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Speaker 1 (00:00):

Case for argument today is 2018-2220, Nevro versus Boston Scientific. Ms. Maynard, please proceed.

Deanne Maynard (00:10):

Good morning and may it please the Court, Deanne Maynard for Nevro. I'd like to reserve five minutes. The district court misapplied the law to three sets of plain terms in holding Nevro's system and device claims invalid as indefinite. I'd like to start with the system claims reciting the paresthesia-free limitations. The district court held that the—this limitation has a clear meaning. [**inaudible**] does not produce sensation, usually described as tingling, pins and needles, or numbness, and the patents teach the signal characteristics for providing that paresthesia-free therapy and for providing traditional paresthesia-based therapy. So at appendix 99 in column five, starting at line six, there's an entire section of the patent called representative therapy parameters. And it discusses a study that Nevro did, first providing patients with their traditional paresthesia-base therapy. And it describes the signal parameters and characteristics used in that.

Deanne Maynard (01:21):

And that starts at line 34 in column six, and it has a paragraph about the signal characteristics. And then it goes on to say, after that portion of the study, it describes the paresthesia-free therapy that was provided an entire study population of patients and the signal characteristics that were used to do that. And in column nine, it shows that the patients preferred—a hundred percent of patients preferred the paresthesia-free therapy. So the intrinsic record teaches a person of skill in the art, both how to get the paresthesia-free therapy, and what's not paresthesia-free therapy.

Judge Taranto (02:02):

What can I—can I just ask you on the method claim, for example, your position is that you run through the method, patient doesn't tingle, then you know you've practiced it. None of which depends on any advanced knowledge of the—I guess everybody calls them parameters, but the frequency pulse, width, and current. Why, with respect to the system claim, does one need to know anything advance—in advance about what signals do this, as long as you test the system, and sometimes it produces non-tingling therapy? So, it's a system for doing that.

Deanne Maynard (02:46):

That's our position is that that's right. As the system claims, a system—the system claims a signal generator that produces this paresthesia-free therapy. And as long as it does so, then it is an infringing system, and that's where the district court went awry because it thought that if at times a system perhaps would not provide the paresthesia-free therapy, then it wouldn't be infringing, but that's not the way one measures system claims. And I would take issue, there—I don't want to tread into their cross-appeal on my opening, but we do think that although we agree the district court knew that there

is lots of guidance in these patents that so a person will know in advance, both when they're practicing the methods and when they're designing the systems, exactly what they need to do and what kind of system it is. And the extrinsic record confirms that. Never did an FDA-monitored study in which 100% of the patients in the paresthesia-free therapy arm received paresthesia-free therapy. And the study was premised on the notion that one arm of the study received the paresthesia-free therapy, and another arm did not.

Judge Taranto (03:55):

Okay. Can I, since time is short, can I ask you to talk about the configured to—

Deanne Maynard (03:59):

Yes, Your Honor. Of course.

Judge Taranto (04:04):

—generate a therapy signal, which I find the most challenging of all the issues. First of all, at a more doctrinal level without before into the specifics, what in your view is the relationship between the difficulty of deciding between two possible claim constructions and the indefiniteness standard of Novelis?

Deanne Maynard (04:29):

So, the Supreme Court rejected the view that as long as there were two reasonable readings, the claim was indefinite and said, instead, the question is whether or not a person, as you know, a person who's skilled in the art—

Judge Taranto (04:41):

Right. But this is to some extent the reverse. As I read the district court opinion, or let's assume I read the district court opinion to say, I find basically that this claim construction question is so perfectly evenly balanced that I can't find a reason to think that one construction is better than the other. Why is that not a basis for concluding indefiniteness?

Deanne Maynard (05:07):

Well, here it's not because I would like to [**inaudible**] the premise. But this court—where this court has found indefiniteness where that's the situation and very different facts than this., like in Teva, where there's a measured quantity and the patents and prosecution history in terms of Gregor give no guidance—in fact, in Teva, conflicting guidance on the exact same indefinite question. There's nothing like that here, Judge Taranto. Here, in fact, the district court's discussion of the term that's an issue, which is signal generator configured to generate or deliver. When he was discussing that term, he recognized that the record pointed only in one direction, and that was in the direction that it needs designed to. And that is the ordinary meaning as this court has recognized, of configured to, so where the judge concluded there was conflicting—

Judge Chen (05:55):

I thought the district court found evidence in his view, going both ways. And that's why he found it indefinite. He didn't only cite to evidence that supported your preferred construction of configured to.

Deanne Maynard (06:09):

But my point, Judge Chen, is when he was pointing to the other evidence that he thought pointed away from our construction, he was looking at different terms in different kinds of claims, like method claims, and not looking at the term that's at issue: signal generator configured to generate or deliver. And especially in a word like "configured" or "configured to," which takes its meaning, it's a connector where it takes meaning from the words surrounding it, the context is key.

Judge Chen (06:41):

And so, I guess following up on Judge Taranto's doctrinal question, I guess you agree then, or your understanding of the law is, if there are two equally strong understandings of a claim term, two competing understandings that are on balance equal, then therefore the claim term is indefinite.

Deanne Maynard (07:02):

I don't think this court has held that the—

Judge Chen (07:07):

I thought you were suggesting Teva was something like that.

Deanne Maynard (07:09):

I think Teva is stronger than what you just articulated, Judge Chen. I think, in Teva, there were conflicting prosecution history answers. There were three possible measurements. Everybody agreed. The range depended on which measurement was chosen. The claim scope would turn on which measurement was chosen.

Judge Chen (07:24):

The prosecution history did something like this.

Deanne Maynard (07:26):

There were two indefiniteness rejections, the same indefiniteness rejection. And at one point the patent dabble camp answered molecular MW and at one point NP, so that was conflicting. That's a direct, conflicting irreconcilable answers in a [**inaudible**]. They are needed to know what that claim turned meant to measure the range quantities. That's nothing like this case here. Every time the patent uses the word "signal generator configured to deliver," it's talking about the kinds of parameters, the signal parameters that need to be available to the user to select, to program, when using the device.

Judge Chen (08:08):

Your brief said something about how configured to in this instance means designed to, and I'm still wondering what does that mean exactly. What is it that the inventors here have done to a signal generator that configures it to generate a paresthesia-free therapist signal, in your understanding of configured to meaning designed to?

Deanne Maynard (08:43):

So, just to be clear, this court has said that it has equated configured to, with designed to, in at least three cases: Aspects, Man Missions Interface, and Gianelli.

Judge Chen (08:51):

Right. And that, to me, is actually a different problem for you, but let's get to my question first and then we'll get to the—what you just triggered me will be the follow-up question.

Deanne Maynard (09:04):

What the patent teaches and what the patents claim with signal generator is one that's configured to generate. So making the certain signals available to the user to select in the product as finished, but not what BSC would like, which is that the actual parameters are already chosen.

Judge Chen (09:25):

Let me—I just want to understand what is it that the inventors here from Nevro did to configure the signal generator? I assume we're just talking about a pretty standard signal generator. And now the claim says, "Let's configure that signal generator to generate a paresthesia-free therapy signal." So what is that action that the inventors have undertaken to accomplish the configuration?

Deanne Maynard (10:00):

They've created a signal generator that allows the user to select the parameters of signals described in the claims—

Judge Chen (10:08):

And when you say they created, what is it specifically that they created?

Deanne Maynard (10:15):

They implemented the ability to choose those signals on a signal generator. And it—the evidence shows it took BSE months and months to take their signal generator and change it into the signal generator that would produce the claimed device. And that's what configured to means in this context.

Judge Chen (10:39):

I guess the other side is saying that your understanding of signal generator configured to really at bottom is nothing more than a prior art signal generator. And then the prior art signal generator ultimately is programmed, i.e., parameters are selected—amplitude, pulse, width, all of that. But that programming stuff, of course, is not what you think configured to means. And so I'm just trying to understand to what degree is the other side correct that at bottom, your understanding of signal generator is a ready-made prior art signal generator that can then be programmed later on.

Deanne Maynard (11:26):

Well, so I think there's a spectrum, right? And at times they want for prior art purposes to say that what we're claiming is just a signal generator that could—whose hardware, software, and firmware could potentially be changed completely to make it into the claimed invention. And on the other end, they want to say, "and the users already selected the signal parameters for the signal." But what we're saying is "no, it's a device that allows the user to select—to make the selection at the end, and the device, as finished, where a user can't modify the hardware, software, or firmware, but it's provided to the user in such a way that they can practice the claimed parameters."

Judge Taranto (12:06):

Would it be a fair summary to say that its, again, generator configured to generate the desired signals, if with merely a selection by a user among presented choices, it will do so when powered on?

Deanne Maynard (12:19):

Well, it could.

Judge Taranto (12:20):

So it builds in the idea of presenting the user, the surgeon, or the attendant or whoever—

Deanne Maynard (12:28):

Often the company [**inaudible**]

Judge Taranto (12:29):

What's that?

Deanne Maynard: (12:30):

It's all [**inaudible**]

Judge Taranto (12:31):

Right, right. Let's call it a menu of options. I don't mean a specific menu. It could be two knobs or something, but that the only thing that stands between the generation of having the device in there and the generation of the signal is turning the power on and punching in, or selecting the three, say, parameters that are discussed in these briefs.

Deanne Maynard (13:00):

So, you know, assuming—right. They allow—it's like programming a VCR. It comes and you can select the parameters that are allowed. And it is different from the prior art, it took months and months and months to develop.

Judge Taranto (13:15):

But does the patent actually describe doing things to the signal generator to make it ready for user input choice?

Deanne Maynard (13:26):

It talks about the parameters that need to be available to perform. That's the representative therapy parameters that I was discussing earlier.

Judge Taranto (13:37):

There's material down at the bottom of column three, top of four, that talk about setting the thing up before the inputting of the parameter values.

Deanne Maynard (13:47):

And then it talks about the user selecting, like lower down in column four, Judge Taranto, like starting at line 40, where it talks about the practitioner can use the external program or to vary the modulation parameters provided to the signal delivery elements. So in other words, put input different, right? And set up for them to input the parameter.

Judge Chen (14:02):

But just to follow up, I'm just curious. Is there any other action that is a precursor to the programming, whether it's an external programmer or a physician programmer or a patient programmer? Is there some other precursor pack or step that this patent discloses that might be understood as something where the inventors are configuring the signal generator?

Deanne Maynard (14:33):

Yes, because they're making—they're configured to. So it's a past tense—and we are taking into account the past tense—as provided, as made, the signal generator allows a user to select these particular parameters. And we know it's not, Judge Chen, what BSE wants it to mean, which we already programmed because there's an independent and a dependent claim that where the only added limitation is programming the signal generator. And that makes clear that they're not the same. But the 842 patent claims, that's what you're talking about yesterday

Judge Taranto (15:09):

I wasn't quite sure. I wasn't quite sure about that because 21 has an "and" in it, right. It's also configured to do two things. The second thing is the and delivered the signal, which it seems to me is not necessarily already incorporated and in claim 18 so that—I'm not sure you need this argument. It seems to me, you may have overstated the stuck point that there is no difference between that defendant claim and its independent claim, except for the punching in of the values.

Deanne Maynard (15:46):

Well, I take your point about the "and," but I still think the point stands that the signal generator in claim 18 is not already programmed.

Judge Taranto (15:53):

Okay. Can I ask you just a practical question? I was just trying to think. Maybe you can answer this or not, but the difference between these two positions on the configure two seems to me to be whether an accused infringer, the device manufacturer, is by selling the device directly infringing or, by making the device, is then and there directly infringing. And, or on the other hand, the company representative in the operating room is the one completing the device. Why, as a practical real-world matter, should that make a difference to you as patent owner? Assuming instructions to do it, so that why is an inducement case not pretty easy?

Deanne Maynard (16:39):

Well, and I think actually it's actually direct infringement by the company representative who's finishing the device.

Judge Taranto (16:40):

Right. It's the same person.

Deane Maynard (16:41):

Yes, I agree with you. We will have an infringement case either way. We think the correct construction is ours, but we will have an infringement case either way, because if, in their theory, the company representative is completing sort of a tailor-made device at the bedside.

Judge 3 (17:07):

I was just wondering along those same lines, is it possibly too late for you to make those inducement-related claims?

Deanne Maynard (17:14):

Well, we've made inducement claims.

Judge 3 (17:18):

If we were to deviate on the claim construction and include programed, you haven't made a claim. Have you—did you make an inducement claim?

Deanne Maynard (17:30):

We made—we included inducement claims in our complaint. The court held configured to make these patent claims indefinite. So they didn't reach infringement device claims at all. I've already run out of my time.

Judge (17:44):

Well, we'll restore some of your rebuttal time. Okay. Mr. Wolf.

Matthew Wolf (17:53):

Thank you, Your Honor. May it please the Court, Matt Wolf for Boston Scientific. Judge Taranto, if I may begin with your question about paresthesia free. I recognize a lot of the discussion was about configured to, but I don't want to lose the heart of the paresthesia-free argument. Nevro told the patent office to, and this is at A-12574, that the high-frequency step stimulation such as claimed by applicant may or may not cause paresthesia. I accept your question, Your Honor, as a possible construction of paresthesia, but Nevro specifically rejected that construction: the capability, the possibility of a paresthesia-free treatment. They specifically pushed back against that, understanding at the patent office to get the patent in the first place. So for example, we have Mr. Thacker, who was an employee of Boston Scientific and then left for Nevro—

Judge 3 (18:49):

What page of the appendix did you say that was in?

Matthew Wolf (18:51):

A-12574.

Judge 3 (18:52):

Do you know what volume that is?

Matthew Wolf: (18:53):

It's a one paragraph summary—invention summary. I can pull it out right here, Your Honor. So if you look maybe six lines down, Your Honor.

Judge Taranto: (19:15):

In the underlined material?

Matthew Wolf: (19:17):

Yes, Your Honor. 1, 2, 3, 4, 5, 6: applicant further argued that high-frequency stimulation, such as claimed by applicant, may or may not cause paresthesia and thus it would not be inherent that high-frequency stimulation would necessarily achieve pain relief.

Judge 3 (19:40):

I guess I don't see how that contradicts the capable of argument.

Judge Chen (19:46):

And my understanding was that the whole point of this is that high frequency alone doesn't necessarily get you paresthesia free. It's also the amplitude.

Matthew Wolf (19:53):

That's absolutely—

Judge Chen (19:55):

And pulse width modulation. So I don't see what you get out of this sentence.

Matthew Wolf (20:03):

The point, Your Honor—and I apologize, I wasn't being clear—is, and this—at A7811, this is admitted. Nevro acknowledged that—

Judge Taranto (20:06):

Are—pardon me. Are you taking us somewhere else?

Matthew Wolf (20:07):

It's the same concept. It's the same notion.

Judge 3: (20:08):

Where do you want me go now?

Matthew Wolf (20:10):

I'll just stick with what we have, just so we don't jump around. The prior art, including our devices, Boston scientific devices, was capable of providing paresthesia-free treatment was that sometimes it did, and sometimes it didn't. And this was presented as a ground for rejecting the claims, and Nevro said no, because it sometimes does. And sometimes doesn't, it doesn't anticipate. But they then didn't complete the sentence. They didn't didn't—they then didn't say, and here's the secret sauce. Here's the magic formula. Here's the combination of parameters that will always, almost always typically—pick whatever adjective you want—create paresthesia. So that's why I don't want to give up on this paresthesia-free argument, Your Honor. It's that this was critical to patentability. The notion that the prior art devices that had precisely the same technical capabilities. That because they didn't always create, they didn't inherently create—sometimes they did, sometimes they didn't—create paresthesia therefore—

Judge Chen (21:22):

Does it discuss specification here? Talk about, want the frequency to be within this range. We think the amplitude should be in this other range, you can have different kinds of duty cycles. There's some guidance in details in the specification that get you to where they want you to get to. Isn't that true?

Matthew Wolf (21:38):

Respectfully, no, Your Honor. The passages that counsel was pointing to primarily, we're talking—and their charts and tables and diagrams—those are all about whether the device created alleviates pain. The statistics, the numbers are all about whether or not it alleviates the pain. The paresthesia point here is one paragraph at the end of that chain that says, and lots of people felt paresthesia free. They didn't tell us at what number—what kilohertz, at what amplitude—at what number you're likely to trigger the threshold. We have—again, this is Mr. Mr. Thacker. This is at A12017. Specific details of the sensations vary patient to patient. Patients can feel paresthesia at frequencies above 2,500 Hertz. And of course the typical range of the patent is one and a half and above. So they're telling the patent office doing a bit of a soft shoe, just because the prior art devices could provide this, these parameters, unless you show that they actually did it.

Matthew Wolf (122:45):

They actually provided paresthesia free treatment routinely. They're not invalidating, but then they don't tell us in the patent of what the—as I said, the secret sauce is, what the algorithm is. So that's why Your Honor, Taranto, I wanted to push back a little bit. Cause I think this is an unimportant point. Most of the claims are structured. Here are frequencies or amplitudes, depending on the complexity of the claim, none of that's new. We have their own expert admitting at A8666 that Nevro didn't invent neurostimulation, SES, a new lead, or even an IPG. The asserted claims rely on known hardware components. So all the numbers in the claims are from known hardware components. What it supposedly knew is paresthesia free. Well then tell us with at least rough numbers, what gets us to paresthesia free. And what His Honor found below and what's subject to clear error review is that you

can't do that. It's patient by patient, just like Halliburton, just like Geneva. So with that, unless you have other questions, I'll turn to the configured.

Judge Chen (23:58):

In Geneva, this court said effective amount of the composition is, although sometimes you're not going to know until after you do the treatment, that's a classic way of writing claims and we don't worry about that. And on the definiteness of report.

Matthew Wolf (24:17):

That's a hundred percent correct, Your Honor. What we have here is an anti-effective amount claim, which Geneva said unambiguously is, "We're going to allow a certain level of experimentation." It almost kind of bleeds into an enablement analysis. It uses the phrase, "undue experimentation." If we can figure out what the parameters are, what the claim scope is without undue experimentation, we'll let you keep the claim. But here we have Nevro telling the patent office for a very important reason, time and time again, we can't tell you what that is, before the fact or after the fact. This isn't a situation where we're coming in here and we say, "Well, you have to perform this procedure on five patients to figure out what the proper dosing is, what the proper signal parameters are." What they said over and over again to the patent office and what Judge Shabrea found, and again, it's subject to a clear error review is you can get as much information as you want patient to patient to patient. It doesn't tell you as to the next in line, are you going to get paresthesia free or are you not going to get paresthesia free? So when—

Judge Taranto (25:19):

So can I ask a question? Why does that matter?

Matthew Wolf (25:22):

Because that's exactly what—

Judge Taranto (25:24):

And I guess I'm thinking particularly of the method names. I mean, I would have thought that there have been a fair number of patents over the time—over time, say here are some sort of objective conditions. And then they say, "wherein" and they state an effect. Why, in your view, with those wherein clauses about effects have any meaning at all? Because either it always has that effect or it would be invalid.

Matthew Wolf (25:54):

Your Honor, you're absolutely right. I could imagine method claims written to these concepts that would not fail the indefiniteness required. At the end of the day, we think they're all invalid under one and two, but putting that aside. But the method claims here are not really traditional method claims. I mean, if we look at claim one of the 102, it has three things: it has a signal deal lead, it provides the treatment at 1.5 to 50K, and, quote, "does not create paresthesia," end quote. That's the entirety of the method claim. So I want to use those parameters because my prior art device can provide 1.5K to 50K, but I don't want to do paresthesia. I don't want to infringe. From patient to patient to patient—

Judge Taranto (26:36):

Right? So you can't know in advance for sure. On why—what is it about—maybe I'll ask it this way. I gather that pre Nautilus, we had a number of cases that said "you don't have to know in advance." Do you think Nautilus changed that?

Matthew Wolf (26:52):

It did. And at the, at least at the broadest level, and we argue this in a brief [**inaudible**], it did. There's still—the Nautilus notion of avoiding the trap of uncertainty, avoiding—you don't—effectively what they've done by writing these method claims is monopolized, not just paresthesia-free treatments, but paresthesia treatment. So if I want to—to have a treat with paresthesia, cause I have a patient that prefers a numbing to that weird kind of nothing feeling, I can't perform the method at the risk of being paresthesia free.

Judge 3 (27:25):

Just to be clear, it was called a weird kind of nothing feeling. Let me understand the technology. You can have tingling and pins and needles, or you can have nothing. And you think the weird one is the nothing?

Matthew Wolf (27:35):

There are patients that if you've lived your whole life with back pain, and then this—there are patients that prefer paresthesia to non-paresthesia that's—the studies have shown. And there are certainly patients that presented with the option of lower frequency and paresthesia and thus far less frequent battery recharging that the studies have shown—this is in our brief—that this—that the patients—many patients prefer that.

Judge 3 (27:56):

Can I ask you to move on to Figure 2 please?

Matthew Wolf: (27:59):

Yes, Your Honor. Yes, your honor. Yes. And here this very discussion that we're having was had in the prosecution of this family of patents.

Judge Chen (28:10):

I'm configured to this dovetails back. I'm sorry to paresthesia free. Yes. If we were to construe configured to, do you mean programmed types?

Matthew Wolf (28:22):

Yes.

Judge Chen (28:24):

Then wouldn't that take care of your indefiniteness concerns about paresthesia because what will—the claims will all mean then that you've essentially customized the signal generator in such a way for a given patient to produce a paresthesia-free therapy signal outcome. And then if that's the case, then

you know you're infringing or not infringing because you've now designed and customized and altered the parameters in such a way that you are yielding a paresthesia free signals.

Matthew Wolf (29:08):

Your Honor, there are—one can envision claims where that would be the result, but these claims as written, if I am doing an iterative process with the patient, that first signal that I give them, if it is paresthesia free by blind luck, I've now infringed their patent. Even though they haven't told me that that signal is or is not likely to cause paresthesia, I know as a factual matter from their own witnesses that it may or may not cause paresthesia. I'm rolling the dice. I could set out to be use, like, in the 1.5 to two kilohertz, therefore battery saving range and say, "I don't want to even risk no paresthesia free. I'm willing to accept the tingling and exchange for the battery." If that first time I plugged that in that's paresthesia free. They've got me for infringement. So the way they've written their claims, it's just—it's a crap shoot. It's a roll of the dice.

Judge Taranto (30:01):

Well, go ahead and explain why figure two means [**inaudible**].

Matthew Wolf (30:07):

In fact we have, and this is a A12929 in the 405 application, which has this exact same spec as the 533 patent, the patent office said configure two means "at least one instance of actually programming." Actually programming. Then they go on a sentence later and use the phrase "actually configure." We see claim language like claim one of the 125 patent at 148, where it says "a step for configuring the signal generator, including programming." So the notion that programming is part of configuring is replete and the position that they're taking today—and let me be—can I take one step back? I know this isn't directly to your question. We're very concerned about this design to construction because it's meant two entirely different things. The gloss they've put on designed to, and at pages 35 to 37 of our opening brief, we have a long colloquy about this, design to blow meant some kind of subjective intent.

Judge Taranto (31:09):

Right now. Look, let's just assume that that's abandoned and abandoned without difficulty. And that it really does mean presenting—setting the thing up so that you present choices to the administer. And once those choices are made about the parameters to put—what values to set the parameters at and the power is on, it does what you say it's supposed to do.

Matthew Wolf (31:35):

In the prosecution history and the claim language, we believe the much better reading is that programming has to be part of configuring in order to be configured, e.g., you have to be programmed, e.g. And we obviously didn't do that. We didn't program in advance. Now, if you're right there, if we're playing games with our salespeople in the field, they have inducement claims and all that. But they said—

Judge Taranto (32:06):

[**inaudible**] direct infringement, if they actually were sales [**inaudible**]

Matthew Wolf (32:08):

Yes, Your Honor. But they unambiguously said to the patent office that actually configure is what this means. That at least one instance of actually programming—that's the patent office's own words, it wasn't rejected—they got the claim actually programmed.

Judge 3 (32:22):

That's not this patent, right?

Matthew Wolf (32:24):

But it's this specification, Your Honor. It's the same—it's the 533 specification, the same spec, but you're right. It's not the same patent. But clearly when you're talking about language in the same spec, I think this court has felt—I mean, it's not without exception, but certainly it was fair for us to read that same--

Judge Taranto (32:49):

I'm sorry, this is the passage in which the examiner said, "I don't like what you have. Here's my suggestion." They said, "No, we don't like that suggestion. We have an alternative, how do we make—

Matthew Wolf (33:00):

And then it was rejected again by the examiner and then they didn't push back on that. So right, there were two steps, Your Honor. But the second time the examiner said, "No, no. I need actual programming to allow this claim." They accepted that and moved it. It took the claim actually—but we don't even have to go there. Claim one of the 125, when it says a step for configuring the signal generator, including programming. That to me, Your Honor, respectfully, is unambiguous. That programming is a subset of configuring. And therefore, if you are configured, you are programmed. That's also the language of the precedent. We cited Intel. We cited Edwards and Fortnite and others. That that just makes sense. That either we're sending it to the customer as programmed or we're not. And if we're not, you know, they have other outcomes—

Judge Taranto (33:49):

This is perhaps a little bit indirect. And I'm not sure the parties cited the core wireless case? You know that case?

Matthew Wolf (33:55):

I'm familiar, but I don't recall—

Judge Taranto (33:58):

It's a case in which I think in the course [**inaudible**], maybe this has—I forget what the language was. Maybe adapted to or something in which the term was—it was explained that the term meant, among other things ,configured to, and the analogy made was to like a three gear gearshift in a car, and the car is configured to operate in gear one. It's also configured to operate in gear two and it's configured to operate in gear three. And I think the opinion says expressly, if the claim is configured to operate in gear one, it doesn't matter that it can also be operated in the other way. And it's configured that way, even before the driver pushes it into the correct place. Why is this—

Matthew Wolf (34:49):

I recognize that, Your Honor, and this is somewhat an exercise in line drawing, right? Because how—infringement kind of hovers over all of this and it's—but when we sell a device that a commercial user can't take and put at in the claimed range, and they say, and they infringed and they argue that kind of device until a month before the summary judgment hearing, when they realized they were on the, between Scylla and Charybdis of 102 and infringement, they were arguing that was infringing under their definition of design to. Where literally we had put a screen that blocked out a commercial user from going into second gear or third gear or fourth gear. So that's why we're kind of angels on the head of a pin Your Honor, and I apologize, but there's a backstory to what was accused—

Speaker Taranto (35:40):

Sometimes, you know, you actually get through [**inaudible**]

Matthew Wolf (35:46):

Yeah, I guess that's true, Your Honor. I'm well into my red light time, your honor.

Judge 3 (35:51):

Thank you, Mr. Wolf. Ms. [**inaudible**] we'll restore your rebuttal time five minutes.

Deanne Maynard (35:58):

Thank you very much, Your Honor. First, this is not blind chance. The patents describe and teach how to provide this therapy. And the extrinsic record shows that BSC did it in its own study, where hundreds of patients, where it said one arm was paresthesia free, and one arm was paresthesia based.

Judge Chen (36:20):

What are your strongest specification passages for giving a skilled artisan clear window into how to achieve a paresthesia-free signal? Paresthesia-free therapist signal.

Deanne Maynard (36:35):

So starting at column six in A-99 at line 51, the patent describes the study that Nevro did, and it gives the three to 10 kilohertz. And in particular cases, it tells you where to place the leads. It gives you the kilohertz. It tells you the amplitudes, the duty cycles, as Your Honor mentioned. And the amplitudes at the top of column 7 line one and two—

Speaker Chen (37:13):

Does this study connect to a paresthesia-free outcome?

Deanne Maynard (37:15):

Yes, Your Honor. So if you go to column nine, the patent makes clear that the patients all preferred—every one of the tested patients preferred the presently disclosed therapy to standards. So they—that implicitly suggests they receive paresthesia-free therapy. And we know they did from the extrinsic evidence, because this is the study that was—that the FTC monitored. And in that study, the report was that a hundred percent of the patients in the paresthesia-free arm received paresthesia-free therapy. So it isn't the case—

Judge 3 (37:53):

Can I get you to turn to the configured to—

Deanne Maynard (37:56):

Yes. I'd be happy to, Your Honor. So on configured to, the part of the—

Judge Taranto (38:02):

And maybe as part of that, can you address the reference? I think Mr. Wolf said your expert testified that—I forget what the phrase was—known hardware components were used [**inaudible**].

Deanne Maynard (38:17):

That the signal generators are known in the art, but that—this is the common—this is a combination. The patent is the signal generator that allows a user to select the novel therapy that's described and claimed in the patent. And that's obviously not unusual. The part that you were discussing with him, the prosecution history, Your Honor, at A12929, that, so as Your Honor noted, we expressly declined to agree to amend the signal, the term that's closest to what's at issue here. And the last sentence of this description makes clear that—so it's about the programmer. Wherein the programmer is configured to transmit effectively two signals, the examiner agreed that a programmer was so configured, even if the user didn't select both signals. So to your car hypothetical. it's like it allows first and second gear, and it would still be configured to do that even though only second gear is chosen. That's completely consistent. Is it,—it's a different claim language in different claims, but it is consistent with our argument on his claim, one on the patent 125 claim one, the—that method claim there, that configuring comma, including program that actually shows that programming and configuring are not equated, that the—

Judge Taranto (39:42):

Which one:

Deanne Maynard:

He was pointing out 125 [**inaudible**] So it's a method that talks about configuring a signal generator, comma, including programming. And that actually shows that that programming and configuring—I mean, we don't think that claim is what you should look at because it's not the same claim term. It's a method claim, not the signal generator configured to generate, but even if you look at it, it debunks the notion that configuring is equated to programming, otherwise that including step would kind of be superfluous.

Judge Taranto (40:26):

Well, but the word equated, I don't think quite captures the point. I think his point is that configured, configuring is not complete until the last step, which is programming. And that's what that language, their argument is, tends to support.

Deanne Maynard (40:46):

But if the—if configuring with—the district court thought that it showed that programming in that context was equated with configuring. And obviously if the signal generator were already—if a configured to signal generator were already programmed, including programming would be superfluous.

Speaker 1 (41:05):

Well, okay. Thank you, Ms. Maynard. We thank both counsel. This case is taken under submission.