

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AQUESTIVE THERAPEUTICS, INC.,
Petitioner,

v.

NEURELIS, INC.,
Patent Owner.

Case IPR2019-00451
Patent 9,763,876 B2

Record of Oral Hearing
Held: May 14, 2020

Before ZHENYU YANG, JON B. TORNQUIST, and JAMIE T. WISZ,
Administrative Patent Judges.

IPR2019-00451
Patent 9,763,876 B2

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The above-entitled matter came on for hearing on Thursday, May 14, 2020, commencing at 1:00 p.m., EDT, via Video Teleconference.

PROCEEDINGS

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1:00 p.m.

JUDGE WISZ: So, today we will hear arguments in IPR 2019-00451 concerning U.S. Patent Number 9763876. I am Judge Wisz and I'm joined today by Judge Tornquist and Judge Yang.

So, let's start with appearances, beginning with Petitioner.

MR. SCOLA: Daniel Scola representing Aquestive Therapeutics. And my partner, Mike Chakansky, is also here and will do some speaking.

MR. CHAKANSKY: Yeah, Michael Chakansky here.

JUDGE WISZ: Thank you. Patent Owner?

MR. GUISE: For the Patent Owner, I'm Jeff Guise, lead counsel. Wendy Devine is going to be arguing today. We also have on the audio line several people from the client Neurelis. Craig Chambliss and Jenny Alonso. Thank you.

JUDGE WISZ: Thank you. And we'd like to remind the parties that we each have a copy of the demonstrative exhibits you provided. But during your argument please identify clearly and specifically each demonstrative referenced by slide or screen number so that everyone can follow along and to ensure clarity and accuracy of the court reporter's transcript.

On that note, we did receive some objection to the demonstrative exhibits from Patent Owner. We reviewed the demonstrative --

MR. SCOLA: I'm sorry, Your --

JUDGE WISZ: Yes?

MR. SCOLA: There was some feedback, Your Honor, I apologize.

1 JUDGE WISZ: Okay. So we've reviewed the demonstrative and
2 the objections, and we have taken the objections into consideration.

3 We note that the demonstratives are just here to guide the arguments
4 and are not coming in as evidence. We also note that we will not consider
5 any new arguments.

6 Just a few more reminders before we begin. I am getting some
7 feedback. We request that you keep your line muted when you're not
8 speaking, which might help some of the feedback.

9 And also please keep in mind that the remote nature of this hearing
10 may result in audio lags. So please pause prior to speaking so as to avoid
11 speaking over others.

12 So with that, consistent with our hearing order, each party has 60
13 minutes to present their arguments. Petitioner, you'll proceed first. And
14 you may reserve time for rebuttal. How much time would you like to
15 reserve, if any?

16 MR. SCOLA: Your Honor, we anticipate about 15 minutes for
17 rebuttal. Approximately. But whatever we don't use in our argument, we'd
18 like to reserve.

19 JUDGE WISZ: Okay. We will keep track of the time and I'll give
20 you a reminder with five minutes left. But we do encourage the parties to
21 keep track of your own time as well.

22 Petitioner, you can proceed whenever you're ready.

23 MR. SCOLA: Okay, thank you, Your Honor. Good afternoon.
24 My name is Daniel Scola, representing the Petitioner, Aquestive, along with
25 my partner Michael Chakansky. And as I mentioned, each of us will do
26 some talking during this hearing.

1 The first issue I'd like to discuss is the lack of description about the
2 glycosides in the 558 provisional application. Which means that Patent
3 Owner cannot rely on the 558 provisional filing date for the 876 patent
4 claims.

5 The reason that the 558 provisional application lacks description of
6 alkyl glycosides is because the Patent Owner didn't even have possession of
7 alkyl glycosides when the provisional was filed.

8 Now, the 876 patent claims recite alkyl glycoside as an essential
9 element. All of the claims require alkyl glycosides.

10 And alkyl glycosides are not disclosed, described or enabled in the
11 priority 558 provisional. Dr. Peppas speaks to this in his declaration.
12 That's Exhibit 1041 at Paragraphs 68 through 70. We raise the petition at
13 Page 20.

14 So once the Petitioner raises this issue, the burden then shifts to the
15 Patent Owner to prove otherwise, as the PTAB recognizes in the decision.
16 And they have not done so.

17 The burden means that they must show that the alkyl glycoside is
18 supported through the chain of priority. Now, there are several reasons why
19 the incorporation by reference of the SIGMA Catalog, which is a non-patent
20 document, is not proper.

21 First, alkyl glycosides is an essential element through all the claims.
22 This is in violation of 37 CFR 1.57.

23 Incorporation of essential material from a non-patent document is
24 improper. 37 CFR 1.57 is controlling. So that's the first reason.

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