

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIQUIDIA TECHNOLOGIES, INC.,
Petitioner,

v.

UNITED THERAPEUTICS CORPORATION,
Patent Owner.

Inter Partes Review No. IPR2021-00406
U.S. Patent No. 10,716,793 B2

PATENT OWNER'S REQUEST FOR REHEARING

TABLE OF CONTENTS

I. Introduction and Background 1

II. Legal Standard 3

III. Argument 3

 A. Liquidia failed to demonstrate that the Voswinckel abstracts are
 prior art 4

 B. The Board’s conclusion that Voswinckel JESC and Voswinckel
 JAHA are prior art conflicts with settled legal principles..... 7

 C. But for the Board’s legal error, the challenged claims would
 have been upheld 12

IV. Conclusion 14

TABLE OF AUTHORITIES

Cases:

Argentum Pharm. LLC v. Research Corp. Tech., Inc.,
IPR2016-00204, Paper 19 (P.T.A.B. May 23, 2016)11

Blue Calypso, LLC v. Groupon, Inc.,
815 F.3d 1331 (Fed. Cir. 2016)7, 8

Caterpillar Inc. v. Wirtgen Am., Inc.,
IPR2017-02185, Paper 48 (P.T.A.B. July 11, 2019).....3

Constant v. Advanced Micro-Devices, Inc.,
848 F.2d 1560 (Fed. Cir. 1988)7

Handi Quilter, Inc. v. Bernina International AG,
IPR2013-00364, Paper 39 (P.T.A.B. Sept. 25, 2014).....12

Kyocera Wireless Corp. v. ITC,
545 F.3d 1340 (Fed. Cir. 2008)8

In re Lister,
583 F.3d 1307 (Fed. Cir. 2009)2, 8

Minnesota Min. & Mfg. Co. v. Chemque, Inc.,
303 F.3d 1294 (Fed. Cir. 2002)1

Samsung Elecs. Co. v. Infobridge Pte. Ltd.,
929 F.3d 1363 (Fed. Cir. 2019)10

Teoxane S.A. v. Allergan,
IPR2017-01906, Paper 15 (P.T.A.B. Mar. 9, 2018).....2, 7, 10

Statutes:

35 U.S.C. §102(a)6, 7, 12, 13

35 U.S.C. §102(b) 1, 2, 6, 8, 9, 10, 11, 12

Regulations:

37 C.F.R. §42.713

37 C.F.R. §42.104(b)(2)..... 12

Other Authorities:

M.P.E.P. §2127 8

Patent Owner United Therapeutics Corporation (UT) respectfully requests that the Board reconsider its Final Written Decision (Paper 78) (FWD) finding claims 1–8 of U.S. Patent No. 10,716,793 unpatentable.

I. Introduction and Background

The Board ruled that all eight claims of the '793 patent are obvious, relying in part on two references: Voswinckel JESC (Ex. 1007) and Voswinckel JAHA (Ex. 1008). The Final Written Decision concluded that these references qualify as prior art under pre-AIA 35 U.S.C. §102(b) because research aids made them publicly accessible. FWD at 8–12. But that prior-art determination rests on a substantial legal error, because the supposed research aids were published *after* the critical §102(b) date of May 15, 2005.

Public accessibility prior to the critical date is the defining feature of a §102(b) “printed publication.” *See, e.g., Minnesota Min. & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1301 (Fed. Cir. 2002). The Board did not find that Liquidia proved that either Voswinckel abstract was *itself* publicly accessible, such as if they had been indexed and catalogued in public libraries more than a year before the priority date. Instead, the Board reasoned that two references the Board described as “research aids”—Ghofrani (Ex. 1010) and Sulica (Ex. 1104)—provided a skilled artisan with a roadmap to the Voswinckel abstracts. FWD at 10–12.

That ruling contravenes settled legal principles. Where a research aid is relied

upon as a “roadmap” to establish public accessibility to a skilled artisan under §102(b), the date of public accessibility is *the date of the research aid*, not *the date of the underlying reference*. See *In re Lister*, 583 F.3d 1307, 1312 (Fed. Cir. 2009) (holding that the date of accessibility through a searchable index was the effective date of an asserted reference). That is because “[t]he touchstone of public accessibility is whether an ordinary artisan exercising reasonable diligence would have been able to locate the document prior to the critical date.” *Teoxane S.A. v. Allergan*, IPR2017-01906, Paper 15, at 11 (P.T.A.B. Mar. 9, 2018) (quotation marks omitted). Ghofrani was clearly published within a year of the priority date (*see* Ex. 1121, at 1; Paper 55, at 9), and Liquidia provided no evidence that Sulica was published outside that one-year window (*see* Ex. 1104, at 1; Paper 55, at 9). Thus, even assuming Ghofrani and Sulica provide a skilled artisan with the requisite “roadmap” to find the Voswinckel abstracts (*see* FWD at 11), neither could have led the skilled artisan to the relevant abstract more than one year before the priority date. The Final Written Decision erred in failing to address this critical distinction and allowing Liquidia to use research aids published within a year of the applicable date to establish the Voswinckel abstracts as publicly accessible more than a year before the applicable date.

With this error corrected, the obviousness conclusion falls apart. Aside from Voswinckel JESC and Voswinckel JAHA, the Board found *no* evidence that either

the claimed drug quantity (15 to 90 micrograms) or the claimed delivery duration (one to three breaths) was disclosed in the prior art. None of Liquidia's other asserted obviousness grounds are viable, either. Each of the other grounds relies on Voswinckel JESC, Voswinckel JAHA, or another reference that the Board concluded does not constitute prior art. *See* FWD at 3–4.

For these reasons, the Board should grant rehearing, vacate the Final Written Decision, and issue a new decision upholding the challenged claims.

II. Legal Standard

A party dissatisfied with a final written decision of the Board may file one rehearing request, without prior authorization, within 30 days of the Board's decision. 37 C.F.R. §42.71. The requesting party “must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, a reply, or a sur-reply.” *Id.* The Board reviews its decision for abuse of discretion, which occurs when “the decision is based on an erroneous interpretation of law, if a factual finding is not supported by substantial evidence, or if an unreasonable judgment is made in weighing relevant factors.” *Caterpillar Inc. v. Wirtgen Am., Inc.*, IPR2017-02185, Paper 48, at 2 (P.T.A.B. July 11, 2019).

III. Argument

A long-established legal principle governs the Voswinckel abstracts' status as

prior art: if a skilled artisan must rely on a research aid to provide a roadmap to access an underlying reference, then the *underlying reference* cannot have been publicly accessible until the *research aid* was. The Final Written Decision contravenes this principle by allowing Liquidia to use two later-published research aids (Ghofrani and Sulica) to smuggle those earlier, otherwise-inaccessible abstracts into the record as prior art. But for this legal error, the Board would have been required to uphold the asserted claims.

A. Liquidia failed to demonstrate that the Voswinckel abstracts are prior art

Liquidia's Petition contained only the most conclusory evidence that Voswinckel JESC and Voswinckel JAHA were prior art. The Petition asserted that the abstracts were published in 2004 (*see* Paper 2, at 22, 24), and an accompanying expert declaration speculated that the abstracts likely would have been received, catalogued, and indexed by libraries by late 2004—without providing any evidence that they actually were. *See* Ex. 1036 ¶¶59–75.

As UT explained in the Patent Owner Response, this cursory showing did not come close to satisfying Liquidia's burden of proof. Liquidia's Petition failed to demonstrate that any library actually received either abstract, let alone more than a year before the priority date. *See* Paper 29, at 12–14. And the Petition further failed to show that any library had indexed or catalogued the abstracts or even the supplements in which they appeared before that date. *See id.* at 14–18.

Evidently recognizing the threadbare nature of its prior submissions, Liquidia shifted stances and sought to rely on new evidence and arguments in its Reply. As relevant here, Liquidia argued for the first time that Voswinckel JESC “was cited in the June 2005 Ghofrani article in the journal *Herz*,” and that a skilled artisan “would have relied on Ghofrani’s disclosures to ... access the JESC abstract.” Paper 44, at 3–4. Liquidia advanced effectively the same argument for Voswinckel JAHA, contending that a skilled artisan “would have been able to access JAHA with Sulica as a research aid.” *Id.* at 7–8. Finally, Liquidia suggested that Sulica’s citation to Voswinckel JAHA itself demonstrated public accessibility of that reference, because it showed that “[t]he Sulica authors were able to access” it. *Id.* at 7.

UT explained in its Surreply that Liquidia failed to show that either Voswinckel abstract was prior art. Instead, Liquidia’s “belated argument establishe[d], at best, that a POSA may have been able to find the Abstract as of the date the alleged ‘research aids’ became available.” Paper 55, at 9. Crucially, “Ghofrani bears a July 2005 date-stamp, while Sulica shows only the year 2005” without any actual evidence demonstrating the March 2005 date that Liquidia asserted. *Id.* (citations omitted); *see id.* at 9 n.4.

UT further explained that the mere fact that Sulica and Ghofrani contain citations to the Voswinckel abstracts cannot establish that the abstracts were publicly accessible to persons of ordinary skill in the art more than a year before the priority

date. The Sulica and Ghofrani authors are not persons of ordinary skill with respect to the Voswinckel abstracts because the Voswinckel abstracts' authors had a close affiliation with the supposed research aids' authors: Voswinckel JESC and the relevant portions of Ghofrani shared coauthors (Dr. Voswinckel and Dr. Seeger), Paper 29, at 46–47 (citing Ex. 2066 at 3, ¶7); Paper 55, at 10, and Dr. Sulica was a principal investigator in the TRIUMPH study group (there, too, along with Dr. Seeger) who participated in the clinical trials reported in the Voswinckel publications, Paper 55, at 10. Thus, the fact that the authors of Sulica and Ghofrani had access to and could cite the Voswinckel abstracts, given their affiliation with those abstracts, is irrelevant to whether a person of ordinary skill could have publicly accessed them, much less accessed them more than a year before the priority date. *See* Paper 55, at 10.

As UT explained, “if the Abstracts only became publicly accessible (via these alleged ‘research aids’) after May 15, 2005, they do not qualify as prior art under 35 U.S.C. §102(b).” *Id.* at 10. “And if the Abstracts are not Section 102(b) prior art, they are not prior art at all because they are not ‘by another’ under Section 102(a), given Patent Owner’s showing that the subject matter of both Abstracts is the

inventors' own work." *Id.*¹

B. The Board's conclusion that Voswinckel JESC and Voswinckel JAHA are prior art conflicts with settled legal principles

The Board erroneously concluded that Voswinckel JESC and Voswinckel JAHA were prior art. According to the Final Written Decision, because "both the Ghofrani article and the Sulica article" cite the Voswinckel abstracts, they are research aids that serve as "roadmaps" to establish public accessibility of those abstracts. FWD at 11–12 (citing *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1350 (Fed. Cir. 2016)). That conclusion conflicts with settled legal principles.

As the Board has previously explained, "[t]he touchstone of public accessibility is whether an ordinary artisan exercising reasonable diligence would have been able to locate the document prior to the critical date." *Teoxane*, IPR2017-01906, Paper 15, at 11 (quotation marks omitted). Indeed, the decisions of both the

¹ This showing was uncontested. Liquidia did not object to or move to exclude any of Exhibits 2003, 2061, and 2071, which were first filed with the Patent Owner Response (Paper 29) and later cited in the Surreply (Paper 55, at 10) to show that the abstracts were not §102(a) prior art. Furthermore, Liquidia declined the opportunity to depose Dr. Seeger in the IPR in relation to Exhibits 2003 and 2071 following their submission with the Patent Owner Response, and it made no request to submit any rebuttal evidence on this issue following the Surreply.

Federal Circuit and this Board have repeatedly underscored the point: what matters is public accessibility as of the critical date. *See, e.g., Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1568 (Fed. Cir. 1988) (“The statutory phrase ‘printed publication’ has been interpreted to mean that before the critical date the reference must have been sufficiently accessible to the public interested in the art[.]”); *In re Lister*, 583 F.3d 1307, 1312 (Fed. Cir. 2009) (analyzing whether a reference was “publicly accessible as of the critical date”); *Kyocera Wireless Corp. v. ITC*, 545 F.3d 1340, 1350 (Fed. Cir. 2008) (similar).

These principles apply with equal force regardless of whether a reference is publicly accessible on its own or instead becomes publicly accessible only by way of a “research aid.” As the Federal Circuit has explained, “the presence of a ‘research aid’ can ... establish public accessibility” by “provid[ing] a skilled artisan with a sufficiently definite roadmap leading to ... the potentially invalidating reference.” *Blue Calypso*, 815 F.3d at 1350. By simple logic, that roadmap can “lead[] to ... the potentially invalidating reference” only if and when it becomes publicly accessible—before then, there is nothing to guide the skilled artisan to the underlying reference. *See Lister*, 583 F.3d at 1312 (for a reference that becomes publicly accessible through a searchable index, the relevant date is the date of indexing); *cf. M.P.E.P. §2127* (“An abandoned patent application may become evidence of prior art only when it has been appropriately disclosed, as, for example,

when the abandoned patent application is referenced in the disclosure of another patent, in a publication, or by voluntary disclosure[.]” (brackets omitted)). The key issue in this case is therefore when *the research aid* providing the roadmap became publicly accessible, and whether that was before the §102(b) critical date.

The Final Written Decision did not address that question and overlooked UT’s arguments doing so. Even assuming that “the Ghofrani article and the Sulica article provide roadmaps directing a person of ordinary skill in the art ... straight to Voswinckel JESC or Voswinckel JAHA” (FWD at 11–12), the question is when those roadmaps became available to an ordinary artisan in this field. The answer: not before the critical May 15, 2005, §102(b) date. Ghofrani is an article from the June 2005 issue of *Herz*; the exhibit in the record bears a July 2005 date-stamp. *See* Ex. 1121, at 1. And Sulica bears a “2005” date with no indication of when in 2005 it was published—much less when it became publicly accessible.² *See* Ex. 1104, at 2.

² Liquidia asserted that Sulica is a “March 2005 article” (Paper 44, at 7), and the Final Written Decision quoted that statement (FWD at 11). But there is no evidence that it appeared in any publication in March 2005. The document itself, Exhibit 1104, only references the year “2005” and offers no other date information. Paper 55, at 9. And there was no other evidence supporting Liquidia’s March 2005 date.

In short, neither of the alleged research aids were shown to have been publicly accessible before the critical §102(b) date. And Liquidia essentially conceded this point—it argued, for example, that Ghofrani would have provided a roadmap to an ordinary skilled artisan to locate Voswinckel JESC “*before May 15, 2006.*” Paper 44, at 4 (emphasis added); *accord id.* at 7–8 (arguing that Sulica would have allowed an ordinary skilled artisan exercising reasonable diligence to access Voswinckel JAHA “*before 2006*” (emphasis added)). In nevertheless concluding that Sulica and Ghofrani establish the Voswinckel abstracts as prior art under §102(b), the Board effectively blessed an end-run around the principle that a reference must be publicly accessible before the critical date. That legal error infected the Board’s decision, and warrants rehearing.

Furthermore, to the extent the Board concluded that Ghofrani and Sulica’s mere citations to the Voswinckel abstracts demonstrated that those references were publicly accessible because it demonstrated that the authors of Ghofrani and Sulica were able to access the abstracts—as Liquidia argued in its Reply (Paper 44, at 7)—that conclusion is equally erroneous. Section 102(b) requires prior-art references to be “publicly accessible” to an “ordinary” skilled artisan. *Teoxane*, IPR2017-01906, Paper 15, at 11; *Samsung Elecs. Co. v. Infobridge Pte. Ltd.*, 929 F.3d 1363, 1369 (Fed. Cir. 2019) (whether “persons of ordinary skill in the art” were able to locate the abstracts through the exercise of “reasonable diligence”). The authors of

Ghofrani and Sulica were not ordinary skilled artisans with respect to the Voswinckel abstracts. Rather, they were coauthors of one Voswinckel abstract (citing their own prior work) and a principal investigator of the team conducting the clinical work described in the other abstract; they therefore would naturally have known about (and had access to) those documents irrespective of their public accessibility. Paper 55, at 10.

In other words, if a petitioner is relying on a research aid to establish public accessibility of a reference by a hypothetical person of ordinary skill, it is not enough for a petitioner to point to the mere existence of a citation in a research aid authored by someone affiliated with the cited reference. Doing so simply demonstrates that the research aid's author was aware of the work he or she contributed to—not that the public (or an ordinary skilled artisan) had access to it. *Argentum Pharm. LLC v. Research Corp. Tech., Inc.*, IPR2016-00204, Paper 19 at 11 (P.T.A.B. May 23, 2016) (concluding that references citing a disputed prior-art thesis, authored either by the student who wrote the thesis or by the student's thesis advisor, only indicated that the authors “had personal knowledge regarding the cited thesis”).³ Nor, of

³ Although the Board mentioned Liquidia's argument that Voswinckel JESC was publicly presented, *see* FWD at 10, the Board did not adopt that argument, and Liquidia offered no evidence of what was presented or to whom. Nor did Liquidia

course, does it demonstrate that an affiliated author who published *after* the critical §102(b) date had access to the reference *before* that date.

C. But for the Board’s legal error, the challenged claims would have been upheld

For the foregoing reasons, the Board erred in concluding that Voswinckel JESC and Voswinckel JAHA are prior art under §102(b). And without that erroneous conclusion, the Board’s decision cannot stand.

Nor would there have been any basis for concluding that the two Voswinckel abstracts are prior art under §102(a). First, it would be improper for the Board to entertain the Voswinckel abstracts as §102(a) prior art because the Petition alleges them only to be §102(b) art. *Compare* Paper 2, at 22, 24 (addressing the abstracts and identifying §102(b)), *with id.* at 25, 27 (addressing Ghofrani and Voswinckel 2006 as prior art under §102(a)). The Board has held that belated conversion from §102(a) to §102(b) is not permitted. *See Handi Quilter*, Paper 39, at 6; *see also SAS Inst. v. Iancu*, 138 S. Ct. 1348, 1356 (2018) (holding that an *inter partes* review must

anywhere argue or explain how any public presentation could have served as a “research aid” that establishes any specific date of public accessibility sufficient to render JESC a §102(b) reference, especially given that the only reference of record which actually cites JESC (Ghofrani) was published less than a year before the priority date.

proceed “in accordance with or in conformance to the petition”); 37 C.F.R. §42.104(b)(2) (providing that a petition must state “[t]he specific statutory grounds under 35 U.S.C. 102 or 103 on which the challenge to the claim is based and the patents or printed publications relied upon for each ground.”). Second, even if Liquidia had raised a §102(a) argument, the argument would have failed on the merits. Section 102(a) applies only to printed publications by “others”—*i.e.*, individuals other than the inventors. As already explained, Voswinckel JESC and Voswinckel JAHA are not by “others”: they reflect the inventors’ own work. *See* Paper 55, at 10; Ex. 2003 ¶27; Ex. 2061 ¶¶12–13; Ex. 2071¶¶6–8; *supra*, pp. 5–6, 10.

There is also no basis for adopting any of the other obviousness grounds in the Petition. Ground 2 also relies on Voswinckel JESC. FWD at 3. Ground 3 relies on Ghofrani, which the Board correctly found not to constitute prior art because it was not by “others.” *See id.* at 37–40. Ground 4 relies on Voswinckel JESC and Ghofrani. *Id.* at 3. And Grounds 5 and 6 rely on Voswinckel 2006, *see id.* at 3–4, which the Board correctly found not to constitute prior art because it was not by others, *see id.* at 40–41.

In short, the Board’s erroneous conclusion that Ghofrani and Sulica could establish public accessibility—without any proof that those sources provided a roadmap to the Voswinckel abstracts before the critical date—was an outcome-

determinative error.

IV. Conclusion

The Board should grant rehearing, vacate its prior final written decision, and enter a revised final written decision confirming that Liquidia has not shown that claims 1–8 of the '793 patent are unpatentable.

August 18, 2022

Respectfully submitted.

/Stephen B. Maebius/
Stephen B. Maebius (Reg. No. 35,264)
FOLEY & LARDNER LLP
3000 K Street, NW
Washington, DC 20007
Telephone: (202) 672-5569
Facsimile: (202) 672-5399

Counsel for Patent Owner
United Therapeutics Corporation

CERTIFICATION OF SERVICE

The undersigned hereby certifies that a copy of the foregoing “Patent Owner’s Request for Rehearing” was served on August 18, 2022, via e-mail on the following counsel of record for the Petitioner:

zLiquidiaIPR@cooley.com
ielrifi@cooley.com
emilch@cooley.com
dkannappan@cooley.com
ssukduang@cooley.com

August 18, 2022

/Stephen B. Maebius/
Stephen B. Maebius (Reg. No. 35,264)
FOLEY & LARDNER LLP
3000 K Street, NW
Washington, DC 20007
Telephone: (202) 672-5569
Facsimile: (202) 672-5399

Counsel for Patent Owner
United Therapeutics Corporation