware

BEFORE: THE HONORABLE COLM F. CONNOLLY
United States District Court Judge

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2 APPEARANCES:3
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6 -and-

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P R O C E E D I N G S

(Proceedings commenced in the courtroom beginning at 9:00 a.m.)

THE COURT: Good morning. Please be seated.

All right. Let's start. We've got a lot of folks here. I guess I'll just do it in the order I have with Mr. Hitch. Oh, Mr. Egan, you're on that side. Go ahead and start.

MR. EGAN: Good morning, Your Honor. Brian Egan from Morris Nichols on behalf of plaintiff Novo Nordisk. Joining me today from the Fenwick law firm are Jeff Oelke, Robert Counihan.

MR. COUNIHAN: Morning, Your Honor.

MR. EGAN: Ryan Johnson, Erica Sutter, and Laura Moran.

We also have a number of client representatives here today, Your Honor, from Novo Nordisk: Kathryn Jones, Chloe Jiang, Wesley Nicolas, and Lori Klewin. And just in terms of order of presentation today, Your Honor, the parties have agreed to argue in the order in which they were briefed.

THE COURT: Okay.

MR. HITCH: Good morning, Your Honor. On behalf of Rio Pharmaceuticals, it's Cortlan Hitch from

1 Morris James. And joining me today is Phil Kouyoumdjian
2 Taft Stettinius & Hollister.

3 **MR. STAMOULIS:** Hi, Your Honor. Good morning.
4 Stam Stamoulis here on behalf of Mylan. With me here at
5 counsel table is Emily Greb and Brandon White from the
6 Perkins Coie firm and Matt Greiner is in-house counsel for
7 Mylan. He's here today. Thank you, Your Honor.

8 **MS. KELLER:** Good morning, Your Honor, Karen
9 Keller from Shaw Keller on behalf of Alvogen. And with me
10 today is Aziz Burgy from Axinn, Veltrop.

11 **MS. STOMBAUGH:** Good morning, Your Honor.
12 Alexis Stombaugh from Young Conaway, on behalf of
13 defendant Zydus. Thank you.

14 **MR. GATTUSO:** Good morning, Your Honor.
15 Dominick Gattuso from Heyman Eneria Gattuso & Hirzel on
16 behalf of DRL. I also have with me Jovial Wong.

17 **MR. WONG:** Good morning, Your Honor.

18 **MR. GATTUSO:** And Ashley Graham, from Winston &
19 Strawn.

20 **THE COURT:** Thank you.

21 **MR. GATTUSO:** Thank you.

22 **MS. METZLER:** Good morning, Your Honor. Sara
23 Metzler from Richards Layton & Finger, on behalf of
24 defendant Sun. With me today are Kelly Farnan from my
25 office and Brian Sodikoff and Christopher West, from

1 Katten Muchin.

2 **THE COURT:** Good morning.

3 Okay. So we'll start with the first term is
4 "piston rod rotates," right?

5 **MR. OELKE:** Your Honor, it's the '462 patent,
6 method of treatment. We're doing it in the order of the
7 briefing.

8 **THE COURT:** Which is different than the order
9 of the amended claim construction chart, right?

10 **MR. OELKE:** That's right, Your Honor.

11 **THE COURT:** Let's do in the order of that.
12 Since that's the last thing you presented to me, that's
13 the thing I went by. Let's start with piston rod rotates.

14 **MR. OELKE:** Mr. Counihan will be handling the
15 device terms.

16 **THE COURT:** Why did you do it in a different
17 order?

18 I mean, I have to say that threw me for a loop.
19 It made it much more difficult to prepare.

20 You know, you have a joint brief. You've got
21 all your table of contents. You've got your terms.
22 That's what I look at, and then I get an amended joint
23 claim construction chart, which has a completely different
24 order, and I've got to go match it up to Claim A to
25 Page 89 to 91.

1 I'm just curious what the thinking is when you
2 put something together like that.

3 **MR. OELKE:** Your Honor, I think we should have
4 redone the claim chart. The briefing was done in order of
5 the '462 patent first and then the device terms. That's
6 how we did the briefing. We should have just re- -- we
7 should have amended the claim chart to have it in that
8 order as you said.

9 **THE COURT:** Why? I'm just curious. Seriously,
10 I just want to understand. Because you're advocates.
11 You're presenting things to the Court. You want me to
12 engage.

13 I'm just kind of curious, so how did you come
14 up with this?

15 You have spent all this time briefing it. You
16 have a table of contents. You've got the order of the
17 terms. You give that to me. Then you have this meet and
18 confer. Not the longest meet and confer by the way, but,
19 you know, and you come up with an amended thing, you file
20 it.

21 I'm not even being critical. I'm just trying
22 to understand, since you're trying to persuade me and
23 engage me, how did you come up with let's have a
24 completely different order that we're going to submit this
25 to the Court. Just curious. What was it?

1 **MR. OELKE:** The chart, I think, was in the
2 order in which the defendants presented the terms, and
3 then when we briefed it, we did it with the '462 patent
4 first. That's all, Your Honor.

5 **THE COURT:** All right. Well, anyway, let's
6 start with the piston rod rotates.

7 **MR. OELKE:** We're happy to start with the
8 device terms, Your Honor.

9 **MR. COUNIHAN:** Your Honor, may I approach?

10 **THE COURT:** Sure.

11 **MR. COUNIHAN:** Is two copies good for Your
12 Honor or would you like more?

13 **THE COURT:** Yeah, that would be great. Thank
14 you. Unless you've got more.

15 **MR. COUNIHAN:** I have more.

16 **THE COURT:** All right.

17 **MR. COUNIHAN:** So, Your Honor I apologize in
18 advance. Our slides are in the order of the briefing, so
19 I will -- what I'm going to do is start at the very
20 beginning and then I'm going to jump to where the piston
21 rod rotates slides are.

22 So I'd like to start at the tab that says
23 device patents, Mr. Watkins, and I'm going to just give a
24 two-, three-minute overview of the issues and then jump
25 into the disputed term, if that works.

1 **THE COURT:** That's great.

2 **MR. COUNIHAN:** Okay. Great.

3 So, Your Honor, Robert Counihan, Fenwick &
4 West, on behalf of the plaintiffs. So the invention of
5 the device patents -- okay. So the invention of the
6 device patents relates to limiters for injection pens. So
7 dose limiters are important in injection pens because they
8 allow users or patients to be confident that the amount of
9 dose that they want to give themselves is, in fact,
10 available in the pen.

11 So if you've ever had a small child and given
12 them medicine from a syringe that you get at the pharmacy,
13 you can visibly see if you happen to pull up some air and
14 there's less than what you intend to give to your child,
15 but the injection pens, you often cannot actually see the
16 amount of dose available. And that's because the pen is
17 designed to be efficient, compact, easy to use, and so
18 what the user requires is some piece of mind that they are
19 actually giving themselves the right dose.

20 So as the patent acknowledges, the general
21 concept of dose limiters was known in the art at the time.
22 But those mechanisms were cumbersome. They were -- if
23 they were internal to the device, they were positioned
24 outside of the driver, a common component found in
25 injection pens, which made the pen unnecessarily large and

1 unwieldy, or it involved exterior mechanisms that would
2 require user to flip a switch or do something else that
3 could be complicated and add additional issues to the
4 device.

5 What the inventors came up with is a design
6 where they took the limiter and they moved it inside of
7 the driver. So this is one of the figures from the
8 patent. The driver is in green. The piston rod is in
9 blue. Those are two common components in injection pens.
10 The limiter in is in orange.

11 What they did is they took advantage of the
12 inner space within the driver walls. And they increased
13 the space a little bit and they created a limiter that
14 could move within it.

15 This might look like a relatively simple design
16 there's only four or five components, but what needs to be
17 appreciated is that these components are moving with
18 respect to each other. So there's a number of forces
19 going on; there's a number of different aspects of what's
20 happening.

21 And what the inventors created was a
22 streamlined, slimmed-down profile design. Something that
23 was critically robust, that was accurate, that was
24 reliable. And they described their design through three
25 different embodiments. On the screen here are figures 1,

1 5, and 8, which reference at three embodiments. They
2 describe different arrangements of limiting mechanisms. I
3 don't think today we need to go into the different types
4 of limiting mechanisms described, but we can if Your Honor
5 is interested. But what they say is that each of these
6 limiting mechanisms has three critical components: The
7 piston rod, the limiter, and the driver.

8 **THE COURT:** What's a limiting mechanism?

9 **MR. COUNIHAN:** A limiting mechanism, Your
10 Honor? Well, the claim term is a limiter, but to answer
11 your question of what a limiting mechanism is, if they had
12 used that term, that, to me, would have sounded like the
13 means-plus-function issue that's at dispute. Because,
14 then, they would have used a nonce term like "mechanism"
15 and a functional word like "limiting."

16 They used the word "limiter." Limiter has
17 structural understanding in this field. It's a Component
18 that is used to limit, in this situation, the amount of
19 dose that can be set.

20 And the claim --

21 **THE COURT:** You say it's in the field. Do I
22 need to go to extrinsic evidence to know that? Because
23 I'm not a -- what's the field?

24 **MR. COUNIHAN:** The field here is injection
25 pens.

1 **THE COURT:** Okay. So I'm not an injection
2 medicine guy, so how do I know that "limiter" is a defined
3 term in the field?

4 **MR. COUNIHAN:** Well, because in the patent when
5 they talk about limiters, they talk about limiters in a
6 structural sense. They don't use "limiters" as a
7 placeholder for the function of limiting that then has a
8 broad scope. They're talking specifically about different
9 types of limiters, limiters with different designs. All
10 of the limiters have engaging surfaces. Engaging surfaces
11 that engage with the piston rod and the -- let me go back
12 one slide.

13 **THE COURT:** But how do I know that that's in
14 the field that has that definition as opposed to in the
15 specific patents it has that definition? Don't I have to
16 resort to extrinsic evidence to know that?

17 **MR. COUNIHAN:** Your Honor, I don't think you
18 need to, but here you can. Because Dr. Cameron did put in
19 a declaration on behalf of the plaintiffs explaining how
20 the term limiter is used in different situations in the
21 field of mechanical engineering and injection pens.

22 **THE COURT:** Right. And they have a different
23 definition from their expert, right, a different
24 understanding?

25 **MR. COUNIHAN:** Their expert does not actually

1 opine on whether the term is means-plus-function or not.
2 He offers an opinion about the proper construction if it's
3 not means-plus-function, but I don't --

4 **THE COURT:** Right. But, I mean, doesn't he
5 have opinions about what's understood in the field by that
6 term.

7 **MR. COUNIHAN:** He does, but he does not
8 actually take the next step and say that means in this
9 situation, limiter, the claim term, does not have a
10 structural meaning. What he is saying, as I understand
11 it, is limiters in general have these various uses and
12 different applications and -- and then, yeah.

13 It deserves this very unique, very specific
14 construction that is, in essence, taking
15 means-plus-function concepts and injecting it into a
16 nonmeans-plus-function construction.

17 **THE COURT:** All right.

18 **MR. COUNIHAN:** So when the patents use --
19 discuss these embodiments, the patents refer to them as
20 general embodiments. They explain even within these
21 embodiments that there are alternative designs, there are
22 options within them, and then they use the figures to
23 illustrate the embodiments.

24 In the present disputes -- I'm not going to go
25 through all of these -- what consistently comes up, Your

1 Honor, is that the defendants are trying to inject
2 specific concepts into the claim terms. You will not,
3 Your Honor, hear today about definitions in the spec.
4 They don't make any of those types of arguments. They
5 make one argument about a prosecution disclaimer, which
6 we'll address.

7 But otherwise, what they are consistently doing
8 is trying to take the embodiments, and specifically the
9 figures, interpret them and say, the figures say you have
10 to have this, therefore, we should inject it into the
11 claims.

12 **THE COURT:** Let's get to piston rod.

13 **MR. COUNIHAN:** Okay. So I'm going to start
14 with piston rod rotates relative.

15 So, Mr. Watkins, if you could turn to slide 71,
16 please. There you go.

17 So, Your Honor, as I'm sure you -- over the
18 course of the briefing, the parties continued to negotiate
19 their constructions. So as I'm sure you saw in the
20 briefing, some of the issues briefed at the outset no
21 longer apply at this point. So what we have consistently
22 in our slides is what the final positions are from the
23 parties, and I believe that's reflected in the chart that
24 you received with the exception of one term that the
25 defendants clarified they're arguing from the brief.

1 I believe it's this term, right?

2 **MS. GREB:** Right.

3 **MR. COUNIHAN:** Sorry. So, anyway, on this
4 term, as we understand it, the only dispute at this point
5 is what the piston rod must rotate relative to. We say
6 it's to another component; they say it's relative to the
7 housing. Now, of course, the term --

8 **THE COURT:** Can you tell me, just so I
9 understand, what component other than the housing would it
10 rotate relative to?

11 **MR. COUNIHAN:** Well, in Claim 1, of the '383,
12 which is where this -- this phrase, that's where this
13 dispute comes up.

14 **THE COURT:** Right.

15 **MR. COUNIHAN:** Here we go. Here's the Claim 1
16 one language. It doesn't require it to rotate with
17 respect to the housing in particular. It just must rotate
18 with respect to another component.

19 **THE COURT:** Right. I get that. So but what --
20 I'm trying to figure out the nature -- well, I kind of
21 want to know. So other than the housing, what else would
22 it rotate relative to?

23 **MR. COUNIHAN:** So if we look at the figures,
24 Your Honor, it rotates relative to other components such
25 as the limiter and the driver in this embodiment. And

1 that's all that's required. It's requiring rotation. It
2 cannot be static in terms of rotational movement. And so
3 the -- well, you know, a critical point in terms of their
4 construction is that they're trying to say most rotate
5 relative to the housing. The concept of a housing is not
6 presented in Claim 1. The concept of housing comes in, in
7 Claim 2 of this -- of the '383 patent.

8 And so they are trying to read in a limitation
9 about -- that is found explicitly in the dependent claim,
10 and under the law, the *Trustees of Columbia University*
11 case, that is not allowed. Because the independent claim
12 was drafted without reference to the housing at all.

13 And their central point about why it's
14 appropriate to focus on the housing or to read the housing
15 in, is what they call a "prosecution disclaimer". And
16 that's with respect to this reference called Burroughs.
17 And this is the language that they side from the
18 prosecution history, Your Honor.

19 **THE COURT:** Actually, don't go there yet.

20 **MR. COUNIHAN:** Okay.

21 **THE COURT:** I'm trying to figure out,
22 essentially, what's really at issue. I mean, the -- and
23 why we even need to construe this because -- and the
24 difference, right, is, they want, or rather you want this
25 to rotate relative to another component undefined.

1 **MR. COUNIHAN:** Correct.

2 **THE COURT:** Right?

3 **MR. COUNIHAN:** Yes.

4 **THE COURT:** They want it to rotate relative to
5 the housing.

6 **MR. COUNIHAN:** Correct.

7 **THE COURT:** Do you dispute that -- actually, in
8 all pens, is this going to rotate relative to the housing?

9 **MR. COUNIHAN:** So one issue with their -- I
10 will come back to your question in a moment. One issue
11 with their construction is that the meaning of "housing"
12 is also disputed. So there's a world where --

13 **THE COURT:** I'm aware, yeah.

14 **MR. COUNIHAN:** There's a world where the
15 housing construction actually informs whether there might
16 be agreement on this term. But to come back to your
17 question, which I understand to be: Is there a world
18 where an infringing pen, if you will, rotates -- the
19 piston rod rotates with respect to anything other than --
20 I assume you're referring to the exterior shell, the
21 outermost housing, Your Honor, when you say, "housing" in
22 that question?

23 **THE COURT:** Yes.

24 **MR. COUNIHAN:** Yeah, here's where the issues
25 start compiling on top of each other. So --

1 **THE COURT:** I mean, should we construe
2 "housing" first? Would that take care of it?

3 **MR. COUNIHAN:** Yes. Your Honor, yes, I think
4 that would help. So we could go there first. It also
5 might help to construe "piston rod" first, because it's
6 the piston rod that's rotating. So the answer to that
7 question might also inform some of these issues too. So
8 whatever Your Honor would prefer. Here's -- yeah.

9 **THE COURT:** So if you were trying to be
10 efficient about this, sounds like what you would say is go
11 with "piston rod" first then "housing" and then this first
12 term?

13 **MR. COUNIHAN:** Yes, Your Honor, because I think
14 we can kind of compartmentalize some of these issues.
15 Like kind of bucket those three, and then the limiter and
16 driver, bucket those together, and then the other two
17 device terms, and then the '462.

18 **THE COURT:** What do you think?

19 **MS. GREB:** Your Honor, this is Emily Greb on
20 behalf of defendants.

21 I think it would be fine if we bucketed them as
22 suggested and started with piston rod and housing and then
23 did this last, or if we wanted to start with limiter and
24 driver. But I do agree that it would be more efficient to
25 talk about piston rod and housing before we do that.

1 **THE COURT:** All right. Let's do that. Let's
2 do "piston rod" first, then.

3 **MS. GREB:** Okay. Thank you, Your Honor.

4 **THE COURT:** Okay.

5 Mr. Watkins, you are ahead of me.

6 **MR. COUNIHAN:** Okay. So, Your Honor, with
7 respect to the piston rod, in general, the parties are
8 pretty close on piston rod. Our view is that it's plain
9 and ordinary meaning, and then we tried to capture what
10 that is. We believe a piston rod is a readily understood
11 term of art in the field and in general parlance.

12 The defendants largely track that -- they
13 obviously use different words, but conceptually it's
14 fairly similar. But they also add in this language that
15 the shaft, that is the rod of the -- the piston rod --
16 must extend into the syringe barrel itself. So the
17 dispute is whether that requirement is required or not.

18 **THE COURT:** Well, let me start -- let's go back
19 to your construction first.

20 **MR. COUNIHAN:** Sure.

21 **THE COURT:** Because, you know, when I read,
22 this strikes me, this is plain and ordinary meaning.

23 **MR. COUNIHAN:** Yes, we agree.

24 **THE COURT:** It's a shaft that causes a piston
25 to be moved. What I don't understand about your

1 construction is the quote "such that the medicament is
2 expelled," unquote. It doesn't make sense to me
3 grammatically that you would have that clause because
4 isn't that covered by a limitation in the claim?

5 **MR. COUNIHAN:** Yes, Your Honor.

6 **THE COURT:** So it's redundant. It's like
7 saying I need a piston shaft such that the medicament is
8 expelled and then later on I have to have a medicament
9 that's expelled. So I don't understand why you repeat it.

10 **MR. COUNIHAN:** Agree. And the reason why we
11 repeat it is during the course of negotiations over the
12 constructions, one of the concerns that was raised by
13 defendants is that our construction of piston rod is
14 untethered to what the piston is dealing with. And so we
15 propose that language as a compromise.

16 We would be happy to have that removed and just
17 stop at "to be moved." Sorry. The constructions are at
18 the top. So we would be more than comfortable with "a
19 shaft that causes the piston to be moved."

20 **THE COURT:** Okay. Let me hear from them. I
21 mean, because plain and ordinary meaning, the burden is on
22 them to come up and say why it should be different, right?

23 **MR. COUNIHAN:** Yes, agreed.

24 **THE COURT:** All right. Let's hear from them.

25 **MS. GREB:** Good morning, Your Honor. Emily

1 Greb on behalf of defendants. I'm happy to address piston
2 rod. If you don't mind indulging me with a few comments
3 on what -- what was said about the device patents in
4 general before I get started on piston rod.

5 **THE COURT:** Sure.

6 **MS. GREB:** So as was mentioned, you know, these
7 patents have sort of been described as the end-of-content
8 patents. And I'd just like to make it clear that these
9 patents disclose a very --

10 **THE COURT:** I have no idea, what is
11 end-of-content patent?

12 **MS. GREB:** We don't have to call it that. It's
13 really just directed towards this dose setting where a
14 user dials in a dose, and you can't --

15 **THE COURT:** Oh, at the end of content.

16 **MS. GREB:** Yep. At the end of content, you
17 can't dial something that's not there.

18 **THE COURT:** Yep.

19 **MS. GREB:** And the point of these patents is
20 that they describe and claim this really specific
21 mechanism. These patents don't claim an injection device,
22 and they don't even claim all mechanisms that prevent this
23 sort of over-dialing of doses. They claim a very specific
24 mechanical design. And to that end, the bulk of the
25 specification is directed toward two embodiments. Now,

1 you heard counsel say, I think, three embodiments, but the
2 specification pretty clearly only talks about two.

3 Figure 8 that he talked about is the third
4 embodiment. The specification ties in Column 5 actually
5 to the second embodiment. So the specification has two
6 embodiments and a number of figures that provide details
7 about those. So I just want to make that clear.

8 So with respect to the piston rod in
9 particular, as was mentioned, so defendants' proposed
10 construction is a shaft extending into the syringe barrel
11 such that the end of the device shaft drives the plunger
12 in the distal direction to expel medicament from the
13 device.

14 And so I heard your question about expelling
15 medicament from the device, so I'll start there since I
16 know you are thinking about that. The part that's
17 important there and the reason that it's included is
18 because we wanted to make it clear that what the piston
19 rod or shaft is doing is driving this plunger down. And
20 it's true that every single figure and every single
21 embodiment, the way that this worked is the piston rod
22 rotates relative to the housing. And it moves down.
23 There's threading between those two components that causes
24 downward motion and expels the medicament from the device
25 in the distal direction. There's not some sort of other

1 movement in the piston rod where it could move, you know,
2 upwards. And so it was providing clarity about the --

3 **THE COURT:** When you say "clarity," I mean, the
4 claim says it. The claim says "a piston rod having a
5 threaded outer surface wherein piston rod rotates and
6 translates axially forward during expelling of
7 medication."

8 **MS. GREB:** Yeah.

9 **THE COURT:** So it would be during that, right?

10 **MS. GREB:** Yeah. And your Honor is right with
11 respect to the '383. This terms is also in the '953
12 patent, and I think the claims of the '953 are a little
13 less clear because that rotation term that's in the '383
14 patent is not in the '953 patent in the same way.

15 **THE COURT:** Hold up. Show me. Where are you
16 now? You're on --

17 **MS. GREB:** Yes. So this would be the '953
18 patent, Claim 1, and it starts with in Column 9 and then
19 goes to Column 10.

20 **THE COURT:** Hold on. Can you go back and let
21 me just look at both the competing --

22 **MS. GREB:** This is Slide 27.

23 **THE COURT:** All right. So putting all your
24 disagreements aside, so then what you would say is
25 because -- if you agreed with them, if I could get you to

1 agree with them, you'd say: Well, include the "such that
2 the medicament is expelled because it would bring clarity
3 for the '953 patent claims," because you admit it's
4 totally redundant for the first patent.

5 **MS. GREB:** I would agree with Your Honor that
6 it would be -- if we're just talking about the back end of
7 the construction. I certainly have a number of
8 disagreements on the front end of the construction.

9 **THE COURT:** We will get to those, right.

10 **MS. GREB:** But, yeah, on the back end of the
11 construction, I agree that in the '383 patent, there is
12 the portion that expels medicament, but the '953 does not
13 have that same term. And I think, frankly, too, the other
14 part that sort of is important --

15 **THE COURT:** Hold on one second.

16 **MS. GREB:** Sure. Of course.

17 **THE COURT:** All right. Well, the more I think
18 about it, though, I mean, this patent, the '953, you know,
19 we're talking a mechanism for an injection device.

20 I mean, what else does an injection device do
21 except it expels medicament, right? All right. So maybe
22 then we have to include that. I don't really get it. But
23 all right. It certainly would be redundant and confusing
24 for the first patent if we were to construe it that way to
25 a jury, I think. But let's deal with then, go back to

1 your main arguments then. Go ahead.

2 **MS. GREB:** Sure. The other components of the
3 construction the defendants have put forward talk about a
4 shaft extending in a syringe barrel. So location of the
5 shaft where the piston rod is. And it talks about driving
6 the plunger, which we would posit are both important
7 components based on how the specification is written. And
8 that's because, as I mentioned --

9 **THE COURT:** Let me stop you there. You say
10 "the way the specification is written."

11 Do you mean the claims?

12 **MS. GREB:** Well, Your Honor, the claims, of
13 course, are construed in light of the entire
14 specification. And here, this is a really narrow
15 invention again. It discloses -- they disclose two
16 general embodiments and have a number of figures that
17 describe them.

18 **THE COURT:** Let me stop you. Let me read from
19 your brief.

20 You say, quote -- this is at the outset of your
21 position on piston rod.

22 Quote, "Based on the words of the claims
23 themselves and the remainder of the specification, as well
24 as extrinsic evidence, the Court should adopt defendants'
25 construction." Right?

1 **MS. GREB:** That's correct.

2 **THE COURT:** Okay. Now, so the first part,
3 based on the words of the claims themselves and the
4 remainder of the specification. Now, normally you apply
5 plain and ordinary meaning.

6 And you say it's not plain and ordinary meaning
7 here, correct?

8 **MS. GREB:** Correct. We've offered a
9 construction. That's correct.

10 **THE COURT:** Is it fair to say, then, that the
11 burden is on you now to show, by clear and convincing
12 evidence, that there's lexicography or some kind of
13 disavowal that requires your construction?

14 **MS. GREB:** Your Honor, yes.

15 The claims are to be read in light of the
16 specification. And I do appreciate in our brief we
17 started by the claims. I think here in this case, the
18 specification and how the patent is written, and the
19 disclosures in the specification are what drives the
20 requirements and the specific construction that we've
21 offered. I'm happy to sort of walk through the
22 specification and where in the specification that
23 information is provided.

24 **THE COURT:** That's fair, but I just want to
25 first establish kind of what the standard is going to be.

1 So are you relying on extrinsic evidence?

2 **MS. GREB:** I think for the piston rod term, I
3 think we cited a couple of dictionary definitions,
4 perhaps. I don't think we need those. I think the
5 intrinsic evidence here drives the definition of "piston
6 rod."

7 **THE COURT:** All right. Is it lexicography in
8 the written description that drives it?

9 **MS. GREB:** The written description does not
10 have a specific definition, Your Honor. It does not say,
11 for example, "As used herein, piston rod means X."

12 **THE COURT:** All right. So it's not
13 lexicography, then, you are saying?

14 **MS. GREB:** You're right. What we're saying is
15 that the intrinsic evidence and the file history -- and
16 here, I think, with respect to piston rod, it's really the
17 specification and the embodiments that are disclosed and
18 the way that the disclosures show how the device must
19 work, show that this is how "piston rod" should be read in
20 this patent.

21 **THE COURT:** So is it disavowal?

22 **MS. GREB:** I don't think I would say that we're
23 saying it's disavowal. I think it's --

24 **THE COURT:** So it's not lexicography.

25 **MS. GREB:** -- reading the claims in light of

1 the specification.

2 **THE COURT:** If it's not lexicography, it's not
3 disavowal, what is it? What's the construction theory?

4 **MS. GREB:** Reading the claims in light of the
5 specification on the whole.

6 **THE COURT:** What's the burden?

7 **MS. GREB:** Your Honor, I apologize. I don't
8 recall if it's clear and convincing evidence with respect
9 to claim construction in reading the specification on the
10 whole, but I'm happy to look that up and provide it to
11 you. But I can tell you that it is proper to use the
12 specification to drive the definition that's used in the
13 claims in the patent, and that's exactly what defendants
14 are doing here with respect to piston rod.

15 **THE COURT:** Well, I think it's undisputed and
16 fundamental law that you have to read the claims in light
17 of the remainder of the specification. I can't imagine
18 they would dispute that. I think, though, the issue is if
19 you have plain and ordinary meaning proffered, which they
20 do, and somebody wants to say it's not the plain and
21 ordinary meaning, don't you have to show by clear and
22 convincing evidence that there's been some kind of
23 lexicography in the specification or disavowal of
24 certain -- disavowal, no?

25 **MS. GREB:** Your Honor, I think we certainly

1 agree that it's sort of a fundamental principle of claim
2 construction that the claims are read in light of the
3 specification. And I apologize, I don't have that case
4 right in front of me right now. And I would have to look
5 up specifically. I know for the burden of proof for
6 patentability, it is clear and convincing to prove a
7 patent invalid. But I don't have, at the tip of my
8 fingers, whether it's clear and convincing evidence --

9 **THE COURT:** Well, I guess it's really clear and
10 unequivocal, isn't it? Isn't that really the standard?

11 **MS. GREB:** Yeah, Your Honor. I apologize. I
12 just don't have that. I'm happy to look it up and provide
13 it to you.

14 **THE COURT:** Okay. Well, why would I depart
15 from the claim, then? Go ahead. Why would I --

16 **MS. GREB:** Here, the reason for departing from
17 plain and ordinary meaning --

18 **THE COURT:** Incidentally, let me just -- don't
19 you agree that a piston rod, under the plain and ordinary
20 meaning, is a shaft that causes a piston to be moved? You
21 don't dispute that, do you?

22 **MS. GREB:** I would not dispute that a piston
23 rod can be a shaft that causes a piston to move. I would
24 dispute that that's the appropriate construction in light
25 of the specification here.

1 **THE COURT:** I get that. But my question is
2 don't you agree that that's plain and ordinary meaning of
3 a piston rod?

4 **MS. GREB:** I think that outside the context of
5 this patent, somebody could certainly think about a piston
6 rod that way. I think that that would be the wrong
7 construction when you look at how the term is used in the
8 patents here.

9 **THE COURT:** Okay.

10 **MS. GREB:** And I'm happy to walk through the
11 intrinsic evidence on that.

12 And so, as I mentioned, there are two general
13 embodiments. Each of the embodiments is disclosed in a
14 number of figures. And, in particular, up on the screen
15 we have color-coded corresponding figures 1, 5, 4, and 7,
16 and you'll see in each of the instances, the piston rod we
17 have colored blue, the housing is purple, the plunger is
18 green, and the syringe barrel is orange. And in each of
19 the embodiments, the piston rod is a shaft that is driving
20 the plunger down. And in each of them, it extends into
21 the syringe barrel.

22 Now, you know, Your Honor asked about plain and
23 ordinary meaning, you know, could you make a device that
24 somehow doesn't have a piston rod extending into the
25 syringe barrel and pushing the plunger down. Maybe. But

1 that's not what they claim in this patent.

2 In this patent, they claim a very narrow
3 invention, and they talk about the disclosures and
4 specifically how they're put together. And here, each and
5 every embodiment -- and, in fact, the only way that you
6 can make it is by having that piston rod rotate relative
7 to the housing, push the plunger down and into the syringe
8 barrel. And because they've disclosed it that way,
9 there's no way to broaden -- they shouldn't be able to
10 broaden the claims in a way that's --

11 **THE COURT:** Isn't that like an enablement
12 argument?

13 **MS. GREB:** -- broadening the specification.

14 I'm sorry, Your Honor?

15 **THE COURT:** Isn't it like an enablement
16 argument?

17 **MS. GREB:** An enablement argument that they
18 haven't --

19 **THE COURT:** You said --

20 **MS. GREB:** -- enabled other embodiments? I'm
21 sorry.

22 **THE COURT:** You said that they claim a very
23 narrow invention, they talk about disclosures, and,
24 specifically, how they're put together here in the written
25 description. They shouldn't be allowed to broaden the

1 claims beyond that. That's sounds like an enablement or
2 written description argument to me. It doesn't sound like
3 a claim construction argument.

4 **MS. GREB:** Yeah, I mean, it's certainly the
5 case, I think, if Your Honor adopted a broad construction,
6 this patent may have enablement issues. I think the
7 appropriate construction, though, would be a narrow
8 construction that would provide -- and I don't think it's
9 actually narrow. It would be a construction that
10 accurately reads the claim in light of specification as
11 disclosed, rather than something potentially broader that
12 would lead to an enablement problem.

13 **THE COURT:** All right.

14 **MS. GREB:** And I am cognizant of time here. I
15 want to make sure I've addressed all Your Honor's question
16 with respect to piston rod.

17 **THE COURT:** I don't have any more questions.
18 Anything else you want to say?

19 **MS. GREB:** I guess my only comment would be
20 whether Your Honor would like to hear about translates or
21 whether you'd like to defer that until after we talk about
22 housing, the rotates and translates that you briefly heard
23 from plaintiffs.

24 **THE COURT:** All I want to hear about right now
25 is piston rod.

1 **MS. GREB:** Okay. Thank you, Your Honor.

2 **THE COURT:** All right. Thank you.

3 I'm going to construe piston rod, I'm going to
4 give it its plain and ordinary meaning, which is "shaft
5 that causes the piston to be moved," unquote.

6 If, at a later date, we think because of the
7 '953 patent not saying explicitly that there's an
8 expelling of the medicament that we need to further
9 construe it, we can do it at that point, but I'm going to
10 adopt this construction because claims, generally, are
11 given their plain and ordinary meaning to one of skill in
12 the art when read in the context of the specification
13 prosecution history.

14 And there's only two exceptions to this general
15 rule: First, when a patentee sets out a definition and
16 acts as her own lexicographer; and, second, when a
17 patentee disavows the full scope of the claim, either in
18 the specification or during prosecution, and either
19 disavowal of such lexicography must be clear and
20 unmistakable.

21 I refer you all to *Thorner against Sony*
22 *Computer*, 669 F.3d 1362 at Page 1365, and in particular at
23 Pages 1367 to 68, when the clear and unmistakable standard
24 is discussed.

25 "Additional limitations that do not appear in a

1 claim generally should be not read into a claim." Here,
2 defendants don't argue that their construction is plain
3 and ordinary meaning. In fact, they don't even contest
4 that the plaintiffs have offered the plain and ordinary
5 meaning of the disputed term.

6 But defendants make no argument that plaintiffs
7 acted as a lexicographer, nor that there was a clear or
8 unequivocal disavowal of the full scope of the disputed
9 term. And their proposed definition is also redundant
10 with other claim limitations that they're trying to read
11 into the definition of "piston rod."

12 And the Federal Circuit has cautioned,
13 particularly in *Apple against Ameranth*, A-M-E-R-A-N-T-H,
14 842 F.3d 1229 at 1238, that construing a claim to include
15 features of a term already recited in the claims is to be
16 avoided because it makes those expressly recited features
17 redundant.

18 So I'm going to adopt, at least in part, the
19 plaintiffs' proposal. I'm not going to adopt it fully,
20 because I think it's redundant and can cause confusion
21 with at least one of the patents to the jury if I repeated
22 that the medicament is expelled.

23 All right. Next term.

24 **MR. COUNIHAN:** Thank you, Your Honor. I'll
25 turn to housing now, based on our -- okay.

1 Your Honor, just before we continue, just one
2 short housekeeping item. I know this is a device patent,
3 but this is actually a *Hatch-Waxman* case just as a
4 reminder. I know it's pretty atypical to have device
5 patents, so we don't expect there to be a --

6 **THE COURT:** Oh. I mentioned jury a number of
7 times. Thank you very much. It's hard to remember what's
8 what in all these cases.

9 And yes, it is a -- so I'll be able to sort
10 that out. We won't have to reconstrue the term. I'll
11 figure out that we're talking about expelling a medicament
12 when it comes to the second patent. Thank you.

13 **MR. COUNIHAN:** Absolutely. I just wanted to
14 make sure we were all on the same page.

15 **THE COURT:** Yep.

16 **MR. COUNIHAN:** So in the slide deck, I'm now at
17 Slide 47. Thank you, Mr. Watkins.

18 So on the "housing" term. So the dispute with
19 respect to "housing" is whether the housing has to be the
20 outermost exterior shell of the pen, or whether it can be
21 a housing of an internal component. What's very important
22 about --

23 **THE COURT:** Can I ask you --

24 **MR. COUNIHAN:** Yes.

25 **THE COURT:** How about could you just agree that

1 "housing" means "enclosure"?

2 **MR. COUNIHAN:** Yes, Your Honor. We would agree
3 with that.

4 **THE COURT:** Let me hear from them.

5 **MR. COUNIHAN:** Just one very quick
6 clarification -- or, yes, that would be fine.

7 **THE COURT:** Okay.

8 **MR. SODIKOFF:** Good morning, Your Honor. Brian
9 Sodikoff.

10 **THE COURT:** Can you live with "enclosure"?

11 **MR. SODIKOFF:** Your Honor, I think it should be
12 "the outermost enclosure." I think we could live with
13 something that's similar to that. There's -- I think
14 that's inherent in the definition of "housing." Its plain
15 meaning is it's going to be the outermost part. Every
16 example in the patent has it, furthest on the outside and
17 including the nesting components.

18 If I could pull just up quickly our Slide 8.
19 This slide here.

20 So, Your Honor, this is just in the context of
21 entire invention. And what they say the invention is, is
22 this novel nested design on the right in Figure 3 where
23 you have the piston rod on the inside and then you have
24 the limiter and then you have the driver on the outside.

25 When a housing comes in, it comes in on the

1 outside of these. And that's seen in, like, Claim 2 of
2 the '383. The housing comes on the outside of these other
3 three elements. And if you look on the left, housing is
4 26, it's always on the outside. There's never a time when
5 a housing is just internal.

6 They cite to the one sentence where it's very
7 confusing, and it says the housing can be part of the
8 housing. Which doesn't --

9 **THE COURT:** All right. Why don't you walk me
10 through, then. I mean, look, again, plain and ordinary
11 meaning of "housing" is "housing" or "enclosure," right?

12 **MR. SODIKOFF:** I think it's -- not in -- I
13 don't know about that, Your Honor. I think it's going to
14 be the outermost part.

15 I mean, there's -- I think you would define it
16 as some type of internal housing if you were going to do
17 that and you'd have the word "internal." If you just used
18 the word "housing," that's the external part, and that's
19 actually the plain meaning, and they cite to it is they
20 say "the housing can be part of the housing." And so
21 they're suggesting the housing is the outer part, and the
22 part that has some limitations is part of that, but it's
23 always the outer part. So I'm not aware --

24 **THE COURT:** I think the point is that it's the
25 housing -- it's the housing of. It's the object of the

1 "of" that determines what the housing houses.

2 **MR. SODIKOFF:** That's probably true. And it's
3 the outermost portion.

4 **THE COURT:** Right. So my point is, isn't under
5 plain and ordinary meaning, housing is just housing or
6 enclosure, and then what you look to is, well, what's
7 being housed?

8 **MR. SODIKOFF:** I think that's generally
9 correct, Your Honor, but I think it's the outermost
10 housing. If it was going to be an internal housing, it
11 would say that. So the external housing is the -- is
12 what's -- in this device, the housing that they're talking
13 about is the enclosure for the entire thing. So it's
14 the --

15 **THE COURT:** I mean, by definition, you could
16 only have an outermost housing have meaning if there were
17 multiple housings, right?

18 It's a relative term "outermost." So you have
19 to, then, implicit in you asking me to give it the
20 definition "outermost housing" means there's other
21 housings that are not the outermost housing.

22 **MR. SODIKOFF:** I think, as a highly technical
23 matter, anything that has something inside of it could be
24 a housing. So it just doesn't help to say "enclosure,"
25 because --

1 **THE COURT:** The fact that you say that, doesn't
2 that show that there's a plain and ordinary meaning of
3 housing, which does exactly -- it means "housing."

4 **MR. SODIKOFF:** Well, I don't think so, Your
5 Honor. Because then, for example, here, the limiter would
6 be a housing because the limiter has parts inside of it.
7 It's an enclosure with stuff inside.

8 **THE COURT:** So it's got a housing.

9 **MR. SODIKOFF:** The limiter is not a housing.
10 It is a separate part in this patent.

11 **THE COURT:** Well -- I see.

12 **MR. SODIKOFF:** So I think if we define it as
13 just anything that encloses something as an enclosure,
14 then it could be multiple different parts that are
15 clearly, in this patent, not considered the housing. So
16 if you go so broad that anything that encloses something
17 can be a housing, then there's dozens of parts here that
18 could be a housing.

19 **THE COURT:** Could be.

20 **MR. SODIKOFF:** But "the housing" as claimed, is
21 the specific Part 26, which is on the outside. So to say
22 that all these other devices theoretically could be
23 enclosures -- or all these parts, just doesn't make sense
24 in the terms of the patent.

25 And there's plain and ordinary meanings, there

1 are several of them, right? I mean, there's not just one
2 always. So just saying, "enclosure" here, there's a lot
3 of materials that enclose, right? The part that holds the
4 medicine at the bottom, it encloses something, but that's
5 not the housing that we're talking about in this patent.

6 So I think the plain and ordinary meaning for
7 this patent is referring to Part 26. That's what's
8 informing the plain and ordinary meaning here, and it's --

9 **THE COURT:** See, but you've already -- I think
10 you're skipping something, which is the first issue is
11 whether the term has its plain and ordinary meaning.

12 The second thing is whether a term as used
13 should be given its plain and ordinary meaning.

14 **MR. SODIKOFF:** So I think it's, Your Honor,
15 it's always the plain and ordinary meaning in light of the
16 specification.

17 **THE COURT:** Right.

18 **MR. SODIKOFF:** So not just a random dictionary
19 definition that "housing" is "enclosure."

20 **THE COURT:** You're not asking for the plain and
21 ordinary meaning here, right?

22 **MR. SODIKOFF:** I think ours is a variant of the
23 plain and ordinary meaning.

24 **THE COURT:** Where do you say that in your
25 brief?

1 **MR. SODIKOFF:** So on Page 22, we say, "their
2 construction is an attempt to ignore the plain meaning of
3 housing, which signifies the exterior shell of a device."

4 We do have on Page 21 where it's not its plain
5 meaning, which we were referring to the very super-broad
6 definition of enclosure, but our construction is that it's
7 the plain meaning in light of the specification, which we
8 think signifies the outer shell of the device when you're
9 talking about pen devices how it's used in this
10 specification.

11 **THE COURT:** All right.

12 **MR. SODIKOFF:** There's always a super-broad
13 dictionary definition that can be out there, but I think
14 the case law counsels to look at the plain and ordinary
15 meaning in light of the spec. And that is housing that's
16 not just an enclosure, because there's a lot of parts here
17 that enclose, and they're not quote/unquote "housing" for
18 this patent.

19 **THE COURT:** All right. So walk me through your
20 argument. Go ahead.

21 **MR. SODIKOFF:** So that is the main argument,
22 Your Honor, that, when you look at "housing" in light of
23 the specification, you have, in this drawing, this is
24 showing you what the housing is, it's 26, and it's the
25 outer portion.

1 **THE COURT:** Well, this is, it seems to me,
2 classic what I'm not supposed to do. This is looking at a
3 single embodiment and how the word "housing" is used --
4 how's that? And it's not saying it can't be used in
5 multiple ways, it's just saying Item 26 corresponds to a
6 housing.

7 **MR. SODIKOFF:** Yeah, 26 is the housing.

8 **THE COURT:** Right.

9 **MR. SODIKOFF:** And it's telling you in this
10 patent, all these other things that are enclosures have
11 different names, and we're not calling them "housing." So
12 you have to look at the patent, you have to look at
13 drawings and say, what is a housing here? It's not
14 anything that encloses; it's this specific part. Because
15 otherwise, it doesn't make sense because everything is a
16 housing.

17 And I think that's what reading it in light of
18 the specification is, Your Honor. It's not just an
19 enclosure; it's the outermost enclosure here. Because
20 there are other things that -- I don't want to use the
21 word "obviously," but, obviously, other things here
22 enclose stuff. And if you look at Figure 3 --

23 **THE COURT:** Then why didn't you just use in the
24 claim, you know, you would have, then, outermost, I guess.

25 **MR. SODIKOFF:** Because they didn't have to

1 because they put -- the meaning of "housing" is the
2 outermost part. You would have really long claims if you
3 did that for every part. The housing is that Part 26.
4 It's not Part 12. It's not Part 10, which also have
5 things enclosed in them. It is this one with this
6 structure.

7 So a person of skill in the art would look at
8 this patent and not think, oh, a housing is an enclosure
9 because there's a lot of enclosures here. The person of
10 skill in the art would say, let me look deeper about what
11 they're saying is the housing, and it's Part 26, which is
12 on the outside and encloses the driver, the limiter, and
13 the piston rod. And everything that's in the spec is
14 consistent with that because it always has the housing on
15 the outside and these other parts inside engaging with
16 them.

17 **THE COURT:** Housing is in Claim 2, right, of
18 the '383?

19 **MR. SODIKOFF:** Yes, Your Honor.

20 **THE COURT:** Where else?

21 **MR. SODIKOFF:** The housing is in a number of
22 claims. So if we go back.

23 **THE COURT:** I'm just trying to figure out. I
24 focused on Claim 2.

25 **MR. SODIKOFF:** Sure.

1 **THE COURT:** Which requires a housing defining a
2 passage for the piston rod.

3 **MR. SODIKOFF:** Right. It's the outer -- and if
4 you look at Figure 3, what it does is it goes outside what
5 you see in Figure 3 in this cross-section. And it's same
6 thing in this Figure 4, it's what goes on the outside and
7 defines the passage that everything is passing inside.
8 But it's always the outside.

9 **THE COURT:** Well, I think more importantly,
10 it's got to be the enclosure that defines the passage for
11 the piston rod. That's what defines it.

12 **MR. SODIKOFF:** But then you're kind of -- so
13 that's the function of the housing, that's not the
14 definition of it. And it goes kind of a little bit about
15 what you were talking about with the *Apple* case, that you
16 don't put in a limitation. But it's the outermost part,
17 and then --

18 **THE COURT:** Actually, I'm not putting in a
19 limitation at all. I'm saying it's just "enclosure."
20 It's that the claim, then, explains what it does. And
21 what it does is, quote, define the passage of the piston
22 rod.

23 **MR. SODIKOFF:** That's one place it's described.
24 But it's also described in the spec, and it's consistently
25 the outer part. So the -- to be honest, I don't think

1 this is that controversial. I think all our pens have a
2 housing on the outside.

3 **THE COURT:** Well, actually, you guys made it
4 controversial. You're disputing it. It seems to me it
5 should be just enclosure. That's plain and ordinary
6 meaning what a housing means, and then I think we would
7 look to the claims to figure out, oh, well, they meant a
8 specific part.

9 And as far as I can tell, the only thing you're
10 pointing me to, to show that there's some special
11 lexicography here, or disavowal of housings other than the
12 outermost housing, is the figure that you've got on the
13 screen, Figures 3 and 4 where "housing" is illustrated as
14 Number 26.

15 **MR. SODIKOFF:** I think it's beyond that, Your
16 Honor.

17 **THE COURT:** Well, then you need to show me.

18 **MR. SODIKOFF:** Sure. So it's the description
19 about how the nested design is the novel features here and
20 the nested design in Figure 3. So it's not just --

21 **THE COURT:** So show me. Bring me, show me,
22 identify for the record the text where there's a
23 definition of housing.

24 **MR. SODIKOFF:** So there is no definition of
25 housing, Your Honor, and that's why you have to interpret

1 in light of the specification. But if you look at, for
2 example --

3 **THE COURT:** So there is no lexicography. Okay.

4 **MR. SODIKOFF:** No. But they say --

5 **THE COURT:** Where is, then, a disavowal that a
6 housing can't be anything but the outermost exterior?
7 Where's that?

8 **MR. SODIKOFF:** There's not a specific
9 disavowal. It's --

10 **THE COURT:** So if there's no disavowal, there's
11 no specific disavowal, there's no lexicography, how can
12 you possibly go beyond plain and ordinary meaning under
13 the law, which requires, as I've just repeated with the
14 first term, clear and unmistakable or unequivocal
15 lexicography or disavowal?

16 **MR. SODIKOFF:** Because, Your Honor, it's plain
17 and ordinary meaning in light of the specification. So
18 our position is that "enclosure" is not the definition in
19 light of the specification. That's not a plain meaning in
20 light of this specification because that plain meaning
21 would cover a lot of different parts.

22 So in this definition, they are saying the
23 housing is a specific part. It's not just an enclosure.
24 The housing is Part Number 26. Okay? So it's not just
25 any enclosure. It's Part 26 and how Part 26 is described,

1 and that's consistently on the outside.

2 **THE COURT:** Okay.

3 **MR. SODIKOFF:** And just to -- briefly, they
4 point to Figure 1, where you have the housing on the
5 bottom. And there's -- the limiter and the other parts
6 are on the top. But just to be clear, this is not the
7 entire device. So Figure 7 is what the whole device is.
8 This is just a look and focus on certain parts. And the
9 housing always ends up being integrated along the entire
10 outside portion. And even here, there's nothing on the
11 inside -- even in Figure 1 there's nothing outside of the
12 housing. The housing is always on the outside.

13 **THE COURT:** All right.

14 **MR. SODIKOFF:** Thank you, Your Honor.

15 **MR. COUNIHAN:** Your Honor, if I may.

16 **THE COURT:** It's not necessary. I'm going to
17 give it the plain and ordinary meaning. I don't think it
18 even needs definition. If you need a synonym, you could
19 use "enclosure."

20 I don't think the defendants have shown that
21 their alternative term has sufficient support in the
22 written description or figures that reaches the clear and
23 unmistakable standard that we require when we have
24 lexicography or disavowal.

25 I think the fact, I think it's very telling

1 that the references to the "outermost housing" or
2 "outermost exterior" shows that housing can refer to
3 multiple components of a device and still have meaning. I
4 think we have to look to the claims to determine what a
5 particular housing here is referring to. And certainly a
6 housing could be the outermost exterior of a device, but
7 it could also refer to the material that encloses a
8 component of the device.

9 And so rather than repeat the law that I did
10 with respect to the first term about the burden that is on
11 a party wishing to effectively import limitations into the
12 construal of a claim term, I'll just refer back to that
13 case law. All right?

14 All right. Next.

15 **MR. COUNIHAN:** Thank you, Your Honor. So going
16 back to our "rotates" term. So with the clarifications
17 and constructions that Your Honor has given, we can
18 propose a compromise construction that might work for the
19 defendants. We have not talked about this with them
20 before, so I can't speak for them.

21 So the defendants' proposed construction
22 injected the concept of a housing into Claim 1, right?
23 The concept that was not there. And it was also a
24 disputed term.

25 Now, with Your Honor's clarification about what

1 a housing is construed to be in the context of where it's
2 actually in the claims, what we could propose as a
3 construction is that the rotation be relative to either
4 the exterior shell, the outermost part, now that we have
5 a -- we cannot agree to the -- like when it was a disputed
6 term, but we can agree to something like, "relative to the
7 exterior shell" or the phrase that the -- yeah, relative
8 to the exterior shell.

9 **THE COURT:** Let's do this. Let's break it
10 down.

11 **MR. COUNIHAN:** Okay.

12 **THE COURT:** "The piston rod" are the first
13 three words of this disputed term, right?

14 **MR. COUNIHAN:** Right.

15 **THE COURT:** I have defined that.

16 **MR. COUNIHAN:** Correct, Your Honor.

17 **THE COURT:** The next word is "rotates."

18 **MR. COUNIHAN:** Yes.

19 **THE COURT:** I can't believe there's a dispute
20 about what "rotates" means.

21 **MR. COUNIHAN:** Not that I'm aware of. Is
22 there?

23 **MS. GREB:** I don't think so, Your Honor. I
24 think the dispute is correct on the screen, "relative to
25 the housing."

1 **MR. COUNIHAN:** Yeah.

2 **THE COURT:** Hold on.

3 Okay. Go ahead.

4 **MR. COUNIHAN:** Yes. So I believe the only --
5 set aside the differences in some of the later language,
6 which I think are relatively minor, I believe the only
7 dispute is what it is relative to. So I'm happy to argue
8 for our construction of another component if Your Honor
9 would like, but as a compromise, with the clarification
10 that it be relative to the exterior shell, we can agree to
11 that as a compromise proposal.

12 **THE COURT:** Okay. Can you live with that,
13 "rotates relative to the exterior shell of the injection
14 device and moves axially toward the needle end"?

15 **MS. GREB:** Well, Your Honor, respectfully, I
16 think that is still an overbroad reading of the
17 specification. Every embodiment of the specification
18 shows the housing and describes it as "threaded to the
19 piston rod." And if you're construing "housing" to be the
20 whole inner shell, outer shell, I guess I haven't thought
21 through if there's another housing that you could add to
22 it. I need to think about it for a few minutes, if it's
23 possible --

24 **THE COURT:** Yeah.

25 **MS. GREB:** -- to maybe go on to another term

1 and let us think about it in light of Your Honor's ruling
2 and come back to it at the end of the hearing, that would
3 be great.

4 **THE COURT:** That would be great. Let's do
5 that.

6 **MS. GREB:** Thank you.

7 **THE COURT:** So what's next?

8 **MR. COUNIHAN:** So following the order of the
9 chart, I believe the next term is "defining a passage."

10 **THE COURT:** Okay. But let me just ask you
11 this: Is there a more efficient way you think now, given
12 what we've done, that we should proceed to next?

13 **MR. COUNIHAN:** In my mind, those three were the
14 first bucket.

15 **THE COURT:** Okay.

16 **MR. COUNIHAN:** Looking at the quantity of
17 paper, I think the parties might view the '462 terms as
18 maybe an issue that they want to make sure there's
19 adequate time for. That obviously goes outside of the
20 order. But if Your Honor would be willing to do that, I
21 think --

22 **THE COURT:** Hold up. Hold up.

23 Let's quickly do "defining a passage." Can you
24 explain to me why this really makes a difference?

25 **MR. COUNIHAN:** So the dispute here is over the

1 phrase -- we don't understand what "radially inner
2 surface" means. We could probably guess at it, but it's
3 ambiguous to us.

4 The dispute is over "forms an entire
5 circumference," and kind of cutting to -- you know, I can
6 go through all those slides, if it would help Your Honor,
7 but what we struggle with is how does that phrase apply in
8 practice?

9 So, yes, Figure 3 and Figure 6 show the driver.
10 And I assume what they mean is the driver in green on the
11 two left forms an entire circle. The limiter in orange
12 forms an entire circle. I assume that's what they're
13 referring to.

14 But if you look at Figure 6, you can see those
15 very small notches. Does this work? There we go. The
16 little notches there. There's no reason, mechanically,
17 why those notches cannot extend all the way through the
18 green driver. You know, we've exaggerated it here just so
19 it's easy to see.

20 The question for us is, is the green driver now
21 forming an entire surface -- circumference. In our view,
22 that's not clear. But there's no reason why this green
23 driver does not define the passage for the orange limiter.
24 Same for this design where there's only one notch on the
25 side and the same for this design, where, there's actually

1 gaps in the limiter in orange.

2 So, in our view, this phrase "forms an entire
3 circumference" deviates from what "defining a passage"
4 means in the context of this patent. The phrase is just
5 meant to capture -- we've done our best to try to explain
6 it, but having an inner space for another component
7 through which the other component can pass. And
8 consistently throughout the patent, that's all it says the
9 passage needs to do. It doesn't need to have some
10 specific limited structure.

11 A couple other points, Your Honor. In the
12 brief, the defendants even characterize the claims as
13 using the phrase "defining the passage" in the same way.
14 What they do is they try to say the specification deviates
15 from that and it's the same issue that you've heard in the
16 first two arguments where they look at the embodiments and
17 they say the embodiments always do it this way, therefore
18 it needs to be limited this way. That's not the situation
19 in our view.

20 And here we are just pointing out how they
21 specifically say that in the brief.

22 So happy to address any questions, Your Honor,
23 but that, in essence, is our view.

24 **THE COURT:** Give me one second.

25 Just so I'm clear, on this one, there really is

1 no plain and ordinary meaning; is that right? Neither of
2 you take that position. I'm supposed to just take my best
3 shot at interpreting the claim term in light of what's in
4 the written description, fair?

5 **MR. COUNIHAN:** That's our view. This is a
6 situation where our view is that the passage that's
7 referenced is consistently just there to constrain the
8 other components. It's not meant to be a specific limited
9 structure for the passage. And so we have not argued
10 plain and ordinary meaning, but we are trying to capture,
11 basically, the essence of what "defining a passage" means.

12 **THE COURT:** Okay. All right. Let me hear from
13 the other side.

14 **MR. SODIKOFF:** Good morning, Your Honor. Brian
15 Sodikoff again.

16 I guess defining the essence is what we were
17 trying to do with housing, but we'll just move on to this
18 one.

19 I think our point here is that -- and they
20 bring up in their reply brief, without any expert
21 testimony or citation to the patent or the anything in the
22 patent, the specification, or the claims, that suggests
23 that you can have any shape other than the shapes that are
24 specifically shown as being a passage.

25 They mention a C-shaped passage that would work

1 the same way, but there's no extrinsic evidence of that.
2 There's no citation to that. There's no expert report.

3 So what we have is the patent, the
4 specification, and the figures, and the claims. And every
5 time they have a passage where it's all the way around in
6 this nested configuration is what they say is their
7 invention, and the nested configuration including --

8 **THE COURT:** Where is your best example in the
9 written description that the nested configuration is
10 limited?

11 **MR. SODIKOFF:** I think it's -- if we go to --
12 it's not that it's limiting, Your Honor. It's always a
13 physical -- the defining passage is always the physical
14 relationship between the components. The limiter defines
15 a passage for the piston rod. The driver defines a
16 passage for the limiter. The housing defines a passage
17 for the piston rod. And they all have -- you know, they
18 describe how they do that. And it's always, you know, a
19 threaded inner surface for engagement with a threaded
20 outer surface. So that's suggesting that these are, you
21 know, like a screw and a nut, where you're screwing and
22 one is threaded on the inside, one on the outside, and
23 those go all the way around.

24 And that's what we see in Figure 1. Again, the
25 language cited to, describing Figure 1 is the inner

1 surface of the driver. It has this threaded surface. So
2 it's not just like a cave or a weird passage of some sort.
3 In this art in this patent, they're always talking about
4 it being inner structure that is bounded on all sides by
5 the structure on the outside of it.

6 **THE COURT:** How is this going to make a
7 difference? Can somebody put up the slide where we had
8 the one with the entire circumference versus where the
9 notches come out all the way.

10 **MR. SODIKOFF:** That was their slide.

11 **THE COURT:** Yeah, I know. Is that, what, your
12 device? Does your device, the notches come out all the
13 way?

14 **MR. OELKE:** There's just six defendants and
15 there's different devices, Your Honor, just so I make that
16 clear.

17 **THE COURT:** I see. Yeah. I'm trying to
18 understand how this is going to matter.

19 **MR. SODIKOFF:** I honestly can't speak to
20 everyone's devices because I don't know theirs.

21 **THE COURT:** Okay. Can you speak to yours?

22 **MR. SODIKOFF:** I can speak to ours. I don't
23 think we infringe this patent for other reasons either
24 way.

25 **THE COURT:** Fair. But what about this? I'm

1 trying to figure out why this matters.

2 **MR. SODIKOFF:** I can't say that for ours,
3 sitting here today, Your Honor. I can say that we think
4 that the figures on the left are what they say is the
5 passage.

6 **THE COURT:** Gotcha.

7 **MR. SODIKOFF:** They never describe other ways
8 that you can have a passage.

9 **THE COURT:** So then why do I need to even
10 construe this term? Does it matter?

11 **MR. SODIKOFF:** I think it matters for some
12 defendants' devices, Your Honor.

13 **THE COURT:** Maybe we should have those
14 defendants come up and tell me why it matters. That would
15 really help.

16 **MR. SODIKOFF:** I don't know.

17 **THE COURT:** If nobody wants to say it matters,
18 then I think I shouldn't even construe it.

19 **MR. SODIKOFF:** Can we get back to you on it,
20 Your Honor? I just don't know, sitting here today, the
21 position of everybody.

22 **THE COURT:** That's fair. I will just tell you,
23 I've evolved.

24 So I started as a judge in the Judge Stark
25 school, which was: I don't want to know at all about the

1 device or the infringement theories, because I thought,
2 oh, I can make kind of the most neutral-based decision,
3 right. I won't be influenced, because you're not supposed
4 to be influenced, by whether it would infringe or not when
5 you make a decision.

6 I have evolved. I think Ms. Keller was there.
7 We had a great conference with folks from the Federal
8 Circuit, other districts that have a lot of patent cases,
9 experts, and both plaintiff and defendant patent lawyers
10 in the room, very experienced, sophisticated lawyers. And
11 even the Federal Circuit judges were saying, no, it makes
12 sense that you should know why it matters. It can make
13 it, actually, better decision-making.

14 So I've gone the other way. We will see how
15 that works.

16 But it does occur to me to be more efficient to
17 figure out, why does this matter? And it may help me
18 interpret or understand the technology better.

19 But what I'm going to do here, since you all
20 can't figure out or articulate at all why this matters,
21 I'm not going to construe this term. It's a bench trial,
22 so we can always revisit it. But I think that makes the
23 most sense.

24 **MR. SODIKOFF:** Understood, Your Honor.

25 **THE COURT:** All right. You all agree to that,

1 then, right now?

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

3 **THE COURT:** Okay. Sounds good.

4 By the way, have I avoided construing the other
5 terms on that basis?

6 **MR. SODIKOFF:** Again, I can't speak to all our
7 devices, and that's kind of --

8 **THE COURT:** Right.

9 **MR. SODIKOFF:** -- the difficulty in these joint
10 defense groups, is we all have confidential materials for
11 each of our clients that aren't shared.

12 **THE COURT:** Right.

13 **MR. SODIKOFF:** So we can get back to you if we
14 think there's some that we could -- it sounds like you're
15 ruling from the bench, so maybe it's not necessary. But
16 if there's --

17 **THE COURT:** Well, also, you guys have been
18 pretty good -- I hope I'm not confusing with you my other
19 MDLs -- about not taxing the Court. I don't think you've
20 been before the Court much, right?

21 **MR. OELKE:** We've be very careful about that,
22 Your Honor.

23 **THE COURT:** Yeah, I think you have, so, you
24 know, on this one -- when's the trial?

25 **MR. SODIKOFF:** It's in a long time, Your Honor.

1 **THE COURT:** Yeah. So I think the lawyers
2 deserve credit in this one for being really thoughtful and
3 civil and not overly burdening the Court.

4 So what I would say here is, if you decide,
5 look, it does matter, and we think we do need a
6 construction, you know, contact us, and we'll figure out a
7 way to address it efficiently.

8 **MR. SODIKOFF:** Thank you, Your Honor.

9 And part of it may also be on the validity
10 side. So that just to put that in your ballpark too.

11 **THE COURT:** And I get that, but then somebody
12 could tell me why it matters, then I'll --

13 **MR. SODIKOFF:** Yeah.

14 **THE COURT:** And that's a fair point. That's a
15 good point. Okay.

16 **MR. SODIKOFF:** Thank you, Your Honor.

17 **THE COURT:** So then, I won't construe that
18 term.

19 All right. Next.

20 **MR. COUNIHAN:** So following the chart, I
21 believe the next term is "coupled."

22 **THE COURT:** Oh, yes. All right. Before we
23 even get started, does this matter?

24 **MR. COUNIHAN:** Just one clarification just so
25 you have our position. We didn't ask for a construction

1 of any of these terms.

2 **THE COURT:** I don't think "coupled" needs to be
3 construed. I want to hear, does it really matter?

4 **MR. BURG:** Aziz Burg, Your Honor.

5 Yes, it does for our client.

6 **THE COURT:** Okay.

7 **MR. BURG:** With respect to the
8 non-infringement position in particular.

9 **THE COURT:** Okay. Let me tell you where I'm
10 coming from. And I just, you know, I almost think to
11 resolve this one, we should have expert testimony.

12 The only thing I see that could potentially be
13 argued that "coupled" doesn't deserve a plain and ordinary
14 meaning is there's one passage in the written description
15 that says "attached or coupled." Right?

16 But my take on that is attached and coupled
17 are, in the norm -- not always, but in the norm -- two
18 different things. "Attached" is you're joined. And
19 "coupled" is you're linked. So "coupled" would allow for
20 independent movement among the two or between the two
21 parts that are joined, whereas "attached" would not.
22 "Attached" would be they're fixed in their relative
23 movements.

24 That's how I see this. I don't see -- so
25 "coupled," I was like, why don't we just give it its plain

1 and ordinary meaning. It allows for independent,
2 potentially at least, some independent movement, but it
3 doesn't require it, and that's the end of the matter.

4 Can you live with that?

5 **MR. COUNIHAN:** Yes, Your Honor.

6 **THE COURT:** Can you live with that?

7 **MR. WONG:** I think what you're getting at is
8 one degree of freedom. That's from our briefs.

9 **THE COURT:** I don't if I'd used that term, but,
10 I mean, something can be coupled, and they, at some level
11 they move together, but they don't -- that doesn't
12 necessarily preclude them from also moving independent.
13 They're linked at some point. They can't be separated. I
14 mean, they're coupled.

15 **MR. BURG:** I think from Alvogen's perspective,
16 Your Honor, I think we'd be fine with the first part of
17 what you proposed, but the second part, there is
18 definitely an infringement read that they have made
19 against our products, and it goes precisely to that issue
20 of whether there is relative movement with respect to each
21 other. So I think we would be fine.

22 **THE COURT:** And they're arguing, just so I
23 know, and if we have to -- I don't want to breach any
24 confidentiality, so you don't have to answer if it would
25 and you want to approach me at sidebar or something.

1 But if they're arguing that the two parts are
2 precluded from moving relative to each other because they
3 are coupled, if that's the -- that's their argument, and
4 you're saying that you can still have relative movement.
5 Is that where it breaks down?

6 **MR. BURG**: I think we're saying the opposite.

7 **THE COURT**: The opposite, okay.

8 **MR. BURG**: And I don't want to speak for all
9 of the defendants. I think, at least for our client, if
10 it were a construction where you said that the two parts
11 would not move relative to each other, then I think at
12 least from Alvogen's perspective, we would be amenable to
13 that construction.

14 And, again, if it would be helpful to Your
15 Honor to have expert testimony on this or any of the
16 remaining terms -- because they kind of go hand in hand --
17 we would be happy to indulge Your Honor in that respect.

18 **MR. WONG**: Jovial Wong for DRL, too.

19 I think expert testimony might be helpful to
20 Your Honor. If you can hear more, we would be amenable to
21 that as well. But we do disagree with what they're
22 proposing for "coupled" is really an attached engagement,
23 which we think is not the correct term.

24 **THE COURT**: Well, I think there has to be
25 linkage.

1 **MR. WONG:** It's definitely connected.

2 **THE COURT:** It is connected.

3 Is there any dispute, you both agree that there
4 has to be connection?

5 **MR. WONG:** Has to be connection.

6 **THE COURT:** At all times?

7 **MR. WONG:** Yes.

8 **MR. BURG:** Yes.

9 **MR. COUNIHAN:** Yes.

10 **MR. WONG:** But we're saying that connection
11 imparts a rotational movement, but not an axial movement.

12 **THE COURT:** Right. But that movement, which is
13 relative -- that movement of one component to the other
14 component, which is relative movement between the
15 components, does not have a detachment. That movement
16 takes place even when the two parts are connected, in
17 other words, correct?

18 **MR. BURG:** I think what we would say is that
19 the movement occurs with the two components together, but
20 not with respect to each other, that if it's coupled, that
21 Part A can't move relative to Part B, which would be
22 below. I think that's the issue, and that's the
23 distinction between other terms that are used, for
24 example, "fixed." I think that imparts a different
25 meaning.

1 **MR. WONG:** One last point, Your Honor.

2 I guess what we're saying is, if "coupled"
3 meant that when you -- meant that it's attached or
4 snap-fit, we wouldn't think that that would be within the
5 definition of "coupled," because "coupled" does have to
6 allow for 1 degree of freedom; not both rotating, both
7 actually being pushed, which I think is the construction
8 plaintiffs are advocating for.

9 **THE COURT:** What I don't understand about the
10 plaintiffs' proposal is, you say "plain and ordinary
11 meaning," which I don't think it is from what you've got,
12 but "physically connected and either move together or
13 remain connected while one component moves."

14 **MR. COUNIHAN:** Yes, Your Honor. So this is
15 another result of the compromise.

16 **THE COURT:** You guys can be seated. Thank you.

17 **MR. COUNIHAN:** Another result of the compromise
18 process. We understand the defendants' concerns, which I
19 think is consistent with what was just said, that their
20 concern is around the forces and the actions that occur,
21 so when we want to make sure that the dispute is teed up
22 and clear, we added that language to make it clear.
23 Because we're responding to what usury defendants say,
24 which is they're trying to read out "axial force" and say
25 that -- they're saying that coupled -- two components

1 coupled or engagement that exerts a rotational force, but
2 not an axial force.

3 And our view is that that's inconsistent with
4 even their own dictionary definition. So if we look at
5 Slide 59, the dictionaries put up by both parties talk
6 about "coupled," just as you said, Your Honor, tied,
7 joined, linked, things like that.

8 I can keep going with what they focus on. They
9 focus on a physics definition. They focus on a noun.
10 Clearly, the word "coupled" as a component coupled to
11 another component, is being used as a verb. And they're
12 focusing on the wrong application of it. Because here --
13 so this is their definition. They're focused on the one
14 in green. I'm sorry. They're using it as a noun. Yeah.
15 I said it right.

16 They are using it as a noun. It's used in the
17 claim as a verb. That doesn't make any sense.

18 Our view is that the construction should just
19 capture the basic concept that is what "coupled" means:
20 To link together, attach, join. The different phrases
21 that we just talked about.

22 They pull things from mechanical engineering
23 textbooks where they are trying to explain. This is like
24 mechanical engineering 101. You first learn about force
25 diagrams, then when you start introducing the concept of

1 rotation, there's this concept called the "force couple."
2 then that's what they talk about.

3 But a force couple is not at what is at issue
4 in this patent. The patent claims aren't a component is a
5 force couple to another component. That just doesn't make
6 any sense. It's the verb a component coupled to another,
7 and that's how it has to be construed.

8 Then even, in their own brief, elsewhere, say
9 that the piston rod -- they say it in the negative, but
10 what they're essentially saying is that the piston rod
11 must be coupled to a corresponding piston, otherwise, it
12 is not a piston rod.

13 Clearly, a piston rod is exerting an axial
14 force on a piston. That's the vertical up and down
15 movement. So they're inconsistent in their own use of the
16 phrase. That's found in the claims. And I can talk about
17 the screw and nut if you'd like.

18 So in the screw and nut example, they try to
19 use this to explain that -- what they argue is that in a
20 screw and nut, a rotational torque is applied to make the
21 nut move up and down the screw. That is true with respect
22 to the human twisting the nut. Human hand is exerting a
23 rotational torque. But the claim is about the two parts,
24 it's about the screw and the nut.

25 So the reason the nut moves down in this

1 situation, the bolt as it's being screwed -- or I'm sorry,
2 the screw as it's being screwed -- is because you have
3 that thread. And what that thread is doing is it's
4 imposing an axial force, otherwise, it would just spin.

5 And so their example, it focuses on what the
6 human is doing, but that's not what the claim is about.
7 The claim is about what the screw and the nut are doing to
8 each other.

9 So, Your Honor, we're comfortable with sticking
10 with expert testimony if that's what Your Honor would
11 prefer. If Your Honor would like to construe the term
12 now, we would be comfortable with just the bolded part,
13 "physically connected," and we can ignore the part about
14 movement if you'd like, or we're comfortable with the
15 movement language.

16 **THE COURT:** Let me hear from the defendants.

17 **MR. WONG:** Good morning, Your Honor. Jovial
18 Wong for defendant DRL.

19 I think, if I can just cut to the chase.

20 So here are the two constructions. We're
21 proposing engagement between two parts.

22 **THE COURT:** Let me stop you at the beginning.
23 I don't -- and this drives me nuts with the patent stuff
24 with the lawyers, right.

25 "Coupled" is what form of English? What

1 grammar?

2 **MR. WONG:** I guess to be coupled to something
3 is a verb, perhaps.

4 **THE COURT:** Well, couple would be a verb. I
5 think coupled would be an adjective, probably? It's
6 coupled to?

7 **MR. WONG:** Something is coupled to something,
8 right.

9 **THE COURT:** Right. So you're giving me a noun.
10 "Or engagement between two parts to exert rotational
11 torque."

12 **MR. WONG:** Yeah, and maybe we could have been
13 more precise in our wording, but it's describing the
14 relationship, the engagement between two parts, yes.

15 **THE COURT:** Should it be engaged --

16 **MR. WONG:** Right.

17 **THE COURT:** -- between two parts. Is that
18 really what the construction is? Something that's engaged
19 between two parts?

20 **MR. WONG:** Maybe two parts engaged to exert if
21 you want to flip.

22 **THE COURT:** Well, "two parts engaged," then
23 it's a noun.

24 **MR. WONG:** Okay. Engaged between two parts to
25 exert a rotational torque, but not an axial force. You

1 want it to fit within the --

2 **THE COURT:** That doesn't make sense to me. How
3 can you have something that's engaged between?

4 **MR. WONG:** If two parts are engaged to each
5 other, right?

6 **THE COURT:** If two parts are engaged, but now
7 we're off to a noun.

8 **MR. WONG:** Let me see if I can go to the claims
9 and how they use them. The driver being coupled to the
10 dose-setting member. So I guess what we're saying here is
11 the driver is engaged with the dose-setting member where
12 it exerts a rotational force, torque, but not an axial
13 force. The same way in the --

14 **THE COURT:** So then, again, I'm trying to -- so
15 you want to -- the construction should be the driver being
16 engaged to the dose-setting member?

17 **MR. WONG:** In that specific instance, yes,
18 where, you know, the parts exert a rotational torque, but
19 not an axial force.

20 **THE COURT:** Okay.

21 **MR. WONG:** The same would apply to the limiter
22 coupled to the driver and the limiter coupled to the
23 piston rod. Right? The limiter coupled to the driver
24 where --

25 **THE COURT:** All right. So it's engaged to

1 exert a rotational torque, but not an axial force.

2 **MR. WONG:** Right.

3 **THE COURT:** Okay.

4 **MR. WONG:** And there's been a lot of evidence.
5 We've pointed to the specific specification.

6 **THE COURT:** Hold up. But it's not just
7 engaged, right? It's engaged to --

8 **MR. WONG:** We're describing the relationship
9 between two components when it's coupled.

10 **THE COURT:** I just think, grammatically, the
11 construction, I guess, should be "engaged to exert a
12 rotational torque, but not an axial force."

13 **MR. WONG:** We would be comfortable with that.

14 **THE COURT:** All right. Now, let's assume
15 that's the construction, then.

16 Now, go ahead.

17 **MR. WONG:** Sure. And I think Your Honor picked
18 up on it. There's been a lot of evidence, we cited the
19 specification, which is what you're supposed to do.
20 There's also been extrinsic evidence submitted. But I
21 think the specification is dispositive on this issue. I
22 guess, just going back in general, you know, engagement --
23 to exert a rotational torque, but not an axial force,
24 there's 1 degree of freedom there, right, so when you
25 rotate one part, you exert a rotational force on the other

1 part, causes the other part to rotate. But under our
2 construction, if you exert an axial force on one part, the
3 other part will not move axially.

4 **THE COURT:** Okay. But where is that anywhere
5 in the written description?

6 **MR. WONG:** We have, in the written description,
7 that is the understanding of "coupled," and we have
8 submitted -- we've pointed to extrinsic evidence. That's
9 how --

10 **THE COURT:** Wait. So let me ask you this:
11 Fair to say, for you to prevail, you have to resort to
12 extrinsic evidence?

13 **MR. WONG:** I think extrinsic evidence shows how
14 "coupled" is understood, the plain and ordinary meaning is
15 understood, and extrinsic evidence -- intrinsic evidence
16 shows why plaintiffs' construction is not correct. It
17 can't be correct from the paragraph that I think Your
18 Honor is picking up on.

19 **THE COURT:** No, actually, when you say,
20 "picking up on," I have the opposite is -- I mean, they're
21 saying now plain and ordinary meaning is "physically
22 connected." That's what "coupled" means to me, physically
23 connected.

24 **MR. WONG:** I think it's not precise enough.
25 When you say, "physically connected," that could include

1 an attached connection, a snap-fit connection, where, when
2 you --

3 **THE COURT:** Right. So it could. I agree. But
4 then why do you need a construction?

5 **MR. WONG:** Because coupled allows 1 degree of
6 freedom. Coupled does not -- "coupled" allows you to
7 rotate it without also exerting an axial force. It's a
8 specific meaning of "coupled." When you look at our --
9 when you look at way it's used in the specification, it's
10 different from attached. "Attached" would mean connected
11 where you rotate one, you push one, they both move and
12 rotate. Coupled is different. And it's consistent with
13 our dictionary definitions. In the mechanical arts,
14 that's what the term "coupled" means. And --

15 **THE COURT:** Hold on one second. Sorry.

16 Do you think I need extrinsic evidence? Who's
17 argued this term?

18 **MR. COUNIHAN:** No, Your Honor, because I think
19 this is the plain meaning. We think the extrinsic
20 evidence --

21 **THE COURT:** Which is "physically connected."

22 **MR. COUNIHAN:** Correct. We think the extrinsic
23 evidence, even the definitions and whatnot that defendants
24 put forward is consistent with that meaning, but I don't
25 think you need to go to it.

1 **THE COURT:** Just understand, I'm going to be
2 the fact finder here.

3 **MR. WONG:** Sure.

4 **THE COURT:** To me, "physically connected" means
5 they would just have to prove they're linked and that's
6 it. Linked at all times, right, and you don't want that?

7 **MR. WONG:** I think coupled means something
8 different than that.

9 **THE COURT:** Right. Okay. I just want to make
10 sure.

11 **MR. WONG:** And that's, if you talk about later
12 on in the case we'll get to this, but they are accusing
13 certain parts of our device elements as being coupled,
14 when they are not coupled according to what our
15 construction says.

16 **THE COURT:** All right.

17 **MR. WONG:** So --

18 **THE COURT:** Give me one second.

19 I think I have to resort to extrinsic evidence
20 to make a decision, so I'm going to -- we'll just have a
21 hearing, and I'll hear the experts. I think there's some
22 ambiguity. There's not a lot to go by here.

23 My gut tells me, as a Joe Six-Pack, but not as
24 an artisan in the field here that "coupled" would be
25 satisfied by just showing a physical link. The

1 specification in one sentence refers to attached or
2 coupled. That's not inconsistent with what I bring as a
3 Joe Six-Pack to the table, but it suggests to me that the
4 field distinguishes between "attachment" and "coupled,"
5 and it's not clear to me how the field would do that.

6 I don't think there's enough evidence in the
7 written description alone or the claims to make a
8 construction, since there's a dispute, that I would be
9 comfortable with.

10 So we'll bring in experts and they can tell me
11 what they think. All right?

12 **MR. WONG:** Thank you, Your Honor.

13 **THE COURT:** Thank you.

14 So we are left with the means-plus-function?

15 **MR. COUNIHAN:** Yes.

16 **THE COURT:** Okay. Fun time. Here we go.

17 **MR. COUNIHAN:** If you'd like to do the '462
18 first and skip on the means-plus-function.

19 **THE COURT:** Well, wait. If I like to hear, I
20 mean, what do you mean by?

21 **MR. COUNIHAN:** Well, no, I just meant that's
22 the only other bucket. There's the two
23 means-plus-function terms --

24 **THE COURT:** Yeah.

25 **MR. COUNIHAN:** -- and then there's the method

1 patent, the '462 patent.

2 **THE COURT:** But what are the terms of the
3 method patent that I haven't taken care of so far or won't
4 take care of?

5 **MR. OELKE:** It's the preamble, Your Honor.

6 **THE COURT:** Oh, okay. Okay. Sorry, yes.

7 **MR. COUNIHAN:** So comfortable starting with
8 means-plus-function or going to the preamble, whatever
9 you'd like, Your Honor.

10 **THE COURT:** Oh, let's do means-plus-function.

11 **MR. COUNIHAN:** Okay.

12 So, Mr. Watkins, we're at Slide 4.

13 So, Your Honor, what I was planning to do --

14 Sorry, Slide 8. Yeah. Looking at the big
15 numbers, not the small ones.

16 What I was planning to do is address the
17 question of whether they are means-plus-function first and
18 then address the proposed constructions. And I'm just
19 going to do the means-plus-function analysis for both
20 terms, because I think it's largely the same, and then we
21 can do the constructions if that works. Okay.

22 **THE COURT:** Sounds good.

23 **MR. COUNIHAN:** Okay. So summary of the
24 disputes. The basic law, Your Honor, as I'm sure you're
25 familiar, is there is a rebuttable presumption, neither

1 term, "limiter" or "driver," uses the words "means," so
2 the rebuttal presumption is in our favor. To rebut that
3 presumption, the burden is on the challenger to do that.
4 And what they have to do is show that there is inadequate
5 structure.

6 *Williamson* set forth the basic standard back in
7 2015.

8 To start, these are not -- "limiter" and
9 "driver" do not use nonce terms. They don't have
10 substitute generic language, like "mechanism" or "element"
11 or "device" that are used in place of "means." They're
12 not -- they are, in and of themselves, structural terms.
13 Dr. Cameron, in her declaration --

14 **THE COURT:** But you say that, but you,
15 yourself, without prompting, talked about limiting
16 mechanism.

17 **MR. COUNIHAN:** Earlier this morning?

18 **THE COURT:** Yeah.

19 **MR. COUNIHAN:** I believe your question, Your
20 Honor, was about limiting mechanism.

21 **THE COURT:** No, no. My question was because
22 you said it's a limiting mechanism.

23 **MR. COUNIHAN:** Oh, I'm sorry. I didn't intend
24 to.

25 **THE COURT:** I don't think you did intend to,

1 but I noticed you did.

2 **MR. COUNIHAN:** Okay. Well, Your Honor, in the
3 patent, they did not use "limiting mechanism." They used
4 "limiter." And the term "limiter" has an understanding in
5 the art. But it also has a clear structure in the claims.
6 So there is some dispute between the parties about the
7 right legal analysis to apply. There is no dispute that
8 the claims themselves can provide that structure, and I'm
9 going to focus on that here in a moment. But there is
10 also -- there's some dispute about whether the intrinsic
11 record, the specification in particular is relevant. And
12 I think --

13 **THE COURT:** When you say "specification," you
14 mean the written description?

15 **MR. COUNIHAN:** Correct. Yes. Exactly.

16 **THE COURT:** There is no dispute that I looked
17 at the claims.

18 **MR. COUNIHAN:** Correct. Right.

19 **THE COURT:** All right. Why don't you look at
20 the law that says I can look beyond the claims because --
21 actually, let me ask you this before you do that.

22 Where is the structure in the claims?

23 **MR. COUNIHAN:** So that's the, I would say, the
24 confusion. So what the *MTD* case says --

25 **THE COURT:** See, I didn't want to go into the

1 law yet.

2 **MR. COUNIHAN:** Okay.

3 **THE COURT:** I want you to show me where in the
4 claims is their structure for a limiter.

5 **MR. COUNIHAN:** So the --

6 **THE COURT:** You'll have to look at the
7 patent --

8 **MR. COUNIHAN:** Yes.

9 **THE COURT:** -- and show me where in the patent
10 there's structure in the claims for limiter. Or you could
11 just say, you know, you agree there is none.

12 **MR. COUNIHAN:** Well, so, I don't know --
13 Mr. Watkins, if you're able to pull up the patent.

14 If we start at Column 3, starting at line --

15 **THE COURT:** What patent are you on?

16 **MR. COUNIHAN:** The '383 patent, Your Honor.

17 **THE COURT:** '383. Sorry. Okay. And you're on
18 Column 3?

19 **MR. COUNIHAN:** Yes. Starting at Line 40.

20 **THE COURT:** Hold up. Well, that's not the
21 claims.

22 **MR. COUNIHAN:** I'm sorry. I thought you wanted
23 me to look at the specification.

24 **THE COURT:** No. No. I said, I want you to
25 look at the claims and tell me where there's structure for

1 a limiter in the claims.

2 **MR. COUNIHAN:** Oh, okay.

3 **THE COURT:** Or just concede that there isn't.

4 **MR. COUNIHAN:** There is structure in the
5 claims.

6 **THE COURT:** Okay.

7 **MR. COUNIHAN:** So, Mr. Watkins, if we can go to
8 Slide 12.

9 Sorry. I misunderstood your question, Your
10 Honor.

11 **THE COURT:** That's all right.

12 **MR. COUNIHAN:** So this is Claim 1 of the '383.
13 The Claim 1 specifies that this invention is in the
14 context of injection pens. So that informs the analysis.

15 The term "limiter" shows up right before the
16 green. The green specifies what the limiter is doing.
17 It's preventing the setting of a dose.

18 **THE COURT:** Yep. Right.

19 **MR. COUNIHAN:** And then in the yellow, there
20 are specific structures that are identified. The limiter
21 itself has to define a passage for the piston rod. The
22 limiter has to be able to fit inside of a passage defined
23 by the driver. Those are two structural features.

24 In the law, it distinguishes whether -- between
25 whether the additional limitations are functional, which

1 defining a passage has no function, and whether they are
2 structure.

3 A passage is a structure. I don't think
4 there's any dispute about that. And the component, that
5 is the limiter, has to define that structure, the passage,
6 and be able to fit inside another passage defined by a
7 separate component.

8 The claim also requires that the limiter is
9 coupled to the driver and the piston rod. So it requires
10 two particular linkages or joinder, depending on how that
11 term comes out, but two specific components that it is
12 coupled to.

13 It also says, at the end, that based on the
14 fact that it is coupled to those two components, it has to
15 move in a particular way, but in a way that is also
16 structural. Because it says it moves toward a stopping
17 position.

18 **THE COURT:** Let's stop here. Defining a
19 passage to say that that's structure, that's what an
20 enclosure is. That's a housing. It's not a limiter. If
21 you want to just step back and say limiter --

22 **MR. COUNIHAN:** So --

23 **THE COURT:** -- you have equated it. You've
24 reduced it to housing, which is one of the arguments they
25 made with respect to housing.

1 **MR. COUNIHAN:** And I'm happy to address that
2 argument, but the limiter, it's not just that it defines a
3 passage. So using the term "housing," the limiter has to,
4 in and of itself, be a housing. It has to fit inside
5 another housing.

6 And, by the way, Your Honor, just to be clear,
7 we disagree that "defining a passage" and "housing" are
8 necessarily equivalent. But setting that aside for a
9 second, the limiter itself is a housing. It fits inside
10 another housing. And it has to be coupled to those two
11 components where the housing -- that are the housings.
12 And it has to be coupled in a way that dictates how it
13 moves with respect to rotation. And the limiter has to
14 have a stopping position.

15 So it has at least five structural elements.
16 The two passages, the two coupled aspects, and then the
17 stopping position.

18 Under the law, if we look at the *Tek Global*
19 case, Your Honor, where -- and I can -- we can pull up
20 that if we need to -- there was -- the Court found that
21 there's sufficient structure because the term was linked
22 to another component.

23 In the *Inventio* case, it talks specifically
24 about what was necessary and found similar to what we have
25 here, that there was sufficient structure.

1 **THE COURT:** Defining is a verb; it's not
2 structure.

3 **MR. COUNIHAN:** But passage is --

4 **THE COURT:** So doesn't "means-plus-function"
5 mean the whole -- it comes up -- by saying there's a
6 structure doesn't mean that there's some physical
7 component to it, right? It can't mean that. That would
8 swallow everything.

9 I mean, functionality, we're dealing with
10 physical things. At some point, functionality has to have
11 some structure to it. That's not what the test is.

12 **MR. COUNIHAN:** Agreed. The way I understand
13 the test with respect to looking at the claims is whether
14 the claims provide sufficient structure.

15 **THE COURT:** Sufficient structure. Right.
16 That's exactly right. "Sufficient" is the key.

17 **MR. COUNIHAN:** Right. And tied to the
18 function.

19 **THE COURT:** Okay. So the sufficient structure,
20 you say, is that -- and you're referring to a verb,
21 "defining a passage." Doesn't even say it has to have a
22 passage; it has to define the passage.

23 **MR. COUNIHAN:** In the context of injection
24 pens, which are mechanical devices, I believe that
25 "defining a passage" means it has to have a passage. I

1 don't think it can be -- I'm not exactly sure -- I agree
2 it's an interesting phrase to use, but it's -- I -- in my
3 view, "defining a passage" means it has to have a passage.
4 And by having a passage defined for it, it has to be able
5 to fit inside of a passage. Like, to kind of -- to have
6 the situation where they're not fitting inside each other
7 to avoid this nested concept, if you will, would kind of
8 read out a bunch of the elements, if you will, because
9 otherwise it's not clear to me how these different
10 components interact together.

11 Maybe if we could put the *Tek* case on the
12 screen. And I believe it's Page 11 of the PDF. Right
13 where the 786 is, if we can zoom in there.

14 So the term in dispute is "conduits connecting
15 the container." And what the Court recognized is that in
16 the claim, the components that it's connected to have
17 structure. And it says, "although connoting precise
18 physical structure is not a necessary condition, it is
19 generally sufficient -- it is generally sufficient."

20 And in this case, just that simple phrase
21 "connecting the container to the compressor assembly and
22 to an inflatable article," that was found to be sufficient
23 physical structure. And that's what we have here, where
24 you have language that the limiter is coupled to the
25 driver. There's a dispute about that term, obviously, but

1 also coupled to the piston rod. And there's no dispute
2 that the piston rod has structure.

3 We can also look at the -- when you're ready,
4 Your Honor, I would also like to look at the *Inventio*
5 case.

6 I would also add, we can get into other
7 intrinsic evidence in a moment, Your Honor, if you'd like,
8 but *Tek Global* also does talk about how dependent claims
9 add specific structure, and the dependent claims in our
10 case do as well, such as threads and things like that that
11 are on the limiter. And it also talks about how the
12 written description informs the analysis.

13 **THE COURT:** Give me a second.

14 Go ahead.

15 **MR. COUNIHAN:** Thank you.

16 Mr. Watkins, can we put the *Inventio* case up,
17 Page 10. That second paragraph beginning "In sum," if we
18 could highlight "beginning with this case, however."

19 Your Honor, so I would acknowledge that
20 *Inventio* is pre-*Williamson*, so it does -- it is under the
21 strong presumption standard. But I would draw your
22 attention, Your Honor, to what the *Inventio* Federal
23 Circuit Court said was sufficient structure in this case
24 because I don't think it bears on the presumption
25 question, or I don't think it's changed by the presumption

1 issue because it's not talking about the presumption at
2 this point.

3 What it says -- in that case, the term was
4 about a modernizing device. And it says, "The claims
5 delineate the components that the modernizing device is
6 connected to." We have that in our claims. It's coupled
7 to the piston rod and limiter. Describes how the
8 modernizing device interacts with those components. It's
9 coupled, and that rotational -- relative rotational
10 movement causes certain other movements to occur. And it
11 describes the processing that the modern device performs.

12 In our situation, the claim says -- it limits
13 the setting of a dose beyond the amount of medication that
14 is there.

15 So the *Inventio* three parts that were found in
16 those claims, that's present in our claims, too, without
17 even getting to the "defining a passage" issue and not
18 even looking at whether that's structural or not.

19 So between *Inventio* and *Tek Global* -- we can go
20 back to the slide. I don't know if you want to look at
21 that anymore.

22 There is a number of examples in the case law
23 of terms that are, in our view, even less structural on
24 their face that, because of what the claim said or, like
25 in the lower two, they drive the function -- sorry --

1 nouns derive from function that still designate structure.
2 There's numerous examples in the record of the Federal
3 Circuit finding similar terms are ones that are even
4 closer to a nonce term, if you will, to be, in fact,
5 sufficiently structural in the context of the claims for
6 purposes of the means-plus-function analysis.

7 Going back a moment to "driver," Slide 13, it's
8 the same basic things. I think "driver," as we were
9 talking about earlier, Your Honor -- I don't know if I
10 actually have a picture of the driver. Drivers are common
11 components of injection pens that, at their core, what
12 they do --

13 **THE COURT:** So now, isn't this extrinsic
14 evidence? We are off to extrinsic evidence right now.

15 **MR. COUNIHAN:** Well, when --

16 **THE COURT:** Where in the written description
17 does it say, "drivers are common components of injection
18 devices"?

19 **MR. COUNIHAN:** In the background of the
20 invention, it talks about drivers in the context of the
21 prior art.

22 **THE COURT:** Show me.

23 **MR. COUNIHAN:** It's at Column 1, Line 36,
24 referring to WO0119434.

25 **THE COURT:** Where?

1 **MR. COUNIHAN:** This is -- I'm in the '383,
2 Column 1.

3 **THE COURT:** Yeah. I mean, 36, end-of-content
4 mechanisms are known in the art. One such example may be
5 seen in W-O blank, blank, blank, which discloses a
6 limiting mechanism for an injection device.

7 **MR. COUNIHAN:** Yes, Your Honor. But it --

8 **THE COURT:** Now, I agree the next sentence
9 says, a dose is -- I mean, that cuts against you, that
10 first sentence.

11 The next sentence says, "A dose is injected by
12 rotating a disk-setting member, which during this
13 rotation, carries a driver with it to rotate this driver."

14 So I agree there's something being discussed in
15 that which has a driver, but it doesn't say this is a
16 commonly understood term in the art, in the context of
17 that one particular injection device.

18 **MR. COUNIHAN:** Understood. You're correct,
19 Your Honor, there's nowhere that the specification comes
20 out and says the driver or the limiter is a commonly
21 understood term in the art.

22 In my experience, that's pretty atypical in
23 patents. Typically, like, think of the word "clamp," like
24 there's a pretty commonly understood meaning of what a
25 clamp is. But clamps work in different ways. Some are

1 like vice grips, some are screwed down. And so in a
2 patent that involves clamps for some reason, you wouldn't
3 have a statement that says clamps are commonly understood.
4 Right? You would just be, here's the screw-down clamp and
5 here's the -- you know, here's the vice grip clamp and
6 whatnot. It starts from a place of an understanding that
7 the person of ordinary skill knows that it has a common
8 understanding. So I point you to this, Your Honor,
9 because it's using the phrase "driver" in that way.

10 Now, I understand "limiting mechanism" is
11 referenced there. But they didn't use "limiting
12 mechanism" in the claims. They used "limiter." I'm not
13 exactly sure what that mechanism is that's in that patent,
14 but the reason that they're talking about this patent is
15 because they're saying our invention is better than that.
16 They are not saying that invention has the same limiter we
17 have. That's because we invented something better.

18 The overall concept that this claim is about,
19 is about a mechanism. It says, "a mechanism comprising,"
20 when you look at the claim language. So the mechanism
21 comprises specific components, each of which are
22 structural, one of which is the limiter and one of which
23 is the driver.

24 **THE COURT:** Okay. Incidentally, there are two
25 independent questions, right? One was whether "limiter"

1 is a means-plus-function; one was whether "driver." I
2 could find one is and one isn't?

3 **MR. COUNIHAN:** Correct, Your Honor, yes.

4 Mr. Watkins, if we can go to Slide 15.

5 So the defendants reference this *MTD* case from
6 2019. And our read of it is they're trying to downplay
7 the importance of the specification in the analysis of
8 whether a term is means-plus-function or not. But what
9 *MTD* and *Inventio* and consistent other Federal Circuit
10 precedent has said is that you can consider it. But the
11 way you consider it -- this is what *MTD* gets at. You
12 don't look at it to see whether the specification gives
13 you structure, because if you do that, that's the whole
14 point of means-plus-function analysis.

15 What you do is you look at how the claim was
16 used in the specification. Was it used as nonce term, as
17 a substitute for function, or was it used with a
18 structural intent, was it used structurally.

19 So when we look at --

20 If we can go to the next slide.

21 -- just a couple examples from the
22 specification -- and the words "driver" and "limiter" come
23 up throughout. They're used specifically to talk about
24 specific structures that are found in the embodiments, and
25 then when we look at the background of the invention or

1 the summary of the invention, it's using them in the
2 structural context as well.

3 It's not saying, "a limiting mechanism that
4 might do blah, blah, blah, blah." Or a limiter that might
5 do all these different things. It's a limiter that has
6 engaging surfaces. It's --

7 **THE COURT:** Well, to me, what it's doing is
8 it's actually defining "limiter" by the structural -- by
9 the structure that's represented in the embodiments.
10 That's what it appears to be doing.

11 **MR. COUNIHAN:** Well, in these two examples --

12 **THE COURT:** And then, when it gets to the
13 claims because it wants to be broader, or because the
14 patentee wants it to be broader, it abandons the
15 structural limitations that are in the written
16 description, and it instead uses this term "limiter,"
17 which is like the whole purpose of the device, right?

18 I mean, the whole purpose of the device is to
19 limit what the patient is going to get from the
20 medicament, right?

21 **MR. COUNIHAN:** The overall purpose of the
22 mechanism, yes, but the concept, the invention and what's
23 claimed, is a multi-component system that works together
24 to form that overall mechanism.

25 So maybe we could look at the patent again, the

1 '383?

2 **THE COURT:** Well, actually, let's do this. I
3 want to give my court reporter a break. So let's break
4 until 11:15, come back and pick up here, okay?

5 **MR. COUNIHAN:** Thank you.

6 (Whereupon, a recess was taken.)

7 **THE COURT:** All right.

8 **MR. COUNIHAN:** One housekeeping item, Your
9 Honor. The parties discussed the proposed construction
10 over the break, and we have an agreement.

11 **THE COURT:** Oh, great.

12 **MR. COUNIHAN:** I can just read it into the
13 record.

14 **THE COURT:** Sure.

15 **MR. COUNIHAN:** So for the "piston rod rotates
16 relative" term, for shorthand, the agreed construction is:
17 "The piston rod rotates relative to the outermost housing
18 of the injection device and moves axially toward the
19 needle end that expels the medicament."

20 **THE COURT:** You good with that?

21 **MS. GREB:** Yes, Your Honor.

22 **THE COURT:** Excellent. Excellent. Okay.

23 You know, before you get up for
24 means-plus-function, let me tell what you I'm thinking.

25 **MR. BURG:** I'm sorry, Your Honor?

1 **THE COURT:** You're going to do
2 means-plus-function, right?

3 **MR. BURG:** Yeah.

4 **THE COURT:** Let me just tell you what I'm
5 thinking.

6 I don't see how this is not
7 means-plus-function. I mean, is there some reference to
8 attaching the limiter to something that has a function or
9 doing something with regards to something that has a
10 function? Okay.

11 Doing something to or that has an effect on a
12 structure, yeah, okay. That could be in the claims. But
13 is there sufficient structure, I mean, that tells you what
14 a limiter is? No. This limiter is, it limits. Seems
15 very obvious to me.

16 Now, I'm not saying your argument isn't fully
17 supported by certain cases that are out there. I get
18 that.

19 And but I think what I'm going to do is, let's,
20 since I'm going to hear experts anyway on "coupled," let's
21 hear experts on this.

22 **MR. BURG:** That's fine, Your Honor.

23 **THE COURT:** I mean, I want to hear you bring in
24 an expert that says, credibly, oh, yeah, we all know what
25 a limiter is. It's got this structure to it. Everybody

1 knows that. Maybe. But I think that might be the safest
2 way of doing this. Same thing with "driver."

3 But I also thought I may as well tell you where
4 I'm strongly inclined to go. I think there was a great
5 invention here it looks to me set forth in the
6 embodiments. And then lawyers came along and said, how
7 can we cover more in our claims than that limiting
8 mechanism that you referred to right out of the gate and
9 that the patent refers to right out of the gate: The
10 mechanism that limits.

11 So that's where I'm inclined to go, but I am
12 willing to be open minded and not make a definitive
13 judgment and hear expert testimony and then weigh that
14 expert testimony, if necessary, after further
15 consideration of the intrinsic evidence and make a final
16 decision. Does that sound good?

17 **MR. COUNIHAN:** Yes, Your Honor.

18 **MR. BURG:** Yes, Your Honor, absolutely.

19 **MR. WONG:** Yes, Your Honor.

20 **THE COURT:** All right.

21 **MR. BURG:** So should we --

22 **THE COURT:** Then we only have the preamble
23 left.

24 **MR. BURG:** I was going to ask that question.
25 Thank you, Your Honor.

1 **MR. OELKE:** Your Honor, Jeff Oelke for the
2 plaintiffs. I'm handling the '462 patent. Had to wait a
3 while. Thought I was going to get to go first.

4 One term, Your Honor, and that's the preamble
5 of the '462 patent. It's "A Method for Treating Type 2
6 diabetes." There's really only two issues with respect to
7 that term. Is the preamble a limitation to the claim, and
8 if it is a limitation, what's the proper construction?

9 And here's the claim, Your Honor.

10 **THE COURT:** And you both agree it's limited,
11 right?

12 **MS. GREB:** No, Your Honor, we don't agree.

13 **THE COURT:** Don't you really in effect -- all
14 right. Go ahead.

15 **MR. OELKE:** Here's the claim, Your Honor. The
16 preamble is "A Method for Treating Type 2 Diabetes." And
17 there's a lot of case law on preambles, Your Honor. I
18 know I've had arguments with you before on preambles.
19 There's a lot of case law over the last four years.

20 **THE COURT:** You can go either way.

21 **MR. OELKE:** There's a lot about essence of the
22 invention. There's a lot about breathing life into a
23 claim. But for method claims, there is a clear set of
24 cases, Your Honor. And I think it's set forth and
25 summarized well in the *Lilly* case from 2021. The *Lilly*

1 case looked at a series of these cases, and what the *Lilly*
2 Court said was "There's no bright-line rule" -- that's how
3 they started -- but they said, "We have generally
4 construed statements of intended purpose in such method
5 claims as limiting." And that's what the preamble is
6 here. It's a statement of intentional purpose, the
7 intentional purpose of treating Type 2 diabetes.

8 And there's a reason for that. The *Lilly* case
9 says there is a reason for that.

10 If you go to the next slide, you have apparatus
11 claims and you have method claims. And apparatus claims
12 tend to talk about what an invention is. But method
13 claims talk about what an invention does. What a method
14 does is usually in the preamble, and if it's in the
15 preamble, it should be given effect. That's what the
16 *Lilly* case says.

17 If you go to the next slide, you can see what
18 the method does here, it treats Type 2 diabetes. And,
19 again, if you go to the next slide, the end of the claim
20 is really the key here, Your Honor. There's an antecedent
21 basis right at the end of the claim in the body of the
22 claim, "a subject in need thereof."

23 So the question becomes, who is the subject and
24 what do they need? There's no dispute between the parties
25 there's an antecedent basis required for "subject" and

1 "need thereof." But the only answer to the question, who
2 is the subject and what does the subject need, is in the
3 preamble. The subject is somebody with Type 2 diabetes,
4 and what they need is treatment.

5 Go to the next slide.

6 Now, there is a related paid patent, Your
7 Honor. There is another patent on a different method, the
8 '003 patent, and that's a method for reducing body weight.
9 And if you look at the claim in that patent, it also has a
10 claim format, a subject in need thereof. So the next
11 slide shows both patents have this claim format, a method,
12 and in the body of the claim, a subject in need thereof,
13 that ties the body to the preamble. And the only way you
14 know who that subject is, is by looking at the preamble.

15 If you go to the next slide.

16 The one case that the defendants point to is
17 the *BMS* case, Your Honor, from 2001. But that case does
18 not have an antecedent basis in the claims. There is no
19 "in need thereof" language anywhere in *BMS*. And the whole
20 antecedent basis argument isn't part of that case. In
21 fact, what the *BMS* case said was, "the language of the
22 claim strongly suggested the independence of the
23 preamble."

24 Well, if you have an antecedent basis tying the
25 body to the preamble, they can't be independent; they're

1 tied together. If you go to the next slide, what we've
2 seen since *BMS*, there have been a series of cases in which
3 the body of the method claims include "in need thereof"
4 language.

5 In the *Jansen v Rexall* case in 2003, the term
6 in the claim body was "human in need thereof," and the
7 particular method claim there was "a method of treating a
8 particular type of anemia." And the result was, the
9 preamble was found limiting because you had to refer back
10 to the preamble.

11 In the *Sanofi Mature* case, "patient in need
12 thereof" was in the body. It referred back to the
13 preamble: "A method increasing survival," given effect,
14 it was a limiting preamble.

15 Those cases both look back to the *Rappaport*
16 case, which is an interference appeal, and what the Court
17 found, what the Court talked about there is "patient in
18 need of such treatment" had to refer back to the preamble,
19 which in that case, was a treatment of sleep apnea.

20 Even here in this district, Your Honor, the
21 *Novartis* case, Judge Stark found, said subject in the body
22 referred back to the preamble, which included this
23 language "subject in need thereof," and, again, gave
24 effect to the preamble.

25 There's not a single case they can point to in

1 which "in need thereof" language is in the body and
2 preamble was not given effect.

3 Go to the next slide.

4 Now, they talk about the fact that there's a
5 specific dosage in these claims as well as in the *BMS*
6 claims. But there's a specific dosage in a lot of these
7 other cases as well, Your Honor. In the *Sanofi Mature*
8 case, there's a dose of 20 to 25-milligrams per square
9 meter, refers back to "method of increasing survival," and
10 the preamble was found limiting. In the *Jansen* case,
11 there's a daily dose of at least two vitamins,
12 0.5 milligrams of vitamin B12, 0.5 milligrams of folic
13 acid, and the Court in that case found that supported
14 looking back to the preamble and giving effect to the
15 preamble making a limitation.

16 And, again, the next slide, the *Novartis* case
17 is consistent with that. The *Novartis* case has a specific
18 dosage as well.

19 So, finally, the only other thing, really, that
20 goes to this, Your Honor, all of this evidence supports
21 giving effect to the preamble.

22 If you go to the next slide.

23 Another thing the cases talk about, the *Lilly*
24 case talks about, the *Jansen* case talks about as well, is
25 the method of treatment discussed in the specification.

1 Well, "treating diabetes" is mentioned 30 times in the
2 specification.

3 Yes, it talks about other methods. It talks
4 about method of reducing body weight and treating obesity,
5 but that doesn't detract from the fact it mentions
6 "treating diabetes" 30 times. This is just another thing
7 supporting giving effect to the preamble.

8 **THE COURT:** Okay. You know, is this fair, your
9 construction -- or rather, you say that "the
10 administration is intended as part of the care."

11 **MR. OELKE:** Not part of the care, Your Honor.
12 That's their language. Our language comes straight from
13 the specification, which we think has a definitional
14 statement in it.

15 **THE COURT:** Which is for the care or management
16 of, right?

17 **MR. OELKE:** It's treatment or treating the
18 management and care of a patient for the purpose of
19 combating a condition. That's the statement in the spec
20 and our -- that's what our definition comes from.

21 **THE COURT:** So let's go over it again because
22 here's what I've got, "the claimed administration is for
23 the care or management of."

24 **MR. OELKE:** Your Honor, we did that, again, to
25 try to get closer to what their construction was.

1 **THE COURT:** Okay. But you are there.

2 **MR. OELKE:** We did agree -- I would agree with
3 that.

4 **THE COURT:** Okay. I just want to make sure.
5 Right?

6 **MR. OELKE:** Yes.

7 **THE COURT:** Okay.

8 **MR. OELKE:** I mean, I do think, to be clear,
9 though, it's for the intended care. For the intended
10 treatment, right? So their language includes "intent" in
11 it, "intended management of a patient with Type 2
12 diabetes, or "intended care or management." I think
13 "intended" is fine.

14 **THE COURT:** So what's the difference? Is the
15 only difference now that we're down to efficacy?

16 **MR. OELKE:** That's right, Your Honor.
17 Intentional purpose. There's no dispute about efficacy,
18 Your Honor. We never asked that efficacy be read --

19 **THE COURT:** Then I'm having a hard time
20 figuring out what the dispute is.

21 **MR. OELKE:** I agree with you, Your Honor. I
22 don't think there should be any dispute. I think the
23 construction should come straight from the definitional
24 statement in the specification; that is, "A method of
25 caring for or managing the care of a patient so as to

1 combat Type 2 diabetes." That's straight -- consistent
2 with the statement --

3 **THE COURT:** Well, wait. You added the "so as."

4 **MR. OELKE:** Well, that -- or "with the intent
5 to" or "the purpose to" is fine, Your Honor.

6 **THE COURT:** Okay.

7 **MR. OELKE:** But is there any requirement of a
8 negative limitation? There's nothing -- negative
9 limitation about efficacy? That's nowhere in the
10 specification or in the cases that they cite.

11 **THE COURT:** Okay.

12 **MR. OELKE:** I would just point out one more
13 thing, Your Honor, and that is if you go to Slide 22,
14 Mylan, one of the defendants here did file an IPR on this
15 patent, and they proposed a construction, and it's
16 consistent with the construction that we've proposed.
17 "Alleviate or reduce symptoms or complications associated
18 with Type 2 diabetes or otherwise manage the disease."

19 **THE COURT:** So you would be good if I construed
20 this as a limitation, and it has plain and ordinary
21 meaning of, "a claimed administration for the care and
22 management of a patient with Type 2 diabetes"?

23 **MR. OELKE:** I would, Your Honor.

24 **THE COURT:** All right. Let's hear from them.

25 So I said when I walked in here, or when we

1 started to turn to this term, I said, well, you both agree
2 it's limiting, and you say you don't.

3 **MS. GREB:** Your Honor, I think that that is the
4 most correct reading of this patent. I think you are
5 right, though.

6 **THE COURT:** I mean, here is what I have down.
7 I mean, I must be missing something. I thought that you
8 said that appropriate construction would be, quote, "a
9 method for treating Type 2 diabetes" is a limitation.

10 **MS. GREB:** Your Honor, so that --

11 **THE COURT:** Only. And then we go on.

12 But you do agree it's limiting?

13 **MS. GREB:** So I think a little bit of the
14 confusion here is there was a meet-and-confer following
15 the briefing, right? And following the briefing, we
16 proposed a construction in order to try to reach agreement
17 with the parties. And the construction that you're
18 reading is the one that we proposed as part of the
19 meet-and-confer process.

20 **THE COURT:** Right.

21 **MS. GREB:** And so I think the most correct
22 reading of this patent is that it's not a limitation. But
23 I think if it is a limitation, the important thing -- and
24 you keyed into onto this earlier, is efficacy. And I
25 think --

1 **THE COURT:** But they don't dispute. That's
2 where I lose you all. I must be missing something. My
3 law clerks are missing something. I don't get it. It
4 looks like there's no dispute about efficacy.

5 **MS. GREB:** I agree with you, Your Honor. I
6 think their briefing is clear. They said multiple times
7 in their briefing --

8 **THE COURT:** He just said it today, five minutes
9 ago, two minutes ago.

10 **MS. GREB:** He did. But my problem here is that
11 they won't agree that that is part of the construction.
12 There are cases --

13 **THE COURT:** That what is part --

14 **MS. GREB:** That that would be part of the
15 construction, to make sure that efficacy is not part of
16 this claim because --

17 **THE COURT:** Well, I'm the judge. There's no
18 jury here to worry about. I know it's not part of the
19 construction, so what are you worried about?

20 **MS. GREB:** So, Your Honor mentioned, you know,
21 interest in non-infringement and invalidity fights down
22 the road. And the concern would be that when it comes to
23 invalidity, they're going to say it's our burden of
24 proving that this is an efficacious treatment of Type 2
25 diabetes rather than just their claims are directed

1 towards, you know, an intent to treat Type 2 diabetes and
2 sort of when we get to the invalidity and validity phase,
3 we don't want them to be able to say, oh, yeah, but what
4 we really meant or what this claim really means is that
5 for invalidity purposes, you have to prove that this is
6 like an effective treatment of Type 2 diabetes versus an
7 intention to treat. That's why it matters to us.

8 **THE COURT:** I need to get my arms around that.
9 I mean, if you don't have to prove in some way efficacy,
10 how would you address a POSA having a reasonable
11 motivation to combine or a reasonable expectation of
12 success?

13 I mean, even if you define "success" as just
14 doctors using the method, although efficacy isn't a
15 limitation or people generally only invest resources in
16 developing things that they think will work. I mean, you
17 have to be useful to have an invention.

18 **MS. GREB:** I would agree with you, Your Honor,
19 that certainly doctors would only, you know, and people
20 would only try to make things that they think would work.
21 I certainly would agree with that.

22 **THE COURT:** Yeah, doesn't work perfectly, and
23 it doesn't have to be a limitation that you prove that it
24 actually did work, but you've got to think that it offers
25 potential for efficacious treatment; otherwise, nobody

1 would even be motivated to come up with it.

2 **MS. GREB:** I would agree with you, and I think
3 the words that you chose there, you know, "offers
4 potential efficacious treatment" or something that you
5 said, like, "has the potential for efficacious treatment,"
6 that's an important way of --

7 **THE COURT:** That's not going to be a limitation
8 issue. I think that's going to come up in terms of the
9 reasonable motivation of a POSA or expectation of success,
10 right? I mean, you're going to get to address that. I
11 guess I understand now why you're making this argument,
12 because I couldn't coming into the hearing.

13 **MS. GREB:** Yeah. I mean, I guess, like I said,
14 the part here is really the key on efficacy. I think
15 "intention to treat" is different. And, you know, that's
16 the definition that we, as Your Honor noted, put in the
17 chart. And sort of construing the preamble as an
18 intention to treat Type 2 diabetes, you know, while I
19 think it's totally appropriate to add, there's no efficacy
20 required by the claims, as the court did in two separate
21 Novartis cases and a BMS case that we cited in our
22 briefing.

23 It's really the intention to treat rather than
24 just treating. That's the important distinction here.
25 And I think it's supported by the intrinsic evidence, is

1 that it's intention to treat. And also imported by the
2 claims.

3 I mean, Novo has put in other patents where
4 they claim therapeutic efficacy as part of the claims.
5 That's not in the claims here. All that's in Claim 1 is
6 "A method to treat, administering semaglutide with
7 1 milligram." It doesn't say, "administering a
8 therapeutically effective amount." It just says
9 "1 milligram." And, in fact, 1 milligram is never tested
10 in the specification. They have data in their
11 specification with 0.8, 1.6, and other doses, but
12 1.0 milligrams is never tied anywhere to therapeutic
13 efficacy. It's all about intention to treat. And it
14 sounds like plaintiffs agree with that. And like you
15 mentioned, in their briefs, they actually say that.

16 So if that's sort of where we're landing, that
17 the definition is "intention to treat" without a
18 therapeutic efficacy requirement, I think we would agree
19 with that. We already -- I mean, as you mentioned, we
20 already did.

21 **THE COURT:** Right. Goes back to why I don't
22 understand why I am having to resolve this.

23 **MS. GREB:** I think the issue is, is that, you
24 know, the parties' meet-and-confer following the briefing
25 had slightly different definitions.

1 **THE COURT:** "Slightly" is the word, right?

2 **MS. GREB:** I think the two key differences
3 between the two proposals following the meet-and-confer is
4 the "intention to treat" that is in the --

5 **THE COURT:** Hold up. The "intention to treat,"
6 how is that any different than the claimed
7 administration -- how is that any different from, quote,
8 "For the care or management of a patient with Type 2
9 diabetes"?

10 **MS. GREB:** I think it's less -- I think the
11 "care and management" is less clear because it sort of
12 gives -- it sort of leaves to question how many patients
13 is it going to work for? How efficacious does it have to
14 be?

15 **THE COURT:** Would you agree with just
16 "intention to treat"?

17 **MR. OELKE:** Purpose, Your Honor. That's the
18 language from the specification, "for the purpose of."

19 **THE COURT:** Okay. Intent. Purpose. I mean,
20 this is part of the reason why I don't understand the
21 Federal Circuit case law, right?

22 I mean, because if it defines the meaning, then
23 it's limiting, but if it's only for the purpose, it's not.
24 I mean, they are just all over. How is meaning different
25 from purpose?

1 Good luck. I can't. I don't think Aristotle
2 could distinguish between meaning and purpose. But the
3 point is that -- which one do you want?

4 **MR. OELKE:** It's from the specification, Your
5 Honor, "for the purpose of combating Type 2 diabetes."
6 That's the language.

7 **THE COURT:** And you want "intended to combat."
8 Is that right?

9 **MS. GREB:** Yeah. I mean, and I would just say,
10 you know, I don't think that the specification has a
11 specific example. I know there's a specific definition.
12 I know they say, "as used herein." But all of the parts
13 in the specification where they talk about this, the
14 definition is in one embodiment. And so each of the times
15 they talk about treating, it's talking about different
16 embodiments.

17 But that being said, yeah, I do think that the
18 intention as part of the construction is a key component
19 because that's what the claim is really about. It's not a
20 claim to therapeutic efficacy. It's a claim -- if we're
21 in a world where it's a limitation, the claim is about an
22 intention to treat. It's not about a specific level of
23 therapeutic efficacy.

24 **THE COURT:** I think everybody's agreed.

25 **MS. GREB:** Okay.

1 **THE COURT:** I mean, I don't know why you're so
2 worried about "intent" and you're insistent upon "for the
3 purpose" because they'll give you that it's got to be
4 intended. What's the difference between "I intend to do
5 it" and "I did it for the purpose of," how are they
6 different?

7 **MR. OELKE:** It's just the language from the
8 spec, Your Honor, the language from the cases. That's
9 all.

10 **THE COURT:** So why can't you live with "it's
11 intended"?

12 **MR. OELKE:** We're fine with intent.

13 **THE COURT:** I'm not kidding. I'm just trying
14 to understand.

15 **MR. OELKE:** If you're not going to find a
16 difference, you're going to be the fact finder anyway, so
17 that's fine. "Intent" is okay. I'm trying to follow the
18 language from the specification and language of the cases.
19 That's all. I don't see with why they aren't okay with
20 purpose.

21 **THE COURT:** All right. Look, frankly, I don't
22 get it at all. I also don't understand why, if you make a
23 patent and you have a preamble that says you're doing
24 something for a purpose of, it should be limited.

25 **MR. OELKE:** It is limited.

1 **THE COURT:** And if you do it, if the patent
2 said something was administered with the intent to do
3 something, that should be limiting too.

4 Hold on.

5 Well, why don't we compromise and we'll say --
6 I'll say it is limiting, and that it requires that "the
7 method be employed" for the purpose of and with the intent
8 to -- or "for the purpose of treating and with the intent
9 to treat Type 2 diabetes."

10 You good with that?

11 **MR. OELKE:** Fine with that, Your Honor.

12 **MS. GREB:** Your Honor, I query the "and" part.
13 I think my concern is just that I don't understand why
14 they're insisting on including the word "purpose."

15 **THE COURT:** Well, I don't understand why you're
16 insisting on including the word "intent."

17 **MS. GREB:** Well, I think intent is really the
18 key component here, and I think --

19 **THE COURT:** And so I just asked you, what's the
20 difference between intending to do something and doing
21 something for the purpose of something?

22 **MS. GREB:** If Your Honor thinks they're the
23 same, you know.

24 **THE COURT:** If you can answer, go ahead.

25 **MS. GREB:** Well, I think that, you know, and

1 with all respect to Mr. Oelke, I think that they're trying
2 to take, maybe, "purpose" to mean something more than
3 intent in terms of therapeutic efficacy.

4 **THE COURT:** What do you think it is?

5 **MS. GREB:** I'm happy to say that there's no
6 difference, and they're identical synonyms, and that
7 "intent" and "purpose," you know, for the sake of this
8 construction, would be the same if that's what the Court
9 thinks is accurate.

10 **THE COURT:** I don't think either counsel have
11 been able to distinguish a difference between doing
12 something for a purpose of or with the intent to. And for
13 good reason, I don't think there is a difference.

14 **MR. OELKE:** Your Honor, "purpose of" is from
15 the spec, that's the reason I wanted to use it. I don't
16 think "intent" is in the spec.

17 **THE COURT:** All right. Okay. And this is -- I
18 just want to give counsel both, that you've already said
19 you cannot distinguish the difference between "intent to"
20 and "for purpose of," right?

21 **MS. GREB:** Well, I am happy to accept that
22 they're the same.

23 **THE COURT:** That's not what I'm asking. It's
24 pretty straightforward. Can you distinguish the
25 difference between "for the purpose of" and "intent to"?

1 **MS. GREB:** I think "for the purpose of" and
2 "intent to" are synonymous, but my concern is when it gets
3 to the invalidity phase of this case, that there will
4 suddenly be a difference according to plaintiffs.

5 **THE COURT:** Fair. But you can't distinguish a
6 difference?

7 **MS. GREB:** I think that's fair.

8 **THE COURT:** Can you distinguish the difference
9 between "for the purpose of" and "intent to"?

10 **MR. OELKE:** No, but I think "for the purpose
11 of" is in the specification, so that's the language that
12 should control. That's all.

13 **THE COURT:** But I'm asking you, can you
14 distinguish between the two?

15 **MR. OELKE:** Not as I stand here today, Your
16 Honor.

17 **THE COURT:** Okay. Don't try to distinguish
18 them one day if you're in front of the Federal Circuit.
19 This was your opportunity to distinguish them, and you
20 have not been able to.

21 I'll give you one more chance. Would you like
22 to try to distinguish them?

23 **MR. OELKE:** No, Your Honor.

24 **THE COURT:** Okay.

25 And you need to remember this exchange.

1 **MS. GREB:** Yes, Your Honor. Certainly will.

2 **THE COURT:** And then you need to remember the
3 exchange when she couldn't distinguish them. All right.

4 I think the claim is limiting, and you've both
5 agreed that it's limiting. I think this has effectively
6 been stipulated to. And the only difference that the
7 parties have right now is whether to use the words "intent
8 to" or "for purpose of."

9 And so what I'm going to do is I'm going to
10 construe it as limiting, and I'm going to say that it --
11 or find that "The preamble means that the claimed
12 administration is for the purpose of care and management
13 of a patient with Type 2 diabetes" or "The claimed
14 administration is intended to care for and manage a
15 patient with Type 2 diabetes." All right.

16 This is one where I just wonder, you know, what
17 happens. Are these mine fields being laid for the Federal
18 Circuit. I just, I really don't get it.

19 **MS. GREB:** I understand. Thank you, Your
20 Honor.

21 **THE COURT:** All right. Anything else I need to
22 address?

23 **MR. OELKE:** Nothing from plaintiffs, Your
24 Honor.

25 **THE COURT:** All right. You want to talk about

1 timing in this? Where do things stand, I mean, in terms
2 of discovery?

3 **MR. OELKE:** We're just, we're starting fact
4 discovery, fact depositions start up in, like, September.

5 **THE COURT:** Okay. Where are you all from? I
6 forget. Where are you from?

7 **MR. OELKE:** New York, Your Honor. But I live
8 in New Jersey, as I told you before.

9 **THE COURT:** Yeah, I do kind of remember that.

10 **MS. GREB:** We're from all over. I'm from
11 Wisconsin.

12 **THE COURT:** Okay. What do you think about when
13 you want to have this hearing and follow up on the three
14 terms that are out there?

15 **MR. OELKE:** We can confer later, Your Honor,
16 and get back to you with a joint proposal?

17 **THE COURT:** Yeah, that's fine. Sound good?

18 **MS. GREB:** Yeah. I don't want to speak on
19 behalf of everybody, but I think conferring and getting
20 back will be fine.

21 **THE COURT:** I mean, we could also just save it
22 for the trial. I don't know.

23 **MR. OELKE:** I think that makes sense, Your
24 Honor.

25 **MR. BURG:** Would Your Honor be amenable to

1 providing some additional time at trial to address this?
2 Was that the thinking?

3 **THE COURT:** I don't know; I was thinking out
4 loud.

5 **MR. OELKE:** I don't think we need additional
6 time. I think it would just be part of the expert
7 testimony.

8 **THE COURT:** The only downside to not doing it
9 upfront is your experts have to prepare for both theories.

10 **MR. OELKE:** Right.

11 **THE COURT:** And in the normal, a normal patent
12 case, I would take the view to do that.

13 The only reason I hesitate here is because you
14 all have been so good about not abusing Court process, you
15 know, that I'd entertain it.

16 The arguments were very good today and the
17 briefs were good. That makes me think, well, maybe it
18 would be beneficial to have that hearing earlier. But I'm
19 not really -- I don't feel strongly about either way.

20 How much of a burden is it really on the
21 experts to do both ways?

22 **MR. BURG:** What we maybe do is go back to what
23 you originally suggested, Your Honor, or maybe Mr. Oelke
24 suggested, if we could all confer and confer with our
25 respective clients and then propose something for Your

1 Honor.

2 **THE COURT:** Yeah, that makes sense. You said
3 the trial is way off. When is the trial?

4 **MR. OELKE:** September of next year.

5 **THE COURT:** Of next year?

6 **MR. OELKE:** Yes.

7 **THE COURT:** And when is the launch or the
8 30-month stay?

9 **MR. OELKE:** June of the following year.

10 **THE COURT:** June. Okay. That's good.

11 Okay. And how many defendants are there?

12 **MR. OELKE:** Six, Your Honor.

13 **THE COURT:** Six. Okay. Well, great. Thank
14 you very much. We're adjourned.

15 Oh, actually wait. Plaintiffs, Mr. Egan, you
16 take the lead on -- even though I'm postponing
17 construction of the first three terms, I'm going to, for
18 administrative purposes, grant the motions that are
19 pending to construe claim constructions.

20 And I'd like the plaintiffs to spearhead with
21 the defendants getting me a signed order that says, "for
22 the reasons stated today, I adopt the following
23 constructions," and that we leave the other three open to
24 some proposal by the parties.

25 Okay. Thanks a lot.

(The proceedings concluded at 11:49 p.m.)

CERTIFICATE OF COURT REPORTER

I hereby certify that the foregoing is a true and accurate transcript from my stenographic notes in the proceeding.

/s/ Bonnie R. Archer
Bonnie R. Archer
Official Court Reporter
U.S. District Court

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