

UNITED STATES COURT OF APPEALS

FOR THE FEDERAL CIRCUIT

-----x

Neurelis, Inc.,

Appellant,

Vs.

Aquestive Therapeutics, Inc.,

Appellee.

2021-1038

-----x

ORAL ARGUMENT

October 5, 2021

1
2 CHIEF JUDGE MOORE: ...today is 21-1038, Neurelis vs. Aquestive
3 Therapeutics. Ms. Devine, please proceed when you're ready.

4 WENDY DEVINE: Thank you, Your Honor. Good Morning. Wendy Devine
5 on behalf of Neurelis, Incorporated. The Board's obvious misfindings
6 are based on a legally flawed conclusion regarding priority.
7 Specifically, the Board's decision should be reversed because the Board
8 erred in two ways. First, the Board improperly interpreted dependent
9 claims 26 to 28 and 30 to 33, which recite dodecyl maltoside. The Board
10 interpreted those claims as requiring nothing more than the alkyl
11 glycoside limitation of independent claim one. This error led the Board
12 to disregard these dependent claims and failed to address the
13 undisputed support for dodecyl maltoside in the provisional
14 application. Second, with respect to the alkyl glycoside limitation of
15 the remaining claims, the Board failed to apply the correct legal
16 standard in that it first required a disclosure of a preference for the
17 claimed embodiment as opposed to evidence of possession of the claimed
18 embodiment. And then it misapplied the law regarding incorporation by
19 reference, resulting in a failure to treat the entirety of the six
20 pages of the Sigma catalogue, which are indisputably incorporated into
21 the provisional application as incorporated. Now I'd like to begin with
22 the first error, which specifically relates to six of the dependent
23 claims. The Board erroneously interpreted the scope of those six
24 claims. Independent claim one, from which those six claims depend -
25

1 CHIEF JUDGE MOORE: Before you go into the merits, would you just
2 address the waiver argument? Because I understand your opponent to
3 suggest that you didn't make this argument below. It was made only in a
4 single footnote in passing and not a developed argument. So can you
5 show us where you made this argument below in a way that alerted the
6 Board to the fact that you were separately arguing dependent claims and
7 not just hinging your argument on a representative claim, as lawyers
8 often do in these cases?

9 WENDY DEVINE: Certainly, Your Honor. If we turn to Appendix 487,
10 and we did make this argument in a footnote.

11 CHIEF JUDGE MOORE: Page 487?

12 WENDY DEVINE: Appendix 487. In this footnote, we reference the
13 testimony of petitioner's expert, Dr. Peppas, in his cross-examination,
14 his deposition, about his declaration that supported the petition. And
15 we state, and I quote, "Dr. Peppas agreed that the Sigma catalog" --
16 that's the document that was incorporated by reference into the
17 provisional application -- "includes alkyl glycosides specifically
18 identifying dodecyl maltoside." And then we further note that dodecyl
19 maltoside is what is claimed in these six claims and is what is
20 disclosed in that Sigma catalog entry. Now, for context, Your Honor, at
21 this point in the proceeding, it was undisputed that dodecyl maltoside
22 was disclosed in the Sigma catalog and recognized by a person of skill
23 in the art. Patent owner's expert, Dr. Gizurason, said that it was his
24 opinion that that was the case. Dr. Peppas, petitioner's expert, said
25 that he agreed that that was what is disclosed in the Sigma catalog.

1 Now, notably, petitioner, in their petition, did not even address the
2 Sigma catalog. They did not put it in the record. They did not
3 acknowledge its content. And they only made a conclusory statement that
4 somehow alkyl glycosides, and specifically dodecyl maltoside, were not
5 disclosed, described, or enabled. In the institution decision, the
6 Board cited a rule of prosecution to state that the incorporation of
7 the Sigma catalog was somehow improper because you cannot incorporate
8 essential material. That justification that the Board provided for the
9 petitioner was abandoned in the final written decision.

10 CHIEF JUDGE MOORE: So what's the point of that? The Board made a
11 mistake in the institution decision when it said it wasn't
12 incorporated. And then they overcame that mistake in their final
13 decision by treating it as incorporated. Now, we all make mistakes.
14 They were smart enough to recognize it and overcome it. So how does
15 that help you? What's the point?

16 [00:05:00]

17 WENDY DEVINE: When we filed this patent owner response, the
18 context of that was what was laid out. The issue that was identified by
19 the petitioner was a lack of disclosure of alkyl glycosides, and
20 specifically dodecyl maltoside, that did not acknowledge, analyze, or
21 discuss a document that, at this point in the proceeding, is
22 indisputably incorporated by reference into the provisional disclosure.
23 So when we were filing this response, there was no discussion that that
24 disclosure, that literal disclosure of dodecyl maltoside, was somehow
25

1 insufficient to provide written description for a claim that claims
2 dodecyl maltoside.

3 CHIEF JUDGE MOORE: But the problem for me -- and I struggle with
4 this- - it's a "consisting of" claim. It's not a comprising claim. So
5 you have a disclosure that's incorporated by reference that discloses,
6 I don't know, 150 different things? How many does it disclose? 200? I
7 don't know how many.

8 WENDY DEVINE: There are a number of compounds. I believe it's
9 over 100. But they are categorized in the Sigma.

10 CHIEF JUDGE MOORE: In that Sigma document, I think it's over 150,
11 isn't it? Something like that?

12 WENDY DEVINE: I think that's about right.

13 CHIEF JUDGE MOORE: OK. So it discloses 150 different possible --
14 are these compounds?

15 WENDY DEVINE: Compounds, yes.

16 CHIEF JUDGE MOORE: OK. I'm sorry. I'm doing my best here. So 150
17 different compounds. Then you have this "consisting of" claim, which
18 means "this and only this." How does a disclosure of 150 random
19 compounds satisfy the need to show possession of "this and only this"?

20 WENDY DEVINE: So to begin with, that disclosure of all of those
21 compounds are categorized. And that disclosure must be read from the
22 perspective of a person of skill in the art. And when the incorporation
23 by reference appears in the provisional catalog, what it says is you
24 can have these certain agents. Some of them are surface acting agents,
25 which are surfactants. And preferably non-ionic versions of those. Then

1 it goes on to say, also, these biological detergents that are disclosed
2 in the six pages of the Sigma catalog. Now, biological detergents are
3 surface acting agents. They're surfactants. That's not disputed in the
4 record. And petitioner's expert said so at deposition. So what it's
5 pointing you to is the Sigma catalog and saying, look at the biological
6 detergents here. And in particular, look at the non-ionic ones. And if
7 you turn to the first page of the Sigma catalog -

8 JUDGE REYNA: One way or the other, isn't it the specification
9 itself that's got to show possession, and not extraneous documents?

10 WENDY DEVINE: The Sigma catalog is incorporated by reference. And
11 at this point, it is undisputed. The Board accepted that it's
12 incorporated by reference into the provisional application. So what
13 that means is it has to be taken in its entirety with all that it
14 discloses and placed inside the specification. So it's not an
15 extraneous document. It is part of the specification. So we can look at
16 the pages of the Sigma catalog and say, this is the specification of
17 the provisional disclosure. And if I may direct Your Honors to the
18 appendix where that Sigma catalog appears, Appendix 10705, this page in
19 particular exemplifies our point. So here you have selected biological
20 detergents. The specification has told you these biological detergents
21 are part of the inventor's invention. And they pointed you specifically
22 to the non-ionic ones. And within these selected detergents, if you
23 look towards the bottom, the non-ionic compounds listed, there's 10 of
24 them. Seven of them are alkyl glycosides. And Petitioner's own expert
25

1 readily recognized them as alkyl glycosides at his deposition without
2 hesitation.

3 JUDGE NEWMAN: To be absolutely clear, when were the claims to the
4 species that we seem to be concerned with, the dodecyl maltoside, when
5 were those claims added? I gather they were not in the provisional. Is
6 that right?

7 WENDY DEVINE: That's correct. They were in the utility
8 application that followed the provisional, which claims priority to the
9 provisional.

10 JUDGE NEWMAN: OK.

11 WENDY DEVINE: So there is literal support for the dodecyl
12 maltoside limitation. There can be no doubt about that if you are
13 actually accepting the incorporation by reference, which is not in
14 dispute. Moving to the alkyl glycoside -

15 CHIEF JUDGE MOORE: When you say there's literal support, the
16 problem is even if I were to agree, which the Board did not, the Board
17 did not agree that, as a factual matter, you had pointed people to
18 using, in particular, non-ionic detergents. As a factual matter, I'd
19 have to say there's no substantial evidence for that Board fact-finding
20 to get there. But there are, I think, in excess of 60 non-ionic
21 detergents listed, only a handful of which are alkyl glycosides, and
22 only one of which is dodecyl maltoside.

23 [00:10:09]

24 So you have an incorporated by reference disclosure with 150
25 compounds in it, 60 under the header non-ionic detergent. How did the

1 inventor show possession of "this and only this," because of the
2 "consisting of" language, to the exclusion of the other 59 non-ionic
3 detergents that are listed?

4 WENDY DEVINE: So the "consisting of" language does not change the
5 legal standard, which requires only that the inventor show that they
6 possessed what was claimed in the priority document. It does not mean
7 that the priority document must be restricted to and only describe that
8 one embodiment. The inventor was in possession of all of the
9 embodiments. The only question to be asked is -

10 CHIEF JUDGE MOORE: No, the inventor was not in possession of --
11 how can you say the inventor was in possession of all of the
12 embodiments? There are all kinds of compounds in here that wouldn't
13 satisfy these claims, or even the goal of these claims. So you're
14 telling me the inventor is in possession of all 150 possible compounds
15 listed in the Sigma reference, even though many of them would
16 absolutely not function as a method for treating a patient with this
17 disorder?

18 WENDY DEVINE: Yes, and my response to that is that the
19 specification, the priority disclosure, and the claims do not need to
20 be coextensive. The inventor is entitled to claim one of the
21 embodiments that is disclosed in the specification, and to disclose
22 other embodiments that may be claimed later, or may not be. The
23 question to be asked on whether there is written description support in
24 the provisional application is not whether there is pointing to "this
25 and only this" embodiment in the provisional application. The question

1 to be asked is, a person of skill in the art reading this disclosure,
2 do they readily recognize that the inventor was in possession of what
3 they are claiming at the time that the provisional was filed? And the
4 answer here is yes. Does it show that the inventor was in possession of
5 other embodiments of the invention? Yes, but it does not require that
6 it be limited only to a disclosure of the particular claimed
7 embodiment.

8 CHIEF JUDGE MOORE: When you say, does it show the inventor was in
9 possession of other embodiments, I see no evidence in this patent, or
10 otherwise, that other than the alkyl glycosides, the other 143
11 different compounds listed in the Sigma reference would have worked at
12 all. So what we have is an inventor who threw out 150 compounds in a
13 provisional. These provisional applications get filed before inventors
14 have really honed in on what their precise invention is. And so he or
15 she threw out a provisional, which incorporated by reference all of
16 these compounds, but then later determined only a small handful of them
17 actually worked, or were worth claiming, or what? I don't know. And
18 that's why, how are we supposed to figure out the inventor possessed,
19 as of the date of the provisional, the fact that these particular ones
20 would have worked?

21 WENDY DEVINE: So I agree with Your Honor that if the inventor is
22 going to claim something, there has to be both written description and
23 enablement. The person of skill in the art has to be able to practice
24 the invention. But the question at issue here for priority is not the
25 enablement. It is the written description. And did the inventor convey

1 that this was part of their invention at the time of the filing of the
2 provisional? And the inventor did point to dodecyl maltoside. There is
3 literal support in the written description for that claim limitation.
4 That is just a matter of fact that cannot be disputed.

5 CHIEF JUDGE MOORE: You said there's literal support in the
6 written description. You mean because dodecyl maltoside is one of 150
7 different compounds articulated in the Sigma reference.

8 WENDY DEVINE: So because dodecyl maltoside appears in the
9 specification, yes, as part of that incorporation.

10 CHIEF JUDGE MOORE: It appears in the specification by virtue of
11 the incorporation.

12 WENDY DEVINE: Correct.

13 CHIEF JUDGE MOORE: Not separately.

14 WENDY DEVINE: Correct.

15 CHIEF JUDGE MOORE: So did the inventor, just out of curiosity,
16 possess, claim one, but without an alkyl glycoside, suppose instead we
17 added lithium salt, which is one of the anionic detergents listed in
18 the Sigma reference. Did the inventor possess this method of treating a
19 patient with this disorder? So a method of treating a patient assumes
20 as part of the construction that it would actually treat the patient,
21 right? Is that fair?

22 WENDY DEVINE: Correct.

23 [00:15:00]

24 CHIEF JUDGE MOORE: Yeah. So did this inventor possess this method
25 precisely, instead of except for the words "and an alkyl glycoside," we

1 stick in lithium salt? Did he possess that compound, that particular
2 method?

3 WENDY DEVINE: That would have to be assessed from the perspective
4 of a person of skill in the art. And if that was the claim, at issue -

5 CHIEF JUDGE MOORE: But you're telling me the fact that he
6 incorporated by reference something with 150 compounds means he
7 possessed all 150.

8 WENDY DEVINE: So it's not a laundry list of 150 compounds, to
9 begin with. It is a categorized disclosure of different compounds. And
10 the specification does specifically call out that non-ionic is what is
11 important.

12 CHIEF JUDGE MOORE: The Board disagreed with you on that as a
13 factual matter. The Board did not agree that the Sigma reference was
14 limited to the 60 compounds listed as non-ionic detergent.

15 WENDY DEVINE: Yes, but the Board did not disagree that the
16 biological detergents that are disclosed in these six pages are
17 incorporated into the specification. They were identified -

18 CHIEF JUDGE MOORE: So that's 150. So 150 things are incorporated
19 into the specification, most of which probably don't work to treat
20 somebody with this condition.

21 WENDY DEVINE: So Your Honor, that's a question of enablement on a
22 claim that's not at issue. Enablement was not -

23 CHIEF JUDGE MOORE: You're asking me to conclude that a fact
24 finding the Board made about what the inventor possessed at a very
25 early time, the provisional application, whether to overturn a fact

1 finding about what an inventor possessed, and you're doing it based
2 simply on a large- scale disclosure of 150 compounds.

3 WENDY DEVINE: So the Board did not make a finding based on
4 possession. They made a finding based on preference, which was their
5 legal error. That is not the standard. The specification does not need
6 to show a preference for the dodecyl maltoside. It need only show
7 possession. So that is where the Board got it wrong. They applied the
8 incorrect legal standard to the facts. And what the facts show, the
9 only testimony of record are from patent owner's expert and
10 petitioner's initial expert that they readily recognize alkyl
11 glycosides as a subgenus and dodecyl maltoside specifically in the
12 specification of the provisional document.

13 JUDGE REYNA: So what's your strongest evidence for possession of
14 the alkyl glycosides in the provisional?

15 WENDY DEVINE: It's the Sigma catalog. And for dodecyl maltoside
16 in particular, it's part of the specification. That compound appears in
17 the specification as part of the written description. That is what the
18 inventor said. "This is what I've invented. This is my invention," when
19 they filed their provisional application.

20 CHIEF JUDGE MOORE: Well, you've used all of your time and all of
21 your rebuttal time. So why don't we hear from Mr. Scola, please?

22 WENDY DEVINE: Thank you, Your Honor.

23 DANIEL SCOLA: Good morning. May it please the Court. The Board's
24 decision was based on substantial evidence based on the testimony of
25

1 Aquestive's experts that there was no written description for alkyl
2 glycosides or dodecyl maltoside.

3 CHIEF JUDGE MOORE: Just as a matter of housekeeping. You agree
4 that the Board's original conclusion in the petition that this wasn't
5 incorporated by reference was modified in the final decision. And the
6 Sigma disclosure, these six pages, are considered incorporated by
7 reference into the material.

8 DANIEL SCOLA: Yes, Your Honor, yes, certainly.

9 CHIEF JUDGE MOORE: Just as a housekeeping matter. I just wanted
10 to do that. Go ahead.

11 DANIEL SCOLA: The board also found substantial evidence for the
12 motivation to combine the references. And when those references were
13 combined by POSA, there was a preponderance of evidence that led to the
14 unpatentability of all the claims. I would like to address a couple of
15 points before I get into written description. The first is Neurelis'
16 argument that there was not proper notice given in respect to the Sigma
17 catalog and written description. Under Dynamic Drinkware, Aquestive
18 fulfilled its burden of production when it asserted invalidating prior
19 art against the 876 claims. It was not required to recite the Sigma
20 catalog. Once that invalidating prior art was cited, the burden of
21 production shifted to Neurelis. That's all that's required under
22 Dynamic Drinkware. However, in the petition, we did go a step further,
23 and we did give notice there was no written description with respect to
24 alkyl glycosides and dodecyl maltoside. We did that in the appendix at
25 225.

1 [00:20:00]

2 The point about the waiver of the dependent claims. During oral
3 argument, Judge Turnquist asked the following, and I quote: "Counsel,
4 this is Judge Turnquist.

5 CHIEF JUDGE MOORE: What page are you reading from, the Appendix?

6 DANIEL SCOLA: 803 in the appendix. That's when the question was
7 asked. And then the next page is 829. That's when it was answered.

8 "Judge Turnquist: Counsel, this is Judge Turnquist. I have maybe a
9 follow-up question. Where in the patent owner response do you address
10 the claim, the claims as a whole for written description support?"
11 Counsel's answer was, "Regarding Your Honor's questions regarding
12 whether we laid out in our papers the provisional support for each and
13 every limitation of the claims, it's not explicitly here. And that's
14 the waiver of the dependent claims, Your Honors. Now, I would like to
15 say also that the Board expressed -

16 CHIEF JUDGE MOORE: I'm sorry, where were you reading from? I see,
17 "Counsel, this is Judge Turnquist. I have a follow-up question. Where
18 in the patent owner response do you address the claims, the claims as a
19 whole for written description?"

20 DANIEL SCOLA: Yes, and then on the next page, 829 of the
21 Appendix.

22 CHIEF JUDGE MOORE: 829?

23 DANIEL SCOLA: 829, yes. I think it's towards the middle of the
24 page, Your Honor. It starts, "Regarding Your Honor's questions,
25 regarding whether we laid out our papers."

1 CHIEF JUDGE MOORE: Well, counsel, I mean, they asked a question,
2 and then there's 26 pages of testimony that you didn't give me, and
3 then an ambiguous answer, "Regarding Your Honor's questions regarding
4 whether we laid out in our papers the provisional support for each and
5 every limitation of the claims. It's not explicitly there." Each and
6 every limitation? I don't know what limitations they're talking about.
7 I mean, respectfully, I don't see how that helps you at all.

8 DANIEL SCOLA: Yes, Your Honor, when they first asked the
9 question, opposing counsel said that she would answer this on rebuttal.
10 And so that's why there's all this intermediate discussion that went
11 on. And then they asked for written description support of all the
12 claims, and that was the answer.

13 CHIEF JUDGE MOORE: That doesn't mean that she's admitting that
14 there's no written description support for dodecyl maltoside.

15 DANIEL SCOLA: Well, with respect, Your Honor, if there's no --
16 they say it's explicitly not there. I mean, written description--

17 CHIEF JUDGE MOORE: Who says it's explicitly not there?

18 DANIEL SCOLA: If her answer is, "With respect to written
19 description of each and every limitation of the claims, it's not
20 explicitly there."

21 CHIEF JUDGE MOORE: Each and every limitation. She's not saying no
22 claim limitations are supported. She says maybe there's some that
23 aren't supported. When she says "each and every limitation, it's not
24 explicitly there," I'm sorry, but with all due respect, I don't have
25 any clue what limitation she's talking about at that point.

1 DANIEL SCOLA: Yes, Your Honor.

2 CHIEF JUDGE MOORE: Perhaps the 26 intervening pages would have
3 lent some clarity between the question and the answer you want me to
4 assume is an answer to a particular question, but -

5 DANIEL SCOLA: I understand, Your Honor. Those pages do not
6 provide any additional information, however. I do want to state also,
7 however, that the Board did expressly address dodecyl maltoside. They
8 did this in the appendix, page 19 at the beginning, when they said that
9 after they have incorporated, by reference, the 12 alkyl glycoside
10 species, there was no written description for the 12 alkyl glycoside
11 species, which, of course, includes the species dodecyl maltoside. Now,
12 I will also mention that the term alkyl glycosides appears nowhere in
13 the Sigma catalog or in the 558 provisional. That was a term cobbled
14 together.

15 CHIEF JUDGE MOORE: The Board did not specifically address
16 anywhere the dodecyl maltoside, did they?

17 DANIEL SCOLA: I think it does, because when they address the 12
18 alkyl glycosides, it has to include dodecyl maltoside. And they also
19 addressed it later on when it dealt specifically with the dodecyl
20 maltoside dependent claims. It had to.

21 CHIEF JUDGE MOORE: Where is that? What page can I find that?

22 DANIEL SCOLA: One moment, Your Honor. Pages 33 to 35 of the
23 appendix.

24 [00:25:00]
25

1 CHIEF JUDGE MOORE: And where do you say they address whether or
2 not there's support for the dodecyl maltoside? This looks like it's
3 just articulating the arguments. Am I missing something?

4 DANIEL SCOLA: Yes, in the Appendix on page 19, at the top of that
5 page, they expressly -

6 CHIEF JUDGE MOORE: They expressly talk about dodecyl maltoside?

7 DANIEL SCOLA: They talk about that they incorporated the 12 alkyl
8 glycoside species. Once that was incorporated, there was no written
9 description for the 12 alkyl glycoside species.

10 CHIEF JUDGE MOORE: Well, OK, but it's saying there's nothing that
11 leads someone to alkyl glycosides in the Sigma catalog. But is that
12 different from whether there's something that leads somebody
13 specifically to dodecyl maltoside?

14 DANIEL SCOLA: Well, Your Honor, that was just a truncated way of
15 listing the 12 alkyl glycoside species. I'm not sure that the Board
16 recognized all 12. They know there's 12 there because our experts
17 recited 12. But dodecyl maltoside certainly is one of the 12 species.
18 And if they're saying that there's no written description for the 12
19 alkyl glycoside species, that certainly means that there's no written
20 description for each of them, including dodecyl maltoside.

21 CHIEF JUDGE MOORE: So why? I'm confused. If this patent had
22 listed 150 compounds right in the specification, wasn't even
23 incorporated by reference, 150 compounds, why doesn't that satisfy the
24 possession requirement?

1 DANIEL SCOLA: I don't think it's a question of numbers, Your
2 Honor. It's a question of whether there's direction enough to show that
3 they have possession. I think it's instructive to look at the totality
4 of the 558 provisional. What Neurelis is arguing, basically, is that
5 they're focusing on one page of the Sigma catalog, which is six pages,
6 and to the exclusion of those six pages, and all the rest of the
7 enhancer paragraphs in 558. And if you would like to turn to page 8 of
8 the red brief, it's quite instructive because it gives you paragraphs
9 150 to 152. There, you can see that there's a discussion of the
10 enhancers. And in those paragraphs, there's 15 classes that are
11 provided of enhancers. And in fact, in paragraph 151, you can see that
12 there are preferences. Two classes are preferred, the lysophospholipids
13 and the acylcarnitines, with some preferred species of each. Then as
14 you go down to paragraph 152, you see additional classes that are
15 listed. One of them is surface active agents. And in parentheses, it
16 says "especially non-ionics." And then an additional listing -

17 CHIEF JUDGE MOORE: Just out of curiosity, since it says "surface
18 active agents, especially non-ionic materials," why wouldn't that, as
19 opposing counsel suggested, take you to page 10705 of the Sigma
20 reference, which is incorporated by reference, which has a category
21 non-ionic, and it lists 10 things, 7 of which are alkyl glycosides. So
22 why wouldn't that show possession to a skilled artisan?

23 DANIEL SCOLA: We have two comments to make with respect to that
24 question, Your Honor. The first is that we have agreeing testimony from
25 experts on both sides that says that the term non-ionics, as it relates

1 to surface active agents, is not in any way linked or connected to the
2 class of biological detergents. And in fact, even a layman looking at
3 it would see that they are distinct classes. However, Aquestive's
4 expert took this a step further and said, well, what if a POSA was
5 prompted by non-ionics? Then you go to the Sigma catalog, which was
6 incorporated, all six pages by reference, and when you see the six
7 pages -- and that's helpful to look at the six pages, not just focus on
8 one -- that can be found at 10705 of the appendix to 10710. When you
9 look at the entirety of that, you see that there are four subclasses --
10 anionics, cationics, zwitterionics, and non-ionics.

11 [00:30:00]

12 And Aquestive's expert said, even if a POSA were prompted by non-
13 ionics, there's 150 biological detergents that you have to sift
14 through. And then when you get to the non-ionic class, there's 100 non-
15 ionics there, 100 non-ionics, among which there are sprinkled 12 alkyl
16 glycoside species. Again, the term "alkyl glycosides" was in the
17 claims, but it's nowhere to be found in any of the Sigma catalog or the
18 558 provisional. That was cobbled together in order to make a class of
19 alkyl glycosides. But there's testimony from Dr. Wermeling that says
20 that nothing points to, nothing provides direction, and it's not
21 immediately discernible that you would know that alkyl glycosides, or
22 dodecyl maltoside, is part of the invention by going to this catalog,
23 this pricing catalog.

24 CHIEF JUDGE MOORE: So is part of the invention not every one of
25 these 150?

1 DANIEL SCOLA: What we know is that there are some preferred ones,
2 and we can certainly say those are part of the invention. But what we
3 also know is that there's substantial evidence that points to lack of
4 written description with respect to alkyl glycosides and the species
5 dodecyl maltoside.

6 CHIEF JUDGE MOORE: Even though dodecyl maltoside is expressly
7 listed as one of the 150?

8 DANIEL SCOLA: Yes, Your Honor, the mere recitation is
9 insufficient. Unless there's something that shows that the inventor had
10 possession at the time, there's got to be some direction to that
11 species, not just a recitation. And that's what the Board said. The
12 Board relied on the incorporation of those 12 species, and then said,
13 notwithstanding the recitation, there was substantial evidence that a
14 person of ordinary skill in the art would not know that alkyl
15 glycosides or dodecyl maltoside was part of the invention.

16 CHIEF JUDGE MOORE: What was that substantial evidence? Because a
17 lot of times in cases like this, you have literally hundreds upon
18 hundreds of hundreds of possibilities, and it turns out only a couple
19 of them worked, and there wasn't evidence showing the inventor
20 possessed those particular ones. In the Juno case, it was literally
21 billions. So here, we're talking about a list of 150, and I have no
22 idea how many work, but they're claiming 12. And if you were to look at
23 page 1 of the reference, 7 of 10 under the header non-ionic are
24 included. How do we know -- what is the evidence that the Board -- it's
25 a fact question -- so what specifically is the substantial evidence

1 that supports the Board's finding that this disclosure wouldn't have
2 led a skilled artisan to appreciate that this inventor possessed alkyl
3 glycosides in particular?

4 DANIEL SCOLA: Yes, the Board relied on the testimony of a
5 Aquestive's expert, which said that a POSA even being directed to this
6 class of non-ionics in the Sigma catalog still would not know which
7 non-ionic to select, because there's simply no direction as to which of
8 these species would work, which is important. Did the inventor include
9 all of these 150 biological detergents? I mean, after all, this is a
10 pharmaceutical which is intended to go into the body. We don't know
11 which ones work. And there's just simply no direction, no blaze marks
12 that points to dodecyl maltoside among 150 biological detergents. And
13 the substantial evidence was that this testimony of Dr. Wermeling, who
14 was Aquestive's expert, and upon which the Board properly relied.

15 JUDGE REYNA: Counselor, it seems to me that your friend on the
16 other side is arguing that the manner in which the reference is
17 categorized and the categorization of the different non-ionic
18 detergents that are listed here is a sufficient blaze mark. What's your
19 response to that?

20 DANIEL SCOLA: Well, we know from the testimony of Aquestive's
21 expert that even given that as a blaze mark, he even posed that as a
22 blaze mark. If that were to prompt someone who is a POSA to go to the
23 Sigma catalog and look under non-ionics, still no direction as to which
24 one points to dodecyl maltoside. And there is no alkyl glycoside class
25 to point to. There's no sub-subclass.

1 CHIEF JUDGE MOORE: OK, Counsel, I think your time is up.

2 DANIEL SCOLA: Thank you, Your Honor, based on the briefs if
3 there's any further....thank you.

4 CHIEF JUDGE MOORE: Ms. Devine, we'll give you two minutes of
5 rebuttal time.

6 WENDY DEVINE: Thank you, Your Honor. I appreciate it. I will be
7 brief. A couple of notes. The enablement argument, whether it would
8 work, and the "consisting of" argument were not raised below. Those are
9 new arguments raised by Petitioner in their briefing here. And we would
10 submit that under *Bivings v. US Department of Agriculture*, that's 205
11 F.3d 1331 Federal Circuit, 2002, this court cannot affirm based on an
12 argument that was not raised below. The second point I'd like to make
13 is that my friend on the other side continues to espouse a preference
14 argument. And it is not a preference for dodecyl maltoside that must be
15 shown in order to show possession. And there is no evidence of record
16 that says that a person of skill in the art opening the specification
17 and seeing the words dodecyl maltoside would not readily understand
18 that the inventor was in possession of dodecyl maltoside as stated
19 there.

20 JUDGE NEWMAN: Just to be clear, you're arguing that this species
21 would be separately patentable whether or not the reference is prior
22 art listing the 150?

23 WENDY DEVINE: Let me clarify, Your Honor. So we're arguing that
24 the species is patentable because the specification discloses the
25 species. The only -- the reference GWAS that was the basis for all of

1 the obviousness findings, if we are entitled to that priority date, is
2 not prior art. So the obviousness findings cannot stand so long as we
3 are entitled to that priority date, which we are entitled to, at least
4 with respect to the dodecyl maltoside claims, which are literally
5 supported in the provisional application. Does that answer your
6 question, Your Honor?

7 JUDGE NEWMAN: Well, I really was hoping to draw a more precise
8 line when I said whether or not they're entitled to the filing date,
9 the provisional date.

10 WENDY DEVINE: So the support is in the provisional. So we would
11 need to be entitled to the provisional date, which we are. And I see
12 that my time is up.

13 CHIEF JUDGE MOORE: OK, thanks, both counsel. This case is taken
14 under submission.

1 I hereby certify that the foregoing is, to the best of my
2 knowledge and belief, a true and accurate transcription from English to
3 English.

4
5 Anders Nelson
6 Anders Nelson (Jun 16, 2025 10:36 EDT)

7 Anders Nelson
8 Project Manager
9 TransPerfect Legal Solutions

10
11
12 June 16, 2025
13
14
15
16
17
18
19
20
21
22
23
24
25