Trials@uspto.gov
571-272-7822

Paper # 27
Entered: February 2, 2026

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AVATION MEDICAL, INC.,
Petitioner
v.
EMKINETICS, INC.,
Patent Owner.

IPR2024-01375 (Patent 11,224,742 B2)
IPR2024-01378 (Patent 9,002,477 B2)

Record of Oral Hearing
Held: January 7, 2026

Before JOHN G. NEW, BARRY L. GROSSMAN, and
SEAN P. O'HANLON, Administrative Patent Judges.

APPEARANCES:

ON BEHALF OF THE PETITIONER:

KYLE T. DEIGHAN, ESQ.
TODD TUCKER, ESQ.
of: Calfee, Halter, & Griswold LLP
The Calfee Building
1405 East Sixth Street
Cleveland, Ohio 44114
(216) 622-8200
kdeighan@calfee.com
ttucker@calfee.com

ON BEHALF OF THE PATENT OWNER:

DAVID A. GERASIMOW, ESQ.
of: The Law Offices of David A. Gerasimow, P.C.
153 W. Ohio Street
Suite 407
Chicago, Illinois 60654
(312) 919-4254
dave@gerasimowlaw.com

The above-entitled matter came on for hearing Wednesday, January 7, 2026, commencing at 9:00 a.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia.

P-R-O-C-E-E-D-I-N-G-S

(9:00 a.m.)

JUDGE NEW: Good morning, everybody, and welcome to the Board. I'm Judge New, and with me today are my colleagues Judge O'Hanlon and Judge Grossman. We're convened this morning to hear oral argument in the matter of IPR2024-01375 and IPR2024-01378, Avation Medical, Incorporated, v. EMKinetics. This hearing relates to Claims 1 to 13 of U.S. Patent Number 11,224,742 B2 in the 01375 IPR and Claims 1 to 10 of U.S. Patent Number 9,002,477 B2 in the 01378 IPR.

We'll begin by asking counsel to make their appearances, and when doing so, please spell your name for the court reporter. And we'll begin with counselor for the Petitioner, Avation Medical.

MR. DEIGHAN: Good morning, Your Honors. My name is Kyle Deighan, K-Y-L-E, D-E-I-G-H-A-N, from Calfee, Halter, & Griswold in Cleveland, Ohio, on behalf of Petitioner, Avation Medical. And with me is my colleague Todd Tucker, T-O-D-D, T-U-C-K-E-R.

JUDGE NEW: Thank you, Mr. Deighan. And counsel for Patent Owner, EMKinetics?

MR. GERASIMOW: David Gerasimow with Gerasimow Law of Chicago, Illinois. My last name is spelled G-E-R-A-S-I-M-O-W.

JUDGE NEW: Thank you, Mr. Gerasimow. Welcome, once again. Consistent with our Joint Hearing Order, each party has a total of 60 minutes for presentation in both cases. Petitioner may reserve a portion of up to 20 minutes of their time to respond to arguments presented by Patent Owner,

and Patent Owner has also been authorized to reserve a similar portion of its time for rebuttal.

I'm asking you to be mindful to the court reporter who's transcribing this hearing, and as you can see here, it's very important that, when referring to a particular demonstrative exhibit, you clearly identify it by slide number so that it will be reflected in the hearing transcript.

Please remember that this hearing is open to the public. Parties are therefore asked to refrain from disclosing any confidential information during the hearing or including any confidential information in a demonstrative exhibit.

We're in receipt of the parties' objections to and motions to exclude various evidence. However, we will reserve ruling upon the objections and the motions at this time.

And now, Counsel for Petitioner, you may proceed after indicating how much time you would like to save for rebuttal.

MR. DEIGHAN: Thank you, Your Honors. I'd like to reserve about 15 minutes for rebuttal.

JUDGE NEW: Fifteen, very good. If you'll indulge me for a moment, please, I have to set my timer here first. Okay. And you may begin when you're ready, Mr. Deighan.

MR. DEIGHAN: Thank you, Your Honors, and may it please the Board, again, my name is Kyle Deighan, on behalf of the Petitioner, Avation Medical. It's a pleasure to be back before Your Honors here today. As Judges O'Hanlon and Judge Grossman may recall, we were here about a month ago for a PGR proceeding involving a patent that is related to the '742

and '477 Patents that are at issue here today. And like that PGR proceeding, these IPRs are fairly straightforward.

In the 1378 IPR, there are no substantive disputes. The Patent Owner has not challenged Petitioner's invalidity grounds substantively. And so there's no dispute here that the prior art teaches all the claim limitations. And there's no dispute that the art renders the claims obvious. The only disputed issue in that proceeding is purely procedural, and it relates to whether -- it relates to the prior art status of Svihra, which is Exhibit 1004, and Amarenco, 1005.

JUDGE NEW: That's quite correct, Mr. Deighan. There appears to be no substantial dispute between the parties here. However, I will remind you that the burden of demonstrating obviousness or anticipation -- still remains with Petitioner at all times.

MR. DEIGHAN: Yes, absolutely, Your Honor. You're absolutely right. But as we'll see, we have provided sufficient evidence of public accessibility of these references, and our Petition sets forth sufficient grounds and evidence to show that the claims would have been invalid.

So in the 1375 IPR, the disputes here are also very limited. The Patent Owner raises the same procedural issue with respect to Svihra, Amarenco, and Ponsford, which is Exhibit 1085. The only other issue in that proceeding is a limited substantive dispute that really relates to two claims.

So I'll move to Slide 3. So across these IPRs, there's really only two main issues that are in dispute. Again, the procedural issue and the question there is whether the references are publicly accessible printed publications.

This is the same issue that was raised in the PGR proceeding. And we believe that they came up short in the PGR, and they come up short again here, because the references are publicly accessible printed publications, as we'll talk about. They have all the hallmarks. They have established publishers, and the corroborating evidence confirms the public accessibility of those references. And, again, that's the only disputed issue, really, in the 1375 IPR.

And so if the Board finds that either Svihra or Amarenco is a printed publication, then all the claims of the '477 Patent can be found invalid.

And then the second issue, the substantive issue which is specific to the 1375 proceeding is -- the question there is whether the prior art teaches directly stimulating, directly targeting and stimulating posterior tibial nerve branches, and if the art would motivate a person of ordinary skill in the art to modify the teachings of Svihra and Amarenco. Without issue, it does, as we'll talk about.

The Petition cites a variety of references, and we'll go through those, but those collectively teach or suggest, number one, that treating overactive bladder and incontinence by electrically stimulating the nerves emanating from the sacral nerve roots, and that explicitly includes the posterior tibial nerve and branches of the posterior tibial nerve; two, electrical stimulation of the posterior tibial nerve or the posterior tibial nerve branches can be used to treat conditions with the same efficacy; number three, electrically stimulating posterior tibial nerve branches causes signals to travel upstream through the posterior tibial nerve itself and to the sacral nerve roots in the

spine; and then, four, the art teaches how, precisely how to directly target and stimulate posterior tibial nerve branches.

And so based on these teachings, and as supported by Petitioner's expert, a person of ordinary skill in the art would have been motivated to modify Svihra and Amarenco to directly target and stimulate posterior tibial nerve branches, and would have had a reasonable expectation of success in doing so.

So I'll start now on Slide 4 here with the printed publication issue. And there's a lot of overlap here with the PGR, so I won't belabor this too much, but I would like to highlight just a few things.

So obviously here, the touchstone is public accessibility. If a reference is publicly accessible, it's prior art. In the Board's precedential Hulu decision, the Board makes clear that public accessibility is a totality of the evidence test, and that includes indicia on the face of the reference. And that decision is Hulu v. Sound View Innovations, IPR2018-1039, Paper 29. And here, Svihra, Amarenco, Ponsford, they have all the hallmarks of a printed publication.

Additionally, the Federal Circuit has held that if there is an established publisher, there is a presumption of public accessibility as of the publication date. And that comes from the VidStream case, VidStream v. Twitter, 981 F.3d 1060, at 1065 to 66.

And so here, Svihra was published in the Bratislava Medical Journal. It's been around since 2019 -- excuse me -- 1919; the Journal of Urology for Amarenco; the Journal of Neurology, Neurosurgery and Psychiatry for Ponsford. And so the established publisher provides a presumption, but I

think that if the Board looks at the totality of the evidence here, and as shown in our papers, it shows that the journal articles bear all the hallmarks of publicly accessible printed publications.

One more issue that I would like to kind of clear up here is the notion that a -- absent a well-established publisher, that consideration of hallmarks is inappropriate. Patent Owner makes this argument in its papers here, for example, in the surreply in the 1375 IPR, Paper 17 at 8. And Patent Owner cites to VidStream for this proposition. VidStream never mentions hallmarks, let alone says that you should only consider hallmarks if there is an established publisher.

This idea also would contradict the Board's precedential Hulu decision, which never mentions the established publisher presumption but, again, says explicitly that the Board should look to the totality of the evidence to determine public accessibility, and, again, that includes indicia on the face of the reference. And so in other words, if there is an established publisher, you have a presumption, but even if not, the Board should still look to the hallmarks of these references.

So I'll turn to Slide 5 and address the Svihra reference, which is Exhibit 1004. And, again, we went through this during the PGR proceeding, but I'll just highlight a few things. There's --

JUDGE GROSSMAN: Mr. Deighan, just, I think, to make clear, we, at least two of us were here, of the judges, were here for the PGR, but that you still need to establish a record in this case. Just because you said it in the PGR argument, in papers, or at the oral hearing, doesn't automatically transfer everything you said there into these two cases. So just -- I

appreciate the fact that, yes, the issues in those cases are the same, and you don't want to reiterate too much, but you want to repeat enough so that your record in these two cases is also a complete record.

MR. DEIGHAN: Thank you, Your Honor, and you're absolutely right. I just didn't want to, again, like you said, reiterate too much, but I will certainly go through the evidence here to establish a record in these proceedings.

We think that there is ample evidence in the record here to find that Svihra is a printed publication. Turn to Slide 6. Svihra bears all the hallmarks of a publicly accessible printed publication. It's got a journal name, the Bratislava Medical Journal; a publisher, published by the Faculty of Medicine at Comenius University in Slovakia; publication year, 2002; volume; edition; page numbers; date received; date accepted. All the hallmarks are here and present in Svihra.

Slide 7, Svihra was properly authenticated when it was submitted with the Petition, and Patent Owner made no objections, no authenticity objections, no hearsay objections here, so it was properly authenticated.

Slide 8, we also submitted corroborating evidence.

JUDGE NEW: Just one thing I want to interrupt you of, Mr. Deighan, here, fairly briefly. You're saying the notation that the manuscript was received on May 30th and accepted December 9th are indications that it's a public -- printed publication. But those aren't indicators that they were accessible to the public on those dates or, actually, that it was in any way accessible at that time or on those dates. All those show is that the

manuscript was received and that it was accepted after being peer-reviewed. That doesn't mean it was publicly accessible at that time.

MR. DEIGHAN: I think they go to the totality of the evidence. And your point, I think, is correct. It doesn't necessarily -- those hallmarks do not necessarily themselves prove public accessibility, but I think when you consider those factors along with the other evidence of public accessibility here, again, looking to the totality of the evidence, that when you weigh all that together, it shows that the reference was publicly accessible.

JUDGE NEW: Okay.

MR. DEIGHAN: So, again, on Slide 8, we submitted corroborating evidence in our reply to further prove that the Svihra reference was publicly accessible. And there's no question here that this is proper under the Board's precedent and rules. The Hulu decision, the precedential Hulu decision, makes that absolutely clear, makes it absolutely clear that a petitioner may submit additional public accessibility evidence on reply. And, again, that is IPR2018-1039, Paper 29. The Consolidated Trial Practice Guide also says that this is proper. The CFR, 37 C.F.R. 42.23(b), all the Board's precedent and rules say that submitting evidence of public accessibility on reply is permissible, following a challenge to the public accessibility of the references by a patent owner in the response.

And that's exactly what we did here. After the Patent Owner challenged the public -- printed publication status of these references in its response, we followed that in our reply with additional evidence.

Slide 9, I would also note that non-contemporaneous evidence, the Board has held that non-contemporaneous evidence can be used to

corroborate public accessibility. And that's what happened here in the Parse Biosciences case, Parse Biosciences v. 10X Genomics, IPR2023-00958, Paper 48 at 19 to 20. And there, the Board looked to non-contemporaneous evidence, citing to a prior art reference to corroborate that the reference was a printed publication.

So looking to this corroborating evidence, Slide 10, again, in response to the public accessibility arguments that Patent Owner made in the response, we submitted corroborating evidence that includes citations to Svihra and have the exact same -- the exact same citation that appears on the face of the reference. And so that includes the Sherif reference, which in these IPRs is Exhibit 1091; Slovak, Exhibit 1092; and Garcia, Exhibit 1093. And these all have the exact same citation that appears on the cover of Svihra itself. And so this shows that Svihra was published in 2002 and could be located.

And I think, moving to Slide 11, the last thing that I'd like to mention here on Svihra is that the Board found in the institution decision that Svihra was publicly accessible at that time for purposes of institution. And just like in the PGR, Patent Owner has put forth no evidence here to alter the Board's conclusion. And so we submit that the Board got it right at the institution stage and nothing has changed, other than, from Petitioner's side, adding additional public accessibility evidence into the record.

So with that, I'll turn to the Amarenco reference, Slide 11. And, again, ample evidence in the record here for the Board to find that Amarenco is a printed publication.

Slide 13, like Svihra, it has all the hallmarks of a publicly accessible printed publication. The journal name, the Journal of Urology; publication date, June of 2003; volume; page numbers. And Svihra -- excuse me -- Amarenco also has copyright information. It says Copyright 2003 by the American Urological Association. And in addition to that, it has what's called a digital object identifier, which is basically a unique code that would allow somebody to find this publication. So, again, it has all the hallmarks of a publicly accessible printed publication.

Slide 14, Amarenco was properly authenticated, again, when it was submitted with the Petition, no objections by the Patent Owner.

And I'll jump to Slide 16 here. And so in addition to all that, Amarenco was cited on the face of the '742 Patent that's at issue here today and related patents in the family, including the '943 Patent that was at issue in the PGR proceeding. And this shows that persons of ordinary skill in the art could have located Amarenco, and that even applicant identified it with a June 2003 publication date.

One issue that came up during the hearing for the PGR was who found it, who found the Amarenco reference. And I would submit that that's irrelevant. The Federal Circuit, in Valve Corp. v. Ironburg Inventions, 8 F.4th 1364, the court found that a reference was a printed publication largely because it was cited during prosecution of the patents at issue and some related patents.

So there's a couple interesting things here. First, the court said that the fact that the patent examiner found the article was published before the critical date was relevant, because, quote, Patent examiners are trained and

1 required to determine publication dates, end quote, and, quote, The
2 confirmation of the article's publication date by the patent examiner is highly
3 persuasive evidence of public accessibility. And that's at page 1375. So I
4 think that answers the question about who found it. Even if the examiner
5 found the Amarenco reference, still evidences public accessibility.
6 And another thing to note in the Valve Corp. case is the court also
7 found that the fact that the applicants during prosecution did not dispute the
8 publication date of the article was also evidence of public accessibility. And
9 on that note, the court said, the IDS is significant here, not because of its
10 inclusion of the article by the applicant, but because of the applicant's
11 characterization of the publication date before the critical date.
12 So, really, it doesn't matter who found the Amarenco article, whether
13 it was the applicant or the examiner. If the examiner found it and
14 determined it was published in June of 2003, that's highly persuasive
15 evidence of public accessibility. And the fact that it was listed on IDSs in
16 related patents in the family, patents and applications in the family, also
17 evidences public accessibility because the applicant characterized it as
18 having a publication date in June of 2003.
19 So we've also, again, submitted corroborating evidence for Amarenco.
20 One piece of that, one piece of evidence, is what we call Amarenco II, and in
21 these IPRs, that is Exhibit 1094. This is an exact copy of the Amarenco
22 article that was published -- excuse me -- was submitted with the Petition,
23 but we've also included the journal cover, the copyright page, and the table
24 of contents to show -- to further show the publication date and that that
25 article was included in that edition of the Journal of Urology.

I'd also note that you can see on the slide, at the top of the Exhibit 1094, it says Shawnee Mission Medical Center Medical Library, Library Date Received May 13th, 2003, which, again, shows that it was catalogued in the library at that time.

Slide 18, this is just a comparison of Exhibit 1005, which was submitted with the Petition, and Exhibit 1094, Amarenco II, to show that they are identical articles.

Moving to Slide 19, we submitted additional corroborating evidence to show that Amarenco was published and publicly accessible. Again, we cited a number of articles that cite to Amarenco, and that includes Queralto, Exhibit 1016, and that was actually submitted with the Petition; as well as Sherif, Exhibit 1091; Slovak, Exhibit 1092; Guo, Exhibit 1095; and Garcia, Exhibit 1093. And, again, as you can see, all have the exact same citation that appears on the face of the Amarenco article itself.

And so, to kind of wrap up Svihra and Amarenco, the totality of the evidence in the record here shows that Svihra -- both Svihra and Amarenco are printed publications. And, again, this is effectively the only disputed issue in the 1378 IPR. And so Grounds 1 to 3, which relate to Svihra, Grounds 4 to 5, which relate to Amarenco, lead to the '477 Patent being unpatentable and invalid.

And so I'll next turn to Slide 20, which relates to Ponsford. And Ponsford was, again, raised in the 1375 IPR, but the issue, printed publication issue, is the same. Like Svihra and Amarenco, Ponsford, there's ample evidence in the record to show that Ponsford is a publicly accessible printed publication.

Slide 21, Ponsford has all the hallmarks, just like those other references. It includes a journal name. Again, that's the Journal of Neurology, Neurosurgery, and Psychiatry. It's a well-known publisher. And I would note -- I apologize. There's a typo on the slide in the bullets, but you can see the full journal name in the snippet above the article on the right there. Ponsford also includes publication year, 1988; volume, 51; page numbers; date received; date accepted. And so, again, many of the same hallmarks as the other references and, viewed in the totality of the evidence, we think proves that it was publicly accessible.

Ponsford, again, properly authenticated when it was submitted with the Petition; no objections to authenticity or hearsay by the Patent Owners to that. And that was Slide 22, by the way.

Slide 23, I would note that in the institution decision, the Board noted that Ponsford exhibits the same hallmarks of a printed publication as Amarenco and Svihra. And, again, Patent Owner has not put forth any evidence here or argument to alter that conclusion during the course of this trial.

And in Slide 24, once again, really for the avoidance of doubt, we also submitted corroborating evidence here, after the Patent Owner response and after the public accessibility of Ponsford was challenged, and that includes the Kramer reference, Exhibit 1099, and the Galloway reference, Exhibit 1100. Both cite Ponsford; both have the same citation that appears on the face of Ponsford itself.

And one other thing that I would point out here, it's probably too small to see on the slide, but Kramer, Exhibit 1099, was published in

February 2005, which is over a year -- predates the earliest effective filing date of the '742 Patent by over a year, so that clearly demonstrates that a person of ordinary skill in the art could have located Ponsford -- indeed, they did, and they cited it in the paper -- and that Ponsford was publicly accessible well before the earliest filing date of this patent.

We also cited to a number of other journal articles for background, to show the state of the art, and to show the knowledge of a person of ordinary skill in the art, throughout our petitions. Slide 25 lists some of these exemplary references to show that these references have all the same hallmarks. You can see they have journal titles. They have volume numbers. They have publication dates. Some have copyright information. Some have ISSNs and accession numbers, which are similar to DOIs, and allow a person -- would allow somebody to locate those references. And so these are, again, exemplary of the hallmarks that appear in all the journal articles that we submitted.

I won't go through this, but this lists the -- Slide 26 lists the other journal articles that we submitted, and, again, mostly relied on for background, state of the art, and knowledge of a person of ordinary skill in the art, and all bear the same hallmarks as the other publications.

So before I move on, I'll make one final point here. I think we've provided sufficient evidence that all the journal articles are printed publications. But if you set aside the references that we explicitly rely on in our invalidity grounds, I think that the printed publication issue, with respect to these other journal articles, is a little bit of a red herring, and I'll tell you why.

The Federal Circuit and other prior Board decisions make it crystal clear that the Board can rely on evidence other than just prior art. In Yeda Research v. Mylan Pharms., 906 F.3d 1031 at 1041, Fed. Cir. 2018, the Federal Circuit said, and I quote, Based on the statutory scheme, PTO's own regulations, and prior Board decisions, the Board can rely on evidence other than just prior art.

That's been followed by a number of Board decisions, and I'll just give you one example here, Beable Education v. Achieve3000, that's IPR2021-01169, Paper 34 at 89, PTAB, January 3rd, 2023. And there the Board said, the Federal Circuit has held that non-prior art evidence may be used to show the state of the art and the knowledge of one of ordinary skill in the art. And that cites to the Federal Circuit's Yeda decision.

And so, really, the majority of the journal articles that Patent Owner has argued about here are cited in the Petition really for background, state of the art, knowledge of a person of ordinary skill in the art. So the Board can still properly consider them for these purposes, whether or not they're prior art. Although, again, I think we've submitted sufficient evidence to show that they are.

And so turning to Slide 27, where does that leave us here with this printed publication issue? At this point, I think that the record evidence establishes that Svihra, Amarenco, and Ponsford are printed publications and qualify as prior art. Patent Owner provides no evidence to counter any of this evidence in the record for any of these references. There is no evidence to counter the indicia on the face of the references. There is no evidence to counter the corroborating evidence.

Instead, Patent Owner basically just makes general arguments about failing to meet our burden. But the Board has, time and time again, rejected these types of arguments as insufficient to overcome actual evidence in the record of public accessibility. And we cite some cases for that in our replies, for example, in the 1375 proceeding, Paper 15 at 12 to 13.

So with that, I'll turn now to the second issue here, which, again, is specific to the 1375 IPR and related to whether the prior art teaches directly targeting and stimulating posterior tibial nerve branches. And let me explain why I think you should find in our favor on this.

To begin, there doesn't really seem to be a dispute here that Svihra and Amarenco disclose directly targeting and stimulating the posterior tibial nerve itself. Patent Owner's Response says so for Svihra, on page 14. In addition, persons of ordinary skill in the art would have known that posterior tibial nerve branches could also be directly targeted and stimulated to treat overactive bladder and incontinence, and they would have understood exactly how to do it.

I went over this before, but I'll just reiterate. The prior art cited in the Petition, which includes a number of references that we'll talk through, collectively teaches, number one, treating overactive bladder and incontinence by stimulating nerves that emanate from the spinal cord via the sacral nerve roots, such as the posterior tibial nerve and its branches; two, stimulating the posterior tibial nerve branches would provide the same effect as stimulating the posterior tibial nerve itself; three, stimulating the posterior tibial nerve branches would cause signals to travel upstream through the posterior tibial nerve to the spinal cord via the sacral nerve roots; and four,

the prior art taught methods, precisely taught methods for directly targeting and stimulating posterior tibial nerve branches.

And so a person of ordinary skill in the art, based on these teachings and based on the person of ordinary skill in the art's knowledge, would have had motivation to target the branches of the posterior tibial nerve for treating overactive bladder or incontinence. They would've understood that stimulating the posterior tibial nerve branches would be as effective because the electrical signals travel upstream to the exact same place in the spine as they would if you were stimulating the posterior tibial nerve itself. And they would have, again, known exactly how to do it.

JUDGE NEW: Well, Mr. Deighan, if you're stimulating only one of the branches of the posterior tibial nerve, that means you're only stimulating a subset of those ascending axons that are coming from that branch and then entering into the tibial nerve before going up into the central nervous system. So I guess this goes more to reasonable expectation of success than anything else.

How can you say that a person of ordinary skill would reasonably expect stimulating a small subset, say a minor branch of the posterior tibial nerve, and there are a number of branches along it, at different locations, extending from just below the knee to just around the intermalleolar bone of the ankle. If you only stimulate a small subset of those fibers, how can you be certain -- or how can you reasonably expect, I should say, that you'll get exactly the same intensity of response in the bladder contraction -- inhibition of bladder contraction that you would if you stimulated the entire nerve?

MR. DEIGHAN: I'll address that, make a couple points. Number one, I don't think that absolute efficacy is required, so I think that all that needs to be shown is a reasonable expectation of success. And I think that comes from references like Ponsford, and I'll just switch over here to Ponsford, which is Slide 35.

Our expert explained that Ponsford teaches recording sensory action potentials, which are signals that are propagated from a stimulation site to a recording site by noninvasively electrically stimulating the posterior tibial nerve branches. And our expert testified here, which is uncontested, that Ponsford's study would show that those signals travel from the branches to the posterior tibial nerve and upstream into the sacral roots of the spinal cord.

JUDGE NEW: Well, that's just standard neuroanatomy. I mean, the nerve fibers in the branches of the posterior tibial nerve join the tibial nerve and project up into the dorsal roots and into the central nervous system. That's standard. But my question goes more to efficacy of the response.

I mean, you said, basically, the person of ordinary skill would expect the same type of response to stimulation of a branch, even a very small branch of the posterior tibial nerve, than it would to the stimulation of the entire tibial nerve. But in the latter case -- or the former case, you're only stimulating a very small subset of those nerves. So how could you be sure you'll get that effect from stimulating that small branch that you would get if you stimulated the whole nerve?

MR. DEIGHAN: Well, yeah, I don't think you need to show the exact same effect, right, for motivation. There just has to be a suggestion to do it, and we provided a number of those.

And given references like, for example, Mann and Boveja, which explicitly show stimulating nerves and branches, right, that lead to the sacral nerve roots for the treatment of overactive bladder and incontinence, I think that a person of ordinary skill in the art would have understood that stimulating any of those nerves could be used to treat overactive bladder and incontinence and would -- there's a reasonable expectation that that would lead to the exact same success, because otherwise those references would not have said nerves or branches. It's really any nerves that emanate from the sacral nerve roots in the spine.

So I'll jump now into talking through the specifics of some of these references. So I'll start -- excuse me. I'll start with Mann, Exhibit 1084, and Boveja, Exhibit 1080. And so as we pointed out in our papers, and as is shown on the slide here, Mann discloses treating incontinence, urgency, and frequency by stimulating nerves that emanate from the sacral nerve roots. It says that the posterior tibial nerve and other sites along the tibial nerve are acceptable stimulation sites. Petitioner's expert confirmed that the posterior tibial nerve and its branches are nerves that emanate from the sacral nerve roots. And so that shows Mann teaches that conditions like incontinence can be treated by stimulating nerves like the posterior tibial nerve or its branches.

Boveja is similar. It says that bladder contraction can be inhibited by stimulating branches and fibers that reach the spinal cord via the dorsal roots

of the sacral nerves. Again, Petitioner's expert confirmed that the posterior tibial nerve and its branches reach the spinal cord via the dorsal roots of the sacral nerves. And so, again, Boveja teaches that stimulating the posterior tibial nerve or its branches can inhibit bladder contraction.

Patent Owner tries to explain away Mann and Boveja, but I think, in a lot of instances, misreads the teachings of the reference. For example, one of Patent Owner's arguments is that Mann focuses on stimulating the pudendal nerve and its branches. That's Paper 12 at 14. But this ignores, you know, the portions of the reference that we're showing here on the slide, which, again, say that nerves emanating from the sacral nerve roots, like the posterior tibial nerve and its branches, can be stimulated.

As to --

JUDGE GROSSMAN: Mr. Deighan, just to make sure the record is clear, when you say "as shown on the slide," just state what slide you're specifically referring to.

MR. DEIGHAN: I apologize, Your Honor. That's Slide 33. And thank you for that reminder. I'll be sure to do that.

Sticking with Slide 33, Patent Owner also tries to explain away Boveja, but they only -- by saying that Boveja only relates to stimulation of nerves at the bottom of the spine, Paper 12, at 16, but this isn't what Boveja says. It says that nerves that reach the spinal cord at the bottom of the spine can be inhibited to -- stimulated to inhibit bladder contractions. And so, it's not only limited to stimulations, the stimulation of nerves at or near the bottom of the spine.

And so, we'd submit that a person of ordinary skill in the art, from references like Mann and Boveja, teach -- or would understand that overactive bladder and incontinence can be treated by stimulating the posterior tibial nerve or the posterior tibial nerve branches.

Switching here to Slide 34, I'll quickly just mention that the Grey reference, Exhibit 1081, teaches electrical stimulation to treat a variety of conditions. And it says that the tibial nerve and its branches, the medial plantar nerve, the lateral plantar nerve under the foot, can be stimulated to cause the same effect. Petitioner's expert testified that a person of ordinary skill in the art would understand this to mean that you can stimulate either the posterior tibial nerve or its branches and achieve the same efficacy.

And so I think, Judge New, to your question, this is further evidence that shows that there would have been a reasonable expectation of success in stimulating the posterior tibial nerve branches.

Patent Owner, again, attempts to distinguish Grey but I think largely misses the point. Patent Owner contends that Grey focuses on acupuncture. But, really, Grey's statements about acupuncture are really irrelevant here. What matters is what Grey teaches about the posterior tibial nerve and posterior tibial nerve branches, and that's that stimulating the posterior tibial nerve or the branches would cause the same effect.

JUDGE NEW: But does Grey teach anything to do with urinary incontinence or overactive bladder?

MR. DEIGHAN: It does not. It does not. What Grey relates -- Grey relates to some other conditions. But I think, and this is something that the Board pointed out in the institution decision, we need to look at the

collective teachings of the references. We can't look at references in isolation. And so, viewing Grey along with references like Mann, Boveja, Ponsford, and that's what would have provided the motivation, and that's what would have given the reasonable expectation of success. And so, we aren't relying on Grey for the teaching of any specific condition. It's more just the effect on stimulation of the nerves.

JUDGE NEW: So, if I understand your position correctly, it's that although Grey teaches that you can stimulate the tibial nerve or its two plantar branches to get relief from stomach pain, vomiting, dizziness, motion sickness, abdominal pain, diarrhea, and premenstrual cramps, and because you can stimulate the tibial nerve to treat OAB and urinary incontinence, then you can also stimulate the two branches or any other branch of the tibial nerve to treat OAB or urinary incontinence?

MR. DEIGHAN: I think that's exactly right. I mean, at a minimum, and as we pointed out in our Petition, I think that it would make it obvious to try to target the branches of the nerve. And again, we're not relying on Grey alone. It's in combination with the teachings of Mann and Boveja, which talk about stimulating the nerves that emanate from the sacral roots and their branches. And so, it's really the collective teachings here that are crucial.

I'm going to just try to quickly hit Ponsford here. And Ponsford discloses, again, recording sensory action potentials, and that Petitioner's expert testified that what a person of ordinary skill in the art would understand from that is that those signals are traveling upstream to the exact same place in the spine.

Patent Owner disputes this, argues that Ponsford simply teaches that sensory loss in the foot is associated with the presence of lumbosacral regions in the spine. That's at Paper 12, at 18. This is nothing but attorney argument. And the Board has held that that can't overcome record evidence from Petitioner's expert on how a person of ordinary skill in the art would have understood the teachings of the reference.

And then, Slide 36, Ponsford also teaches explicitly how to directly target and stimulate branches of the posterior tibial nerve. And it says in the method, it explains exactly how to do it in the method section there, on page 188 of the reference.

And so, I'll begin to wrap up. I think that viewing the collective teachings of the art, the prior art, without issue, teaches or suggests --

JUDGE NEW: Mr. Deighan, I would just like to go back on Ponsford there a little bit, because I think that, perhaps, Patent Owner's position has a point here.

If I read this correctly from the summary on your slide, as well as on the reference itself, it says, a simple and reliable method of recording medial and lateral plantar nerve sensory action potentials is described. Potentials are recorded with surface electrodes at the ankle -- so, we're just talking about electrode recording at the ankle on the tibial nerve -- using surface electrodes stimulating orthodromically at the sole -- which means that these are ascending action potentials headed up towards the nervous system.

All that says to me is that this is a measure -- a way of measuring conduction from the plantar nerves to the tibial nerves. So, if you have -- and I believe this article is in the context of neuralgia in the foot. Well, what

it's looking for is inhibition of action potentials or inhibition of sensory transmission from the plantar regions of the sole into the tibial nerve. I'm not really sure of the relevance of that, apart from the fact that some plantar sensory neurons are going -- well, all plantar sensory neurons from the medial and the lateral nerves are going into the tibial nerve. And that's fairly trivial. And I'm not really see how -- sure how that goes to your point here.

MR. DEIGHAN: So, I think that we're not relying on Ponsford for any sort of therapeutic effect. We're not relying on it for a treatment of any specific condition.

Ponsford really shows two things. It shows that by recording these sensory action potentials where you're stimulating the posterior tibial nerve branches and recording at a site upstream of that, that shows that the signals are traveling upstream. And I think, you know, Your Honor, you're exactly right. That's somewhat trivial because I think that that's pretty well known. It's not probably too surprising that the signals would travel upstream to the sacral nerve roots of the spine. And then, again, we're also relying on Ponsford for its teachings regarding exactly how to perform the stimulation. Again, in the methods, it explains exactly how to do that.

So, my time is, you know -- concludes here shortly, but just to wrap up, I would submit that we provided sufficient evidence to -- and I'll just flip to Slide 49 here. We'd submit that we've provided sufficient evidence to show that the Amarenco, Svihra, and Ponsford references are prior art printed publications, and that the art discloses directly targeting and stimulating posterior tibial nerve branches. And so, based on this, we

believe that we've proven that Claims 1 to 13 of the '742 Patent and Claims 1 to 10 of the '477 Patent are unpatentable.

Thank you, Your Honors.

JUDGE NEW: Thank you very much, Mr. Deighan. Appreciate that. You have your 15 minutes remaining.

MR. GERASIMOW: He may have 20, right? Did you take 40 or 45?

JUDGE NEW: I think you asked for 15.

MR. DEIGHAN: I asked for 15, but I'm not sure

MR. GERASIMOW: Oh, sorry.

MR. DEIGHAN: But I did --

JUDGE NEW: I set it for 45, so you should be fine.

Mr. Gerasimow, did you want to reserve part of the time of your argument for surrebuttal?

MR. GERASIMOW: Yes, please.

JUDGE NEW: And how much?

MR. GERASIMOW: May I do 20?

JUDGE NEW: Sure.

MR. GERASIMOW: Thank you.

JUDGE NEW: One moment. All right, you are good to go when you’re ready, Mr. Gerasimow.

MR. GERASIMOW: Good morning. Thank you. My name is David Gerasimow of Gerasimow Law for the Patent Owner, EMKinetics. I agree with patent -- excuse me -- with Petitioner that there's two categories of issues. We can say prior art status is the first category, and obviousness is the second. I'm happy to address them in either order, and I was curious if

the Board cared whether I started with the prior art as a status issue first, or with obviousness.

JUDGE NEW: That's at your discretion.

MR. GERASIMOW: I will start with prior art. Thank you, Your Honor.

It's true that the prior art issues affect all grounds in both IPRs that we're here to discuss. Petitioner, in its oral arguments and in briefings, characterized Patent Owner's issues with the Petition as procedural, as purely procedural, as procedural issues, a variety of terms intended to, I think, to dismiss the importance of the issue. This is an IPR. It is based on prior art patents and printed publications, and establishing that those documents submitted to this tribunal are prior art is not a mere procedural issue, but, we would submit, an important and substantive issue.

Further on that point, we certainly heard a lot of things about we need, on the evidentiary side, to look at the totality of evidence, that there's lots of evidence, apparently, in the record, suggesting that these things are prior art. There's this. And then we heard on the substantive side that it's, you know, it's not Ponsford, necessarily. It's not Mann. It's many references we need to consider together to get to the claimed inventions.

I think when you put both of these things together -- like, we have a petition, certainly in the 1375 case, that relies not just on printed publications in the ground, not just patents. It explicitly relies on the knowledge of an ordinary, a person of ordinary skill in the art. We say, as we said in the briefing, we think this is not consistent with the scope of

statutory jurisdiction for IPRs. The statute, 35 U.S.C. 311(b) states that IPRs are based on printed publications and patents.

And here, what we have is the Petition is based on something else. I think we want to interpret these petitions as complying with the statute. Then what they're saying is that the knowledge of ordinary skill in the art is demonstrated by a bunch of patents and printed publications. I think, here, we have -- because knowledge it was cited at the ground and that because we have dozens of articles and references and papers that are said to inform this knowledge that is a ground, that these are very important issues, that it's not just proving Svihra. It's not just proving Amarenco. It's actually proving the secondary references.

And not just the ones that are named in the grounds that are summarized at the beginning of the petitions, but if we look through the petitions and we look through the way they're structured, there's dozens of references that are affected by this issue, that are rolled up in this alleged knowledge of skill in the art that were said in the totality that, whether procedural or substantive, somehow leads to the invalidity of the claims. We strongly disagree.

I think, as Judge New, you noted at the very beginning of the discussion today that petitioner always bears the burden of proving invalidity; that does not change throughout this proceeding, and that that burden includes proving each and every one of the dozens of references that are said to constitute the knowledge of a person of ordinary skill in the art actually constitute prior art.

We're told a lot about the Board's institution decision. That's true. The Board obviously instituted the IPR proceedings in both of these matters, but the standard for institution and the standard for invalidation after this trial are different. And so, the fact that there was information sufficient to support institution in the Board's original decision does not automatically equate to a decision to invalidate at these proceedings here today.

We heard in this proceeding, as well in the PGR proceeding, that Petitioner allegedly had no idea that, you know, that Patent Owner was going to challenge the prior art status until the reply, and that explains the timing of the submission of what they call corroborative or additional evidence. Very clear from the institution decision that it was a known issue at the time of institution, and that's because Patent Owner briefed that in its preliminary response submitted prior to institution.

So, with respect to the notion that this idea came up, this argument came up late in the proceedings and that Petitioner had no opportunity and so had to wait to reply in order to do any of the things that they did in corroboration or addition simply isn't true. Those issues were raised in the preliminary response, and Petitioner did nothing about them. Indeed, the institution decision said -- recognized the issue and said these are things one might be able to do: establish the publisher, get a declaration from a librarian, do these things, and prove them up.

And what we see throughout this proceeding is that Petitioner: I did not do any of those things. Even the corroborative evidence is not very corroborative, let's admit. It's not a declaration from a librarian. It's not a declaration, really, from anybody who would know. We're presented with

the totality of the evidence really being 20 Xerox copies that we were -- that we are told were downloaded and found recently. That's the record evidence.

JUDGE NEW: Is it, Mr. Gerasimow? I've spent a good deal of time looking through the case records and the case law on this, and I have yet to find any case that points to a reprint of a journal article from an accepted peer-reviewed journal. In fact, the Journal of Urology is the flagship journal of the urological field of medicine. It's a highly prestigious journal. I have yet to see anything that requires a statement from a librarian that it was filed or publicly accessible. That's usually the sort of thing you see like in Hall and in Cronyn, who were talking about, you know, a thesis that was put in the stacks of some Eastern European university 20 years ago and has been lying around ever since.

Can you point me to some case law here that says that the reprint of a journal article from an established peer-reviewed journal that bears many hallmarks of authenticity, that it was published and accessible, it requires a statement from a librarian or some other sort of corroborative evidence?

MR. GERASIMOW: I agree that a lot of the case law has to do with things like these, but it's not clear why there would be a distinction in the case law between documents that are alleged to be printed publications that are in a thesis, and printed publications that could be characterized as reprints of an article.

I think we do see in the Ericsson opinion, cited by Petitioner, absolutely relying certainly on the theses-type case, additional evidence

behind some copies of the articles themselves. So, in Ericsson, certainly, the presence of a librarian declaration is credited.

I would certainly say, in cases involving reprints, usually you do see librarian declarations. It's really unclear why we don't have that in this case. That's what I don't understand is why that was not presented with the Petition, why we don't have any of that evidence, even in reply, if that were proper.

JUDGE NEW: I would respond to that by saying that I think it's very unusual to see some sort of a library, certainly in my experience, it's unusual to see anything like a librarian's statement establishing that a reprint was part of a publication. I can't find anything in the case law that suggests that either, if only because it seems to suggest to me that a journal article reprint, which is part of a journal, which circulates substantially through the public and professional communities, particularly in the ones of skill in the art, why that wouldn't be publicly accessible. It seems that I'm having trouble making sense of your argument here.

MR. GERASIMOW: Well, I think Your Honor is actually filling in Petitioner's argument with evidence that's not correct. I think, if we're talking about established publications, where is the record evidence that even the Journal of Urology is an established publication? Your Honor has said it, and I think Petitioner has assumed it, but we don't have record evidence on that. And certainly, outside of the Journal of Urology, there is dozens here that I don't think the same thing could be said of -- even by a person of ordinary skill in the art, in a proper declaration.

I would also add that we have references here that don't have any hallmarks at all. It's relevant where those references are specifically relied on to supply missing claim elements. This is Exhibit 1030 of the 1075 -- excuse me -- the 1375 Patent. That's not just background art. That's not just state of the art, level of ordinary skill in the art. Even if it were, we have petitions here structured to say that we're relying on pretty much every reference that's cited here. But we do have references that are specifically supplied and are not nearly -- that do not look like printed publications, so to speak. Those exist in the record as well. And when they're lumped together, I don't think that Petitioner gets to pick at the end and say, you know, these few are good enough, and that's the totality, and good enough.

JUDGE NEW: Why don't we look to the references that are cited in the grounds as teaching the limitations, and then look at other references that are cited as teaching the knowledge of those of skill in the art?

Because Federal Circuit case law says quite clearly that a person of ordinary skill in the art is presumably familiar with all of the literature of the field in which that person is engaged. So, why is it impermissible to use other types of publications that are present or would have been available to a person of skill in the art at the time of the critical date, just simply to show what a person of ordinary skill in the art would have known? Because we always, as you well know, look at obviousness or anticipation in view of the knowledge of a person of ordinary skill in the art.

MR. GERASIMOW: Well, a person of ordinary skill in the art is presumed to understand the art. In fact, I believe there is the legal fiction that the person of ordinary skill in the art has read everything. What we're

looking at in this proceeding, with the evidentiary basis that these several dozen references are prior publications, you can't use the presumption to skip that evidentiary can proof step, I would suggest.

JUDGE NEW: All right. Thank you.

MR. GERASIMOW: I would like to turn to the obviousness section if -- unless the Court has any further questions on the prior art right now.

JUDGE NEW: No. Please continue.

MR. GERASIMOW: Thank you. In the 1375 proceeding, Petitioner attempts to establish the invalidity of the challenged claims by asserting that a person of ordinary skill in the art would have had several appreciations or understandings based on the prior art. In our response in our sur-reply, we dispute that a person would have those understandings.

In the oral argument by Petitioner just here, they suggested that the obviousness case was uncontested. That's not true. We took the deposition of their expert, cross-examined him, and submitted cross-examine test -- cross-examination testimony with our response in the 1375 Patent. So we disagree that it's not contested.

We also believe that the Board is capable of reading the references and can read the references for what they say, that the notion that an expert can tell the Board what a reference says. The Board might disagree with it because the Board doesn't have a competing expert. It just says, oh, well, we have to believe the expert that was -- whose testimony was submitted by the petitioner. Submit that the Board doesn't have to credit testimony that is provided, even if it weren't controverted, and as we said, we do submit deposition cross-examination testimony in our response.

JUDGE NEW: I'm a little puzzled by your stance there. I think the Board looks at every expert declaration it gets critically to see if what the expert says accurately reflects what's in the prior art, at least the expert here, and then goes directly to the credibility of that expert witness. And it doesn't matter that there's no expert witness for Patent Owner's side in this case. We look critically at the Petitioner's expert to see if what that Petitioner said reasonable corroborates with what our understanding of what the material says. And we weigh that opinion accordingly. Then it goes to credibility.

MR. GERASIMOW: Well, that's great, because I'm asking the Board to look at what the things say and not what the expert says about them. So kind of three teachings in that regard. They lump into Ponsford as the first group, Mann and Boveja as the second group, and I believe Grey as the third.

As mentioned, we don't believe that these references provide the teachings that Petitioner's expert say they do. We start with Ponsford. I think Your Honor had it right during his colloquy with Petitioner's Counsel that Ponsford does not -- let me rephrase. Ponsford teaches measuring action potentials in and around the foot and associating those readings with certain neurological conditions, the lesions that are mentioned, I believe, on our slides and in our briefs, but of certain neurological conditions.

JUDGE NEW: I think I would refine that slightly to say what it does is it teaches measuring action potentials in the posterior tibial nerve, not in the foot, so that would be around the ankle and behind that, in response to orthodromic stimulation of sensory neurons that are located in the plantar nerves farther out. So, in other words, by orthodromically, I mean going

forward, up, in towards the central nervous system, rather than antidromically, which means going backwards, because an action potential can propagate in either direction.

MR. GERASIMOW: Yeah, and Ponsford says nothing about that propagation to the bladder or bladder area.

JUDGE NEW: Right.

MR. GERASIMOW: I certainly don't see it as providing the teachings of --

JUDGE NEW: But I was just refining that to reflect tibial nerve recording as opposed to in the foot.

MR. GERASIMOW: We agree with your refinement. Thank you. I don't have any more on Ponsford for that.

JUDGE NEW: Okay.

MR. GERASIMOW: I think with that second category, Mann and Boveja -- I apologize if I mispronounce it -- what we're looking at is stimulation of nerves at the sacral root. We're talking at the base of the spine, the coccyx. And with respect to any specific disclosures in those references, what we're talking about is stimulating primarily the pudendal nerve, which controls bladder function, and not unrelated nerves, and certainly not distal nerves, so-called downstream from the bladder.

And so, when those references suggest, well, you could maybe target and stimulate other nerves, what they're talking about is the base of those nerves, again, in the sacral root. There's no suggestion in these references that, at that time, anyone understood that a remote -- at least in these particular references, that anyone understood that remote stimulation and

targeting would have that kind of effect on overactive bladder. That's just not what those teach.

JUDGE NEW: Oh, I'm sorry. Doesn't -- are we discussing Mann here?

MR. GERASIMOW: Mann and Boveja.

JUDGE NEW: Okay. Well, Mann expressly teaches, and I'm going to refer you to column 12, starting at line 41: Another preferred stimulation location for purposes of the present invention is the tibial nerve, and it's easily accessible, et cetera, et cetera, at two sites in the leg, at the level of the ankle, immediately posterior to the medial malleolus, and posterior tibial artery and vein, and also at the level of the knee. So we are talking about distal stimulation here of the tibial nerve directly in this case.

MR. GERASIMOW: That's true in Mann, Your Honor. You're right.

JUDGE NEW: And doesn't Mann, taken together with Boveja, which I agree teaches stimulation up at the sacral dorsal nerve roots, doesn't that convey that if you can stimulate the tibial nerve and get the same effect that you get when you teach the sacral nerve, that these are basically equivalent stimulatory sites for achieving the same effect?

MR. GERASIMOW: I don't read Mann as disclosing the stimulation of a branch of the PTN.

JUDGE NEW: It says another preferred stimulation for the purposes of the present invention is the tibial nerve, and they say they're doing it at the malleolus, which is the medial bone of the ankle, which runs -- and the nerve runs around the rest of it. I think there is no difference here between tibial

nerve, as expressed in Mann, and posterior tibial nerve, as expressed in some of the other references. It's the same nerve. It must be.

MR. GERASIMOW: That, well, it doesn't disclose a branch of the tibial nerve.

JUDGE NEW: Not a branch, no, it doesn't say a branch, but you were saying that these references speak only to stimulating at the dorsal sacral roots, and I'm saying, well, this Mann teaches something much closer to where we are. It does not, I agree with, teach a branch, per se, but it does talk about teaching stimulating the tibial nerve as being another preferred stimulation location.

MR. GERASIMOW: It does --

JUDGE NEW: So are we redirecting now to exclude -- considering exclusively the branches of the posterior tibial nerve, or we're talking about posterior tibial nerve as opposed to the sacral nerve roots?

MR. GERASIMOW: I'm not redirecting, Your Honor.

JUDGE NEW: Okay.

MR. GERASIMOW: I apologize for oversimplifying Mann. I agree. I continue with Boveja is limiting to the sacral nerve, and I will say that with Mann, it doesn't disclose branch of the posterior.

JUDGE NEW: Okay.

MR. GERASIMOW: We seem to agree on that as well.

JUDGE NEW: All right. Very good. Thank you.

MR. GERASIMOW: And that leads us to Grey, the kind of final category of -- I want to say it's the reference that leads to the final category of teachings on which Petitioner relies.

I mean, Grey, Grey is an acupuncture reference. I think the consequence of that is that it's a reference that's steeped in Chinese traditional medicine. It refers, as Your Honor noted, refers to, generally, disorders of the stomach condition, symptoms of the stomach, gastrointestinal tract, and refers, in large parts, to acupunctural channels. There's not much record evidence of what these channels are, but in the -- Grey seems to suggest that in traditional Chinese methods, they're pathways for some sort of life energy.

So we, you know, believe that Grey is not a particularly relevant reverence -- excuse me -- relevant reference and doesn't support the teaching that the Petitioner says it does.

JUDGE NEW: Before we move on, I realized that in the grounds of the 1375 IPR, Gerber is not cited. It is, however, cited in the grounds of the 1378 IPR.

And if we take this reference and, just for the moment, put aside your earlier arguments about the knowledge of a person of ordinary skill in the art, basically, Gerber, on paragraph 64, says exploring near the sacral nerve means any one of the sacral nerves, portions of the sacral nerves, neurologically connected to any of the sacral nerves as they -- they're normally close to physical proximity thereto extensions or branches of any of the sacral nerves. And I believe they talk about the tibial nerve here, as well as the pudendal nerve.

MR. GERASIMOW: Did Your Honor reference paragraph 64 of Gerber? I don't have paragraph numbers in Gerber.

JUDGE NEW: Maybe I'm -- hang on. Let me make sure I have the right reference here.

MR. GERASIMOW: I have a U.S. Patent for Gerber.

JUDGE NEW: Yeah, U.S. Patent, '372 Patent, I've got paragraph number 64 in my reading.

And just to my larger question here, though, would it be reasonable to say that because the sacral nerve includes, in this case, branches, extensions of any of the sacral nerves or any of their other branches, that a person of ordinary skill in the art would say, okay, this is all essentially one structure, that there are nerves coming out of -- or I should say going into, because these are afferent neurons -- going into the central nervous system, and they're joined from different streams coming up, until finally, you get to the sacral nerve, and you can either stimulate them up here or stimulate them down there and expect to get the same sort of transmission.

So, in other words, would a person -- I am sorry. This is a rather baroque question. I do tend -- I tend to go on. The question I'm asking, therefore, is if a person knew that you could stimulate a sacral nerve root, dorsal root, and achieve an effect, would that person not also expect the same effect by going, essentially, downstream, or down to the inferior nerves that contribute part of -- they contribute the fibers entering via the sacral root?

(Pause.)

JUDGE NEW: If you stimulate the sacral root, you're stimulating every sensory nerve fiber that's going into the central nervous system, right? And there would also, the sensor -- the sacral nerves are going into the

dorsal plate of the spinal cord, and then they're going down. But all those -- that's all of the branches, if you stimulate at the root. But you're stimulating, certainly, a large subset of them if you stimulate down the tibial nerve. And would a person know that the branches that come out of it are all part of the same structures that go up?

MR. GERASIMOW: I think by the time of -- by the time of invention, the medical science had established this structure --

JUDGE NEW: Right.

MR. GERASIMOW: -- in general --

JUDGE NEW: Okay.

MR. GERASIMOW: -- of the sacral plexus.

JUDGE NEW: All right. So, would a person of ordinary skill in the art have said, hmm, well, I can stimulate the sacral root, except that's very invasive, and it's very difficult to get to, and messing around the spine and spinal cord can be dangerous; maybe I can go farther down and stimulate those nerves and get the same effect? Would that not be something that a person of ordinary skill in the art might be reasonably motivated to do?

MR. GERASIMOW: I don't think so. I think that's what this -- these petitions are about. It's essentially, the human body is one large connected nervous system, and it would be reasonable to try every nerve. I think that's how I read these petitions. And so, no, I don't agree that if you had a knowledge of sacral plexus nerve stimulation that you would then go on anywhere else.

It's true that the sacral plexus collects a bunch of nerves. Some of those nerves control the bladder and anal sphincter. Others don't. Others control legs, or whatever.

JUDGE NEW: Right. But those are motor neurons, and those aren't what we're talking about now. We're talking about sensory neurons that are going upstream.

MR. GERASIMOW: Well, but are we? I mean, with the record evidence and with these references, it's not always clear to me what, whether we're even discussing with those types of control signals. Isn't Ponsford an example of different types of stimulation and purpose of stimulation?

JUDGE NEW: Right, but the purpose of stimulation in Amarenco sets this out really pretty clearly in the very first sentence. Let me pull it up here. Amarenco says, for many years, peripheral electrical stimulation has been widely used to treat urinary disorders. In other words, there's two ways that nerve fibers in the tibial nerve or its branches can transmit information, okay? It's either going to an effector organ like a muscle, or it's sending information upstream to the central nervous from a sensory receptor. Okay.

We are talking about the latter in this case because the posterior tibial nerve does not send effector motor neurons to the bladder, so it's got to be mediated via sensory neurons going up and then coming back down into -- well, actually, connecting to the parasympathetic and sympathetic nervous systems, which control the contraction and relaxation of the bladder. So we're talking about, basically, a reflex arc here. That's just pretty well known in terms of the general organization of the system.

It just seems to me that it's pretty clear what we're talking about here is sensory information being transmitted up into the central nervous system. Am I correct on that, or do you disagree with that?

MR. GERASIMOW: I agree.

JUDGE NEW: Okay. Thank you. So, in other words, if we're doing that, then wouldn't a person of ordinary skill next say, well, it may be better to stimulate a large subset of those, or even a small subset of those fibers that are going up into the central nervous system by using a less invasive method of stimulating a distal nerve branch?

MR. GERASIMOW: And what's the source in the record for this assertion?

JUDGE NEW: There is --

MR. GERASIMOW: I understand it's the question, but I feel that that's actually the question we're here to answer is would it have been obvious to do that.

JUDGE NEW: And I do not have that at my fingertips. Maybe you can help me with this. But there is one of the references quoted saying it's better to do it distally because you are recruiting a smaller number of neurons, and therefore, you don't have all the effects that you'd have. I believe -- let me see if I can find out. I think it's -- I don't have that reference at hand. I know it's in here, right in here. I just have to go through all my bookmarks, and I don't want to take up your time doing that. So let's just move on from that, okay?

MR. GERASIMOW: Okay. All I'll say on obviousness as it relates to Claim 4 is points that I think Your Honor touched on at the beginning of the

1 oral argument by Petitioner. It's that, if we do have, as Your Honor
2 suggests, some notion of taking the art, switching it to a branch, and then
3 what we don't do is in any way modify a treatment schedule or treatment
4 duration with -- but having changed the situs of stimulation, you don't have a
5 reasonable expectation of success. I think that -- how would you measure a
6 reasonable expectation of success without some understanding of what the
7 purpose of the invention was?
8 Petitioner suggests that, I think, essentially, that the method need not
9 actually treat overactive bladder and incontinence. And I think the claim
10 language does require a method of treatment for those things, and that if
11 there's no record evidence suggesting that, you know, the claim treatments
12 schedule was not only would it lead to a reasonable expectation of treating
13 the conditions claimed, that there is a failure, again, of proof by Petitioner on
14 that.
15 JUDGE NEW: Is there a problem for that argument, however, in that
16 none of the claims in either of the two patents, either the '742 or the other
17 one, set forth any criteria for efficacy of the treatment? In other words, it
18 doesn't say reducing the amount of overactive bladder. I think it's simply a
19 method of treatment. It doesn't make any claim as to what kind of degree of
20 efficacy you would get. So, even a very slight method of treatment, or
21 maybe an ineffective treatment, if you're still treating it, because we get to
22 efficacy, there's nothing in the claims about that. It's just a matter of treating
23 it by stimulating the nerve.
24 MR. GERASIMOW: I think the -- this proceeding is limited to
25 invalidity and claim construction in support of invalidity, and with respect to

invalidity, only serve as grounds of it. I don't actually think it's a problem for the patents if they don't claim that. I do think that the -- I'm sorry, they don't claim the specific level of efficacy. I think they do claim efficacy. I disagree that ineffective treatment would be a treatment.

But in any event, I think we have a specification that talks about effective treatment, and since an enablement claim is not at issue in these proceedings, and written description isn't -- because Petitioner hasn't really raised claim construction. It's just that we don't have to go too far into that.

JUDGE NEW: All right. Thank you.

MR. GERASIMOW: Thank you. I will yield the rest of my – the balance of my opening time to Petitioner. Thank you.

JUDGE O'HANLON: I just have one comment.

MR. GERASIMOW: Oh, sure.

JUDGE O'HANLON: There was some question about the Gerber reference that Judge New mentioned earlier. He was referring to Exhibit 1069.

MR. GERASIMOW: Okay.

JUDGE O'HANLON: There are two Gerber references. I just wanted to point that out to you.

MR. GERASIMOW: Okay. Thank you.

MR. DEIGHAN: Thank you, Your Honors.

JUDGE NEW: You have 15 minutes, Mr. Deighan. You may begin.

MR. DEIGHAN: Thank you, Your Honors. I really just have a few points that I'd like to make here.

First of all, one of the issues that was raised by the Patent Owner relates to the timing of the reply evidence. And I would direct you to Slide 52, where we cite the precedential Hulu decision, the Consolidated Trial Practice Guide, the CFR, all of which show that a petitioner is absolutely permitted to submit public accessibility evidence on reply. And that's exactly what we did here. So I don't think there was any issue with respect to the timing.

I would also just note that, in the preliminary responses, the only reference that was mentioned with respect to this issue was Svihra. There was no challenge to all these other references. So again, the -- certainly the timing of the reply evidence, I think that our evidence was perfectly permissible under the Board's precedented rules.

So, as to the -- the 1375 proceeding discussed the obviousness issue here. And one of the things that Patent Owner seems to be asking the Board is, effectively, to ignore our expert, but they never challenge his qualifications. You know, they never said that he wasn't an expert, wouldn't understand how to interpret these references. And so, his testimony is absolutely relevant to how a person of ordinary skill in the art would understand the prior art here, understand its teachings. And any attorney argument here by Patent Owner alone can't rebut this, and I think that's clear from Board precedent as well.

We also discussed Mann and Boveja. Those references explicitly say -- refer to stimulating the posterior tibial nerve, and that the posterior tibial nerve is a nerve that emanates from the sacral roots of the spine. Those references go on to say that you can stimulate the nerves in the -- nerves

emanating from the sacral region, and their branches. So, the references don't literally say medial plantar or lateral plantar nerve, but I think that, based on the teachings, and as our expert has said in his declaration, a person of ordinary skill in the art would have understood that the posterior tibial nerve or the branches could be stimulated.

I would also just point out here, Judge New, you were mentioning a reference that talked about -- provided motivation. And I think what you were referring to is Mann.

The Mann reference says selective stimulation of given branches may offer advantages for the treatment of certain disorders, including avoiding recruitment of nerves unrelated to the desired treatment. And that's Exhibit 1084, at 12, 26 to 41. And that's cited explicitly in our Petition, Paper 2, at page 30.

And so, a person of ordinary skill in the art would have been motivated to modify Svihra and Amarenco to target branches of the posterior tibial nerve to avoid recruitment of other nerves near the original stimulation site.

That's just one of the several different motivations that we discussed. But I did just want to point out that it was the Mann reference.

JUDGE NEW: Thank you for pointing it out to me.

MR. DEIGHAN: I would also like to briefly address here Dependent Claim 4. It was raised during -- Dependent Claim 4 of the '742 Patent that was mentioned by Patent Owner.

I believe that the Patent Owner mentioned that there was nothing in the record that teaches the treatment schedule that's specified in Claim 4, but

there is. Svihra explicitly discloses that treatment schedule, 30 minutes per week. And I think Patent Owner concedes that in their papers, Paper 12, at 25. And then in our Petition, we cite a few other references that disclose that exact same treatment schedule.

And so, with respect to Claim 4, I think taking the primary references one at a time, with respect to Svihra, there's no need to show an additional expectation of success for Claim 4, because Svihra explicitly discloses this. We've shown why Claim 1 would have been obvious and why a person of ordinary skill in the art would have had a reasonable expectation of success.

And the only modification that we're making to Svihra's procedure is instead of targeting the posterior tibial nerve, we're saying that it would have been obvious to target branches of the posterior tibial nerve. And I think, as the Board pointed out in the institution decision, all that requires is moving the electrodes from the ankle to the bottom of the foot.

And so, but getting back to Claim 4, we're not changing the treatment schedule that's already explicitly disclosed in the Svihra reference.

And then, with respect to the Amarenco reference ground, the Amarenco ground, Petition does explain why a person of ordinary skill in the art would have been motivated to use this treatment schedule. That's explicitly in our papers, Paper 2, at 55. Our expert walks through this, Exhibit 1003, at 162. And so, to the extent that Patent Owner is looking for some conclusive proof of efficacy here, that's just not required. And we cite Acorda v. Roxane, 903 F.3rd 1310, at 1333, in our Reply at Paper 15 at 27.

And so, again, for both Grounds 1 related to Svihra and Ground 2 related to Amarenco, we think that Claim 4 of the '742 is also invalid.

And then, just to wrap up, I would direct Your Honors to Slide 2. And just to point out here that -- what our specific grounds are here. So, in the 1378 proceeding, our Grounds 1 to 5, Ground 1, it relies on Svihra, and it argues Claim 1 would have been anticipated; in Ground 2, it's Svihra, Mann, DiLorenzo, Gerber, and Bourget; in Ground 3, Svihra, Mann, DiLorenzo, Gerber, Bourget, along with the knowledge of a person of ordinary skill in the art. And then those same references are relied on in Grounds 4 and 5 for the Amarenco combinations.

And then in the 1375 proceeding, the grounds are Svihra -- Ground 1 is Svihra in combination with Mann, Ponsford, the knowledge of a person of ordinary skill in the art. And then Ground 2 is Amarenco in combination with Mann, Ponsford, and a person of ordinary skill in the art. So I just wanted to clarify exactly what references we are relying on in our invalidity grounds, and that I think, as was discussed, the knowledge of a person of ordinary skill in the art would include some of these other references that we've mentioned here.

JUDGE GROSSMAN: Mr. Deighan, when you identify the person of ordinary skill in the art in some of your 103 grounds, doesn't this, the level of ordinary skill of -- a person of ordinary skill applies in every 103 ground? That's the definition of what an obviousness ground is under the statute is whether it would have been obvious to a person of ordinary skill in the art.

MR. DEIGHAN: That's absolutely right. And I think that it was discussed earlier. An obviousness analysis always includes the knowledge of a person of ordinary skill in the art. A person of ordinary skill in the art is always assumed to have a knowledge of all the references in the field. So I

think you're exactly right. I think we've done that here just to clarify that that's part of the 103 grounds.

So, with that, I will take a seat, and I thank you, Your Honors, very much.

JUDGE NEW: Thank you very much, Mr. Deighan.

Mr. Gerasimow, do you want any -- you have a total of 28 minutes, and you may begin when you're ready.

MR. GERASIMOW: Thank you, Your Honor. I only have one point. It's about Claim 4. It's about paragraph 163 of Dr. Wingeier's declaration in the 1375 IPR. And --

JUDGE NEW: I'm sorry. Could you repeat the paragraph number?

MR. GERASIMOW: I said 163, but I would like -- I meant 162.

JUDGE NEW: Okay. Thank you.

MR. GERASIMOW: And I think this is the paragraph we were -- that the Petitioner was -- I'm sorry. Yeah, Petitioner was alluding to during their response here, and I think that what we see in paragraph 162 is the statement that, you know, results would have been predictable. And there's very little explanation of it other than people do things commonly for 30 minutes. I wanted to point that out for the record, what that declaration actually said.

I don't have any further comments, but I'm happy to answer any remaining questions the Board may have.

JUDGE NEW: Okay. Any questions from the Panel? Judge Grossman, any questions?

JUDGE GROSSMAN: I have no questions.

JUDGE NEW: Thank you very much. I appreciate that.

MR. GERASIMOW: Thank you.

JUDGE NEW: Well, since there are no questions from the Panel, I'd like to thank you, all of you, for a very interesting, productive, and stimulating discussion. It was very ably argued by the counsel for both parties. We have now taken this matter under advisement, and a decision will be issued in due course. We stand adjourned. I'll ask you to please remain for a few minutes to see if there are any questions from the court reporter. As of now, we are off the record.

(Whereupon, the above-entitled matter went off the record at 10:34 a.m.)

Petitioner:

Todd Tucker
Kyle Deighan
CALFEE, HALTER & GRISWOLD LLP
ttucker@calfee.com
kdeighan@calfee.com

Patent Owner:

David Gerasimow
Eran Steinberg
The Law Offices of David A. Gerasimow, P.C.
dave@gerasimowlaw.com
venture@eransteinberg.com