

Case No. 21-1038

**United States Court of Appeals
for the Federal Circuit**

NEURELIS, INC.,
Appellant

v.

AQUESTIVE THERAPEUTICS, INC.,
Appellee

Appeal from a decision of the United States Patent and Trademark
Office, Patent Trial and Appeal Board in IPR2019-00451

APPELLANT NEURELIS, INC.'S REPLY BRIEF

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CERTIFICATE OF INTEREST

Counsel for Appellant Neurelis, Inc. hereby certifies the following:

1. The full name of every entity represented in the case by the counsel filing the certificate: Neurelis, Inc.
2. For each entity, the name of every real party in interest, if that entity is not the real party in interest: Not applicable.
3. For each entity, that entity's parent corporation(s) and every publicly held corporation that owns ten percent (10%) or more of its stock: None.
4. The names of all law firms, partners, and associates that have not entered an appearance in the appeal, and (A) appeared for the entity in the lower tribunal; or (B) are expected to appear for the entity in this court: Lee Johnson, Alina Litoshyk, and Nathaniel Leachman.
5. Other than the originating case number(s), the title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal: None.
6. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees): None.

Dated: May 3, 2021

/s/Richard Torczon

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INTRODUCTION

The Patent Trial and Appeal Board (the “Board”) erred in failing to accord Appellant (“Neurelis”) priority to Provisional Application No. 61/040,558 (the “’558 provisional”). This failure is particularly stark for dependent dodecyl maltoside claims 26-28 and 30-33 of U.S. Patent No. 9,763,876’s (the “’876 patent”), which have uncontested support in the ’558 provisional. Indeed, Appellee (“Aquestive”) has no answer on the merits for these claims and only spurious process arguments. In its final written decision, the Board concluded “Claim 1 requires ‘an alkyl glycoside’” and “[s]ince all of the remaining claims of the ’876 patent depend, directly or indirectly, from Claim 1, they also require the presence of ‘an alkyl glycoside.’” Appx14 n.6. As a result, the Board improperly treated the priority issue for dependent dodecyl maltoside claims 26-28 and 30-33 as standing or falling with claim 1, despite Neurelis’ express identification of specific support for the dodecyl-maltoside limitations in these claims in its patent owner response during the trial. At the very least, the Board’s failure to consider or address the express requirement for dodecyl maltoside in these dependent claims is reversible error.

Had the Board considered those dependent claims in light of the *entire* ’558 provisional disclosure—necessarily including the incorporated and subcategorized compounds in the six SIGMA catalog pages—it would have been clear that the

incorporated material explicitly supports the dodecyl-maltoside claim limitations. Aquestive's brief disputes none of this. *See generally* Aquestive Br.

Rather than identifying a factual basis for denying priority for the dodecyl-maltoside dependent claims, Aquestive attempts to paint the Board's claim construction error as a concession by Neurelis—an assertion that is not only new and unsupported, it is clearly false. Had the Board mistakenly believed Neurelis made a concession, the Board would have said as much but did not. Instead, the Board simply misconstrued dependent claims 26-28 and 30-33 by ignoring their further limitations and thus improperly denied Neurelis priority to its '558 provisional.

Indeed, the Board's failure to address the incorporated disclosure for these dependent claims after Neurelis specifically pointed it out underscores that the Board did not treat the incorporated material as actually incorporated at all—or at the very least failed to apply the right legal analysis to it. The Board's decision on priority for all of the challenged claims, and Aquestive's defense of it, rest on a non-sequitur: the Board both said it assumed disputed disclosure was incorporated into the '558 provisional and then inexplicably looked for blaze marks to see what should be incorporated. Yet either the disputed SIGMA catalog pages were treated as incorporated—in which case the Board's search for additional blaze marks was prejudicial error—or they were not treated as incorporated—which is what the

Board’s blaze-marks analysis specific to alkyl glycosides indicates. In fact, both Aquestive and the Board have consistently—from the filing of the petition through entry of the final written decision—ignored or deprecated the only blaze marks that really mattered: the express incorporation of *all* of the biological detergents in the SIGMA catalog pages as enhancers, coupled with an express preference for non-ionic materials. A person with ordinary skill in the art (“POSA”) reading this disclosure would have been inexorably led to a small set of non-ionic biological detergents that were overwhelmingly alkyl glycosides, expressly including dodecyl maltoside.

The Board’s error on priority was the sole basis for treating the key intervening reference (“Gwozdz”) as prior art for all obviousness grounds under 35 U.S.C. § 103;¹ hence, this error alone suffices to refute the Board’s entire basis for obviousness and cannot be cured by a remand. The only evidence of record addressing how the claims would be understood if the SIGMA materials were actually incorporated is uncontroverted evidence from Neurelis. Aquestive provided no contrary evidence; instead, Aquestive relied solely on its evolving priority theories. Because the only evidence of record under the proper legal standard shows clear support for the contested claims in the priority ’558

¹ Substantive patent statutes refer to the versions in effect prior to March 16, 2013.

provisional, Aquestive cannot meet its ultimate burden of proof on unpatentability under 35 U.S.C. § 316(e) and a remand would only offer additional opportunities for error and new improper theories. Neurelis respectfully asks the Court to reverse the Board's final written decision.

ARGUMENT

A. The Board Failed to Treat Incorporated Subject Matter as Actually Incorporated and Misapplied the Written-Description Standard, Resulting in Reversible Error

The test for sufficient written description is whether the disclosure of the application reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). The written description requirement of 35 U.S.C. § 112, first paragraph, is incorporated into the priority determination for provisional applications. 35 U.S.C. § 119(e)(1).

Although written description is a question of fact (*Ariad*, 598 F.3d at 1351), findings based on an erroneous legal standard receive no deference and must be set aside. *Cooter & Gell v. Hartmarx Corp.*, 496 U.S. 384, 402 (1990) (“Of course, [a deferential] standard would not preclude the appellate court's correction of . . . legal errors, e.g., . . . relying on a materially incorrect view of the relevant law . . .”).

The “Board's ultimate claim constructions” are reviewed “de novo and its underlying factual determinations involving extrinsic evidence for substantial evidence.” *Prolitec, Inc. v. ScentAir Techs., Inc.*, 807 F.3d 1353, 1358 (Fed. Cir. 2015).

1. Improper Claim Interpretation and Consequent Disregard of Dependent Claims 26-28 and 30-33 Is Reversible Error

The final written decision erroneously construed claims 26-28 and 30-33 of the '876 patent to eliminate an express further limitation. A dependent claim must “specify a further limitation of the subject matter.” 35 U.S.C. § 112, fourth paragraph. The Board inverted this requirement by attributing the same scope to all of the claims despite argued further limitations. Specifically, the Board stated that “Claim 1 requires ‘an alkyl glycoside[]’” and “[s]ince all of the remaining claims of the '876 patent depend, directly or indirectly, from Claim 1, they also require the presence of ‘an alkyl glycoside.’” Appx14 n.6. While literally true, this claim construction ignores the further limitation in dependent claims 26-28 and 30-33 to a specific alkyl glycoside: dodecyl maltoside. Thus, despite Neurelis having pointedly argued that Aquestive’s expert,

Dr. Peppas agreed that the 1988 SIGMA catalog includes alkyl glycosides, specifically identifying dodecyl maltoside (claimed in claims 26-28 and 30-33) as disclosed within the catalog entry

(Appx487 n.7), the Board failed to separately consider these dependent claims and failed to account for the uncontested disclosure of the alkyl glycoside—dodecyl maltoside—they expressly require. Indeed, the SIGMA catalog discloses dodecyl maltoside as a nonionic biological detergent *twice* in the six incorporated pages of the SIGMA catalog. Appx10705, Appx10708. This claim construction is simply wrong and should be reversed.

2. The Board’s Failure to Address “Dodecyl Maltoside” Shows It Did Not Treat the SIGMA Catalog Pages as Incorporated

The Board acknowledged that claims 26-28 and 30-33 require dodecyl maltoside specifically. Appx33-35. Aquestive concedes that the Board found that the SIGMA catalog expressly discloses dodecyl maltoside. Aquestive Br. 53; Appx15. Aquestive argues, however, that Neurelis is wrong to say the Board failed to address the dependent claims directed to using dodecyl maltoside (rather than any alkyl glycoside) as the enhancer. Tellingly, Aquestive cannot point to any such analysis in the Board’s decision.

Instead, Aquestive asserts that the Board addressed all alkyl glycosides, so it must have addressed dodecyl maltoside, which is an alkyl glycoside. Aquestive Br. 53. Aquestive’s assertion that the Board’s substitution of the alkyl glycoside limitation for the dodecyl maltoside limitation is somehow proper makes no sense, because a written-description analysis is based on what is claimed. *See X2Y*

Attenuators, LLC v. Int’l Trade Comm’n, 757 F.3d 1358, 1366 (Fed. Cir. 2014) (“[E]ntitlement to priority is decided on a claim-by-claim basis, and various claims may be entitled to different priority dates.”). Dependent claims 26-28 and 30-33 do not call for using alkyl glycoside generally—they require using dodecyl maltoside specifically—which makes any general finding about alkyl glycoside irrelevant to the more specific dependent dodecyl-maltoside claims. A holding that claims 26-28 and 30-33 lack support cannot be squared with the undisputed express disclosure of dodecyl maltoside from the SIGMA catalog as an enhancer for use in the invention. This paradox can only be resolved by recognizing that neither Aquestive nor the Board treat this express disclosure as actually incorporated into the specification of the ’876 patent, regardless of what they may say.

a. Neurelis Argued Dodecyl Maltoside Below

Aquestive accuses Neurelis of a new argument on appeal about the dependent claims being further narrowed to dodecyl maltoside. Aquestive Br. 51 (“Neurelis’ argument is too little, too late.”). Neurelis’ opening brief, however, points to express argument in its Patent Owner Response before the Board connecting these dependent claims to the express disclosure of dodecyl maltoside in the incorporated material. Neurelis Br. 35; Appx487 n.7. Like the Board below, Aquestive simply ignores this argument rather than addressing it.

Instead, Aquestive asserts that “Neurelis candidly conceded” these dependent claims. Aquestive Br. 51. Yet the quote Aquestive cites from the oral argument at the Board does not mention even dependent dodecyl-maltoside claims 26-28 and 30-33, let alone concede them as Aquestive asserts. *Id.* In context, the quote simply states that Neurelis responded to every claim limitation that Aquestive challenged. The full quote is:

Regarding Your Honors' questions regarding whether we laid out in our papers the provisional support for each and every limitation of the claims, it's not explicitly there. We submit that under *SAS* [*SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348 (2018)], the Petitioner must frame the issues. And the only issue the Petitioner framed here was an alleged lack of disclosure of alkyl glycosides, and that issue is one that we addressed.

Appx829 (59:7-12). Understood in context, this quote in no way “concedes” the separate patentability of dependent dodecyl maltoside claims 26-28 and 30-33, or even that it was not separately argued. Certainly, the Board did not rely on any such concession in holding these dependent claims unpatentable without any analysis—the Board’s decision instead rested on its erroneous claim construction that appeared for the first time in the Final Written Decision. *Bivings v. U.S. Dep’t of Agri.*, 225 F.3d 1331, 1335 (Fed. Cir. 2000) (“A court ordinarily must review a decision of an administrative agency on the basis of the agency’s own rationale; unlike the situation involving appellate review of judicial decisions, it cannot affirm the agency on a theory that, although supported by the record, was not the

basis of the agency's ruling[.]"); 35 U.S.C. § 144 (“[t]he Federal Circuit shall review the decision from which an appeal is taken on the record before the Patent and Trademark Office.”).

Aquestive also relies (Aquestive Br. 52) on the Board's incorrect statement that Neurelis “does not present separate arguments for any of the dependent claims. *See generally* PO Resp. 23-38.” Appx27. However, the Board's clear error is not a Neurelis concession. Neurelis expressly pointed to additional limitations in these dependent claims with specific support in the specification (including the incorporated SIGMA catalog pages). Appx487 n.7 (noting Aquestive's expert “Dr. Peppas agreed that the 1988 SIGMA catalog includes alkyl glycosides, specifically identifying dodecyl maltoside (claimed in claims 26-28 and 30-33) as disclosed within the catalog entry.”). The Board's failure to address this uncontested disclosure of the specific alkyl glycoside recited in these claims is reversible error.

b. Board Ignored Express Disclosure

Due to its failure to address dependent claims 26-28 and 30-33 separately, the Board never explained why these claims are not separately supported. This silence is particularly striking because it is not contested that the incorporated SIGMA catalog pages disclose dodecyl maltoside. If the Board had actually treated the SIGMA pages as incorporated into the '558 provisional disclosure, it unavoidably would have found the use of dodecyl maltoside as an enhancer is

expressly described in that application. Reversal is appropriate because, under the right legal standard for written description, no reasonable fact finder could fail to find that dodecyl maltoside is expressly disclosed as an incorporated enhancer.²

3. The Board Improperly Required Preference for Certain of the Expressly Incorporated Subject Matter

The blaze-marks test is a useful test where it applies, which is when a genus is disclosed but the claimed species is not specifically identified. *See Ariad*, 598 F.3d at 1348 (“The specification as filed disclosed a genus encompassing about ‘half a million possible compounds,’ but it did not disclose chlorpropamide specifically[.]”), explaining *In re Ruschig*, 379 F.2d 990, 994 (C.C.P.A. 1967) (“Surely, given time, a chemist could name . . . all of the half million compounds within the scope of the broadest claim, which claim is supported by the broad disclosure. This does not constitute support for each compound individually when separately claimed.”). By contrast, far from lacking blaze marks, the ’558 provisional expressly directs the reader to select an enhancer from the biological detergents disclosed in the SIGMA catalog, and also expresses a preference for non-ionic enhancers (which in the SIGMA catalog are overwhelmingly alkyl

² Aquestive does not and cannot point to evidence that dodecyl maltoside is not expressly disclosed in the incorporated SIGMA pages identified as a source for enhancers used in the invention.

glycosides). Appx10705, Appx10708-10710. A search for blaze marks through a forest of possibilities cannot justify ignoring the paved pathway to what is claimed.

Aquestive and the Board insist that the '558 provisional lacked sufficient blaze marks to guide an artisan to select the “about 12 alkyl glycosides in a list of about 150 biological detergents” listed in the SIGMA catalog. Appx19-20; Aquestive Br. 40-41. This statement of the problem underscores the Board’s failure to actually consider the full disclosure of the incorporated material, necessarily including the incorporated *and subcategorized* compounds. The inventors expressly possess all 150 biological detergents for use as enhancers, including the “about 12 alkyl glycosides” and specifically including dodecyl maltoside. As Neurelis explained to the Board, the '558 provisional provides more than a generic laundry list of possible enhancers; rather, it identified non-ionic materials as preferred surfactants and then identified six specific pages of the SIGMA catalog with 150 biological detergents in which the alkyl glycosides were grouped in one labeled subcategory of non-ionic biological detergents. Appx478-480, Appx10932-10938; *see also* Appx499 (explaining “Alkyl glycosides are known nonionic surfactants.”). If the SIGMA catalog pages were properly treated as fully incorporated, no reasonable artisan would have needed any further blaze mark to know that the inventors possessed alkyl glycosides, specifically including dodecyl maltoside, as enhancers for the invention.

Even the Board recognizes the “about 12 alkyl glycosides” as a group of alkyl glycosides. Appx19. Rather than having no guidance about using alkyl glycosides as enhancers, a person with actual *skill* in the art would have to be willfully blind not to recognize them within the labeled subcategory of nonionic detergents in the SIGMA catalog. The Board and Aquestive misapply the blaze-marks analysis to the present facts to treat the incorporated SIGMA pages as a massive, unorganized laundry list of possibilities—out of context with the rest of the ’558 provisional disclosure about enhancers—and then require a preference for (and incorporation of) *only* the claimed alkyl glycosides.³ This prejudicial error warrants reversal.

Aquestive makes this misapplication plain in arguing that the specification had to show that the inventors intended the use of *only* alkyl glycosides as enhancers. Aquestive Br. 37 (“[A] POSA reading the ’558 provisional would have

³ Aquestive asserts that Neurelis is “disingenuous” and actually admits the Board treated the SIGMA catalog as incorporated. Aquestive Br. 39 n.6. Aquestive misleadingly clips the quote to change its meaning by eliminating the rest of the sentence which makes clear that the Board required further blaze marks before it would consider alkyl glycosides to have been disclosed as part of the invention. Neurelis Br. 29 (“Yet the Board incongruously stated that it found no blaze marks to restrict the incorporation to just non-ionic detergents, improperly treating the incorporated biological detergents as a laundry list of 150 uncategorized compounds that a POSA would not select as part of the invention without even more guidance.”). The fact that Neurelis knows the biological detergents—expressly including the alkyl glycosides—to have been properly incorporated is not proof that the Board treated them as such.

had to understand that *the inventors were excluding all* of paragraphs 150-152's 'absorption enhancers', including the listed preferred lysophospholipids and acyl carnitines (§151), *and excluding all but 12 of the 150 biological detergents* incorporated by reference.”) (emphasis added), *citing Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) (“[A] prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought.”). *Lockwood* does not support the proposition for which Aquestive cites it, nor could it. Instead, *Lockwood* simply requires clear disclosure of the element as claimed, which in the present case is expressly provided in the '558 provisional once the expressly incorporated and subcategorized enhancers are included.

In making this new argument, Aquestive ignores express disclosure as it has consistently done in this case since its petition—i.e., express disclosure that “the invention may advantageously comprise *an* absorption enhancer” (Appx7814 (emphasis added)), meaning a POSA would have understood the enhancer could be chosen from any of the disclosed options, with additional guidance in the form of expressed preferences. Aquestive's additional requirement that inventors identify using *only* alkyl glycosides is exactly the preference-for-what-is-claimed argument Aquestive insists neither it nor the Board made. Aquestive Br. 40 (“The PTAB did

not require a ‘preference for alkyl glycosides’’). Aquestive’s new argument is contrary to law and ignores express disclosure.

4. Obviousness Is Moot Because the Intervening References Are Not Prior Art

The key reference underpinning all grounds for the Board’s obviousness conclusions—Gwozdz⁴—is not prior art once Neurelis is given priority to its ’558 provisional. Without Gwozdz, Aquestive’s obviousness case is moot. In any event, the other obviousness issues have been fully developed in Neurelis’ opening brief and need no further amplification here.

Aquestive argues that “Neurelis failed to provide any support evidencing that each application in the chain complied with the written description requirements of Section 112.” Aquestive Br. 7. Yet Aquestive only challenged Neurelis’ claim to priority for the ’558 provisional. Indeed, Aquestive’s petition admits that the only contested disclosure—alkyl glycosides—was disclosed in the next Neurelis application. Appx209-210; *see also SAS*, 138 S. Ct. at 1355 (“in an inter partes review the petitioner is master of its complaint”). Certainly, the Board did not base its decision on any of the other Neurelis applications. Once again, Aquestive improperly attempts to shift its burden to demonstrate unpatentability to Neurelis.

⁴ WO2009/120933 (Appx8081-8033); Neurelis Br. 1 n.1.

B. Due Process Issues In This Case Counsel Against A Remand

From the start, the *inter partes* review proceeding now on review was infected with prejudicial irregularities. Aquestive's entire original theory in its petition rested on ignoring an express incorporation by reference; indeed, Aquestive did not even file the SIGMA catalog with its petition, much less address its contents. The Board initially inverted a USPTO rule to ignore the incorporation and then misquoted Neurelis' rehearing request and improperly shifted the burden of persuasion for priority to Neurelis despite contrary legal authority to continue the proceeding. Next, the Board permitted Aquestive to switch to its blaze-marks analysis for the first time in its reply (after Neurelis could no longer respond with evidence) and accepted Aquestive's misapplied analysis as correct. Finally, the Board ignored expressly argued dependent claims. By any measure, this case has been extraordinary.

Aquestive's response brief pointedly ignores the controlling authority cited in Neurelis' opening brief that in USPTO proceedings the initial burden on priority lies with *the challenger*. Neurelis Br. 17, 32 (citing *In re Alton*, 76 F.3d 1168, 1175 (Fed. Cir. 1996); *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989)). It makes sense for IPRs to follow this precedent. Given its extremely limited discovery, *inter partes* review is much more like examination in which the record is developed in a few communications with none of the pre-trial insight that

develops through discovery. Indeed, this case is a poster child for why the controlling authority is correct: here Aquestive first articulated its improper blaze-marks analysis after the record was closed for Neurelis. Allowing a petitioner to shirk the pivotal fact in its unpatentability argument until the record is closed for the patent owner falls woefully short of due-process minimums for an agency proceeding. 5 U.S.C. § 554(b)(3) (“When private persons are the moving parties, other parties to the proceeding shall give prompt notice of issues controverted in fact or law[]”).

The Board’s decision can be reversed on the merits without remand to address the due-process violations. Instead, Neurelis rehearses these irregularities simply to underscore that this is not a case in which a remand can be expected to tie up a few loose ends in the Board’s decision. If the history of this proceeding is any guide, a remand will result in new and erroneous legal theories and another appeal.

CONCLUSION

Here, the Board made one of two reversible errors: either it did not actually treat the SIGMA pages as incorporated (without any explanation) or it misapplied the blaze-mark analysis to require a preference for only the claimed subject matter. Under the proper written-description standard, the evidence only supports one holding: the inventors expressly possessed the use of alkyl glycosides generally,

and dodecyl maltoside specifically, as enhancers in the claimed invention, the only contested priority issue. With this issue resolved in favor of Neurelis, obviousness is moot. Reversal is the only reasonable outcome; a remand is unnecessary and, given the convoluted history below, unlikely to resolve this case.

Dated: May 3, 2021

/s/Richard Torczon

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CERTIFICATE OF SERVICE

I certify that today I caused this paper to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system, and thus caused to be served on all registered counsel of record a copy of the same via the CM/ECF system.

Dated: May 3, 2021

/s/Richard Torczon

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit in Federal Circuit Rule 32(b)(1). The brief contains 3,668 words, excluding the parts of the brief listed in Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2).

This brief complies with the typeface and type style requirements of Federal Rule of Appellate Procedure 32(a). This brief has been prepared in a proportionally-spaced 14-point Times New Roman using Microsoft Word.

Dated: May 3, 2021

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