

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIQUIDIA TECHNOLOGIES, INC.,
Petitioner,

v.

UNITED THERAPEUTICS CORPORATION,
Patent Owner.

IPR2021-00406
Patent 10,716,793 B2

Before ERICA A. FRANKLIN, CHRISTOPHER M. KAISER,
and DAVID COTTA, *Administrative Patent Judges*.

KAISER, *Administrative Patent Judge*.

DECISION

Denying Patent Owner's Request on Rehearing of Final Written Decision
37 C.F.R. § 42.71(d)

INTRODUCTION

Liquidia Technologies, Inc. (“Petitioner”) filed a Petition (Paper 2, “Pet.”) requesting an *inter partes* review of claims 1–8 of U.S. Patent No. 10,716,793 B2 (Ex. 1001, “the ’793 patent”). United Therapeutics Corporation (“Patent Owner”) filed a Preliminary Response. Paper 13 (“Prelim. Resp.”).

On August 11, 2021, we instituted *inter partes* review of claims 1–8 of the ’793 patent on all grounds set forth in the Petition. Paper 18 (“Inst. Dec.”). After institution of trial, Patent Owner filed a Response (Paper 29, “PO Resp.”), Petitioner filed a Reply (Paper 44), and Patent Owner filed a Sur-Reply (Paper 55). In addition, both parties filed Motions to Exclude Evidence (Papers 65 and 66), Oppositions to their respective opponents’ Motions to Exclude (Papers 68 and 69), and Replies in support of their own Motions to Exclude (Papers 71 and 72). At the request of both parties, we held an oral hearing, the transcript of which was entered into the record. Paper 77 (“Tr.”).

On July 19, 2022, we issued a Final Written Decision determining that Petitioner had proven by a preponderance of evidence that all the challenged claims were unpatentable. Paper 78 (“Final Dec.”). On August 18, 2022, Patent Owner requested rehearing and filed a request that rehearing be conducted by the Precedential Opinion Panel. Paper 79 (“Req. Reh’g”); Paper 80. The request for rehearing by the Precedential Opinion Panel was denied, returning jurisdiction to us to consider the rehearing request itself. Paper 81.

For the reasons discussed below, we deny Patent Owner’s Request for Rehearing. Where the present decision differs from the Final Written

Decision, the present decision controls. Otherwise, the Final Written Decision remains in force.

ANALYSIS

A. The Final Written Decision

Petitioner asserted the unpatentability of the challenged claims on six separate grounds. Final Dec. 3–4. Four of those grounds relied on references referred to as Voswinckel 2006 and Ghofrani, both of which we determined did not qualify as prior art. *Id.* at 3–4, 36–41. The remaining two grounds both relied on a reference referred to as Voswinckel JESC, and one of the grounds also relied on a reference referred to as Voswinckel JAHA. *Id.* at 3.

Patent Owner argued during the trial that Petitioner had not proven that either Voswinckel JESC or Voswinckel JAHA had been made publicly accessible early enough to qualify as prior art in the way that Petitioner argued they did. PO Resp. 11–18; Sur-Reply 2–11. Petitioner countered these arguments with several arguments for the public accessibility of Voswinckel JESC and Voswinckel JAHA. Reply 2–9. In particular, Petitioner argued that each of these references was cited in a publicly available journal article that could have served as a research aid to help a person of ordinary skill in the art locate the references. *Id.* at 3–4 (arguing that Voswinckel JESC was cited in Ghofrani), 7–8 (arguing that Voswinckel JAHA was cited in Sulica).

In the Final Written Decision, we were persuaded by Petitioner’s argument regarding these research aids. Final Dec. 10–12. Based in part on our determination that these research aids established the public accessibility of Voswinckel JESC and Voswinckel JAHA, we determined that Petitioner

had proven by a preponderance of the evidence that each of the challenged claims would have been obvious over the combination of the '212 patent, Voswinckel JESC, and Voswinckel JAHA. *Id.* at 12–35.

B. The Rehearing Request

Patent Owner seeks rehearing of our Final Written Decision on the ground that we overlooked Patent Owner's argument that the Ghofrani and Sulica research aids had been "published *after* the critical §102(b) date of May 15, 2005." Req. Reh'g 1 (emphasis in original). Patent Owner notes that this argument appeared in the Sur-Reply. *Id.* at 5 (citing Sur-Reply 9). According to Patent Owner, had we not overlooked this argument, we would have determined that Petitioner had not shown that Voswinckel JESC and Voswinckel JAHA were publicly accessible in the way necessary to treat them as prior art to the '793 patent. *Id.* at 5–14.

When it requested rehearing, Patent Owner also requested that the rehearing be conducted by the Precedential Opinion Panel. Ex. 3003. The Precedential Opinion Panel denied that request and directed us to consider Patent Owner's rehearing request. Paper 81, 3. The Precedential Opinion Panel directed us, "in [our] consideration on rehearing, to clearly identify whether the Voswinckel JESC and Voswinckel JAHA references qualify as prior art" and specified that "[s]uch analysis shall clarify whether the relied upon research aids were available prior to the critical date and whether the Voswinckel JESC and Voswinckel JAHA references were publicly accessible by way of their presentation and/or inclusion in distributed materials, such as at a conference or library." *Id.*

C. Standard of Review

A request for rehearing of an institution decision is reviewed under the abuse of discretion standard. 37 C.F.R. § 42.71(c). “The burden of showing a decision should be modified lies with the party challenging the decision.” 37 C.F.R. § 42.71(d). “The request 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, reply, or a sur-reply.” *Id.* An abuse of discretion may be found where a decision “(1) is clearly unreasonable, arbitrary, or fanciful; (2) is based on an erroneous conclusion of law; (3) rests on clearly erroneous fact findings; or (4) involves a record that contains no evidence on which the Board could rationally base its decision.” *Redline Detection, LLC v. Star Envirotech, Inc.*, 811 F.3d 435, 442 (Fed. Cir. 2015) (quoting *Abrutyn v. Giovannello*, 15 F.3d 1048, 1050–51 (Fed. Cir. 1994) (citation omitted)).

D. We Overlooked Patent Owner’s Argument

Patent Owner is correct that its argument that the Ghofrani and Sulica research aids were dated after May 15, 2005, appeared in the Sur-Reply. Sur-Reply 9–11. Patent Owner also is correct that we overlooked this argument in relying on these research aids as supporting that Petitioner had established that Voswinckel JESC and Voswinckel JAHA were prior art to the ’793 patent. Final Dec. 11–12; Paper 81, 2 (“the Board’s analysis did not consider whether the research aids themselves were available prior to the critical date”).

E. Reconsideration of the Record Shows that the Research Aids Did Not Establish the Prior-Art Status of Voswinckel JESC and Voswinckel JAHA

Petitioner argued that Voswinckel JESC and Voswinckel JAHA were “prior art to the ’793 Patent under at least 35 U.S.C. § 102(b).” Pet. 22, 24. In the Final Written Decision, we determined that Petitioner had shown that these references were prior art based on the existence of research aids. Final Dec. 10–12. As noted above, that determination overlooked Patent Owner’s argument that the research aids themselves were published too late for their mention of Voswinckel JESC and Voswinckel JAHA to render those references prior art under § 102(b). We now consider that argument.

To qualify as prior art under § 102(b), a reference must have been publicly accessible “more than one year prior to the date of application for patent in the United States.” 35 U.S.C. § 102(b) (2006). Here, the parties agree that the application that ultimately led to the issuance of the ’793 patent was filed May 15, 2006. Pet. 12; PO Resp. 5. Thus, to qualify as § 102(b) prior art, Voswinckel JESC and Voswinckel JAHA must have been publicly accessible before May 15, 2005.

Petitioner argues that Voswinckel JESC “was cited in the June 2005 Ghofrani article in the journal *Herz . . .*, an article that was publicly accessible.” Reply 3 (citing Ex. 1010, 298, 301). Patent Owner argues that “Ghofrani bears a July 2005 date-stamp.” Sur-Reply 9 (citing Ex. 1121, 1). Petitioner does not explain its characterization of Ghofrani as a “June 2005” article. The pages of Ghofrani cited by Petitioner do not indicate a June 2005 publication date. Ex. 1010, 298, 301. The same article appears, however, as Exhibit 1121, which bears a date of July 7, 2005. *Compare* Ex. 1010, *with* Ex. 1121. Accordingly, Patent Owner’s characterization of

Ghofrani as having been published in July 2005 is better supported by the evidence of record than is Petitioner's characterization of Ghofrani as having been published in June 2005. Even if the evidence of record supported Petitioner's June 2005 publication date, that date is still later than May 15, 2005, so the citation of Voswinckel JESC in Ghofrani does not show that Voswinckel JESC was prior art under § 102(b).

Petitioner argues that Voswinckel JAHA "was cited by a March 2005 article authored by Roxana Sulica et al. in the *Expert Review of Cardiovascular Therapy*." Reply 7 (citing Ex. 1104, 359). Patent Owner argues that the Sulica article "shows only the year 2005." Sur-Reply 9 (citing Ex. 1104, 347). We agree with Patent Owner. The Sulica article bears a 2005 copyright date but otherwise does not indicate when it was published. Ex. 1104, 347. The 2005 copyright date does not support a finding that the Sulica article was published before May 15, 2005, so the citation of Voswinckel JAHA in the Sulica article does not show that Voswinckel JAHA was prior art under § 102(b).

F. Reexamination of the Record Shows that Voswinckel JESC and Voswinckel JAHA Were Prior Art to the '793 Patent Due to Distribution at Conferences

The Precedential Opinion Panel directed us, "in [our] consideration on rehearing, to clearly identify whether the Voswinckel JESC and Voswinckel JAHA references qualify as prior art" and specified that "[s]uch analysis shall clarify . . . whether the Voswinckel JESC and Voswinckel JAHA references were publicly accessible by way of their presentation and/or inclusion in distributed materials, such as at a conference or library." Paper 81, 3. Accordingly, we consider below whether the evidence of record establishes the prior-art status of Voswinckel JESC and Voswinckel

JAHA due to presentation and/or inclusion in distributed materials. We answer this question in the affirmative.

“Because there are many ways in which a reference may be disseminated to the interested public, ‘public accessibility’ has been called the touch-stone in determining whether a reference constitutes a ‘printed publication.’” *Jazz Pharm., Inc. v. Amneal Pharm., LLC*, 895 F.3d 1347, 1356 (Fed. Cir. 2018) (quoting *In re Hall*, 781 F.2d 897, 898–99 (Fed. Cir. 1986)). A reference is considered publicly accessible if it was “disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it.” *Id.* at 1355–56 (citing *In re Wyer*, 655 F.2d 221, 226 (CCPA 1981)). Under at least some circumstances, a reference may be a printed publication under § 102(b) if it was “displayed to the public,” even if it “was not later indexed in any database, catalog, or library.” *In re Klopfenstein*, 380 F.3d 1345, 1350 (Fed. Cir. 2004). There are several factors relating to whether such a display is sufficient to constitute a printed publication, including “the length of time the display was exhibited, the expertise of the target audience, the existence (or lack thereof) of reasonable expectations that the material displayed would not be copied, and the simplicity or ease with which the material displayed could have been copied.” *Id.* In addition, distribution of a reference at a professional conference may, under at least some circumstances, constitute sufficient dissemination to show public accessibility. *Nobel Biocare Services AG v. Intradent USA, Inc.*, 903 F.3d 1365, 1375–80 (Fed. Cir. 2018); *Medtronic, Inc. v. Barry*, 891 F.3d 1368, 1380–83 (Fed. Cir. 2018).

1. *Voswinckel JESC Was Sufficiently Distributed at a Conference to be Publicly Accessible as of the Conference Date*

A reference may be “[a] printed publication ‘ . . . if it was sufficiently disseminated at the time of its publication.’” *Medtronic*, 891 F.3d at 1381 (quoting *Suffolk Techs., LLC v. AOL Inc.*, 752 F.3d 1358, 1365 (Fed. Cir. 2014)). Several factors are relevant to the determination of whether distribution of a reference at a conference constitutes such sufficient dissemination. *Id.* at 1381–82. These include “the size and nature of the meetings and whether they are open to people interested in the subject matter of the material disclosed,” as well as “whether there is an expectation of confidentiality between the distributor and the recipients of the materials.” *Id.* at 1382. “The expertise of the target audience can [also] be a factor in determining public accessibility.” *Id.* To the extent that these factors are addressed via testimonial evidence, corroboration of that evidence may be necessary. *Nobel Biocare*, 903 F.3d at 1377–78. “Corroborating evidence may include documentary or testimonial evidence,” and “[c]ircumstantial evidence can be sufficient corroboration.” *Id.* (citing *TransWeb, LLC v. 3M Innovative Props. Co.*, 812 F.3d 1295, 1301 (Fed. Cir. 2016)).

Voswinckel JESC is an abstract contained in “Volume 25 Abstract Supplement August/September 2004” of “European Heart Journal,” with a subtitle indicating that the journal is the “Journal of the European Society of Cardiology” and that the supplement relates to “ESC Congress 2004,” held “28 August – 1 September” in “Munich, Germany.” Ex. 1007, 1; *see also* Ex. 1089, 1. The Table of Contents organizes abstracts into categories, including “Epidemiology and treatment of pulmonary arterial hypertension,” with each category associated with an entry corresponding to a day of the

conference, such as “Day 2—Sunday 29 August 2004.” *Id.* at 2. Each of these categories points to a page or pages in the supplement, with those pages containing abstracts that report the “Background,” “Methods,” “Results,” and “Conclusion” of studies. *Id.* at 7.

The conference with which Voswinckel JESC is associated “is the largest medical congress in Europe and among the top three cardiology meetings in the world,” and “it has become an established forum for the exchange of science as much as education.” Ex. 1105, 19. Attendees of the conference include “basic scientists, nurses and allied professionals working in the field of cardiovascular care of patients.” *Id.* At the 2004 conference, there were “24,527 attendees,” including “18,413 professionals, 4,715 exhibitors, 636 journalists and 763 accompanying persons.” *Id.* Both Petitioner’s declarant, Dr. Nicholas Hill, and Patent Owner’s declarant, Dr. Aaron Waxman, testify that anyone who paid to attend the ESC Congress 2004 would have received a copy of the abstract book from which Voswinckel JESC is excerpted, either at the meeting itself or as a distribution before the meeting. Ex. 1106 ¶ 28; Ex. 1108, 105:16–108:1.

Thus, the evidence of record shows that Voswinckel JESC was distributed to more than twenty thousand people before or at the time of the ESC Congress 2004 in late August and early September of 2004. Those twenty thousand recipients included both highly skilled professionals, including scientists, nurses, and other clinicians, as well as journalists and those who accompanied the professionals and the journalists. That the recipients included journalists and “accompanying persons” suggests very strongly that there was no expectation that the contents of Voswinckel JESC would be kept confidential. Moreover, Drs. Hill and Waxman corroborate

one another's testimony, and their testimony is further corroborated by the contents of both Voswinckel JESC itself and Exhibit 1105. The distribution of Voswinckel JESC to over twenty thousand recipients, including thousands of experts in the field of cardiology, with no expectation of confidentiality, establishes that Voswinckel JESC was a printed publication as of the date of the conference at which that distribution occurred. Because that conference occurred in August and September 2004, more than one year before the May 15, 2006 application date of the '793 patent, Voswinckel JESC was a printed publication early enough to qualify as prior art under 35 U.S.C. § 102(b).

2. *Voswinckel JAHA Was Sufficiently Distributed at a Conference to be Publicly Accessible as of the Conference Date*

Like Voswinckel JESC, Voswinckel JAHA is associated with a professional conference. Ex. 1008. It is an abstract that has been extracted from a document headed "Supplement to Circulation," subtitled "Journal of the American Heart Association" and "Abstracts from Scientific Sessions 2004," indicating that those sessions occurred "November 7–10." *Id.* at 1. The abstract in question appears in a section titled "Pulmonary Arterial Hypertension: New Therapies," subtitled "Subspecialty: Integrative Biology" and indicating that the session occurred on "Wednesday" in "Hall I2" of the "Ernest N Morial Convention Center." *Id.* at 3. We take official notice that the range of dates from November 7, 2004, to November 10, 2004, includes Wednesday, November 10, 2004.

Both Dr. Hill and Dr. Waxman agree that attendance at the Scientific Sessions 2004 conference was large. Ex. 1106 ¶ 22 ("a [person of ordinary skill in the art] would have attended the Scientific Sessions 2004

Conference, as it is one of the principal conferences on the circulatory system and diseases and conditions affecting circulation”); Ex. 1108, 116:4–21 (testifying that attendance at Scientific Sessions 2004 was likely larger than the 18,000 professionals who attended ESC Congress 2004). Dr. Hill testifies that the conference was “attended by physicians and researchers working on and studying the cardiovascular system, including pulmonary circulation.” *Id.* Both Dr. Hill and Dr. Waxman also agree that a copy of the abstract book from which Voswinckel JAHA is excerpted would have been provided to all attendees at Scientific Sessions 2004. Ex. 1106 ¶ 23; Ex. 1108, 108:3–20. We have not been directed to any evidence of record indicating there was any expectation of confidentiality. The distribution of thousands of copies of Voswinckel JAHA at the conference is strong evidence that Voswinckel JAHA was a printed publication as of the date of the conference. Because that conference occurred in November 2004, more than one year before the May 15, 2006 application date of the ’793 patent, Voswinckel JAHA was a printed publication early enough to qualify as prior art under 35 U.S.C. § 102(b).

3. *Conclusion*

As instructed by the Precedential Opinion Panel, we have considered “whether the Voswinckel JESC and Voswinckel JAHA references qualify as prior art” and in particular “whether the Voswinckel JESC and Voswinckel JAHA references were publicly accessible by way of their presentation and/or inclusion in distributed materials, such as at a conference.” Paper 81, 3. As discussed above, we find that both references were distributed sufficiently at professional conferences to be publicly accessible at the time of those conferences. By virtue of this public accessibility, both Voswinckel

JESC and Voswinckel JAHA were printed publications early enough to qualify as prior art under 35 U.S.C. § 102(b).

G. Asserted Obviousness over '212 Patent, Voswinckel JESC, and Voswinckel JAHA

Petitioner argues that claims 1–8 would have been obvious over the combination of the '212 patent, Voswinckel JESC, and Voswinckel JAHA. Pet. 30–46. As discussed above, Petitioner has shown by a preponderance of the evidence that both Voswinckel JESC or Voswinckel JAHA qualify as prior art. Accordingly, we do not disturb the obviousness analysis in the Final Written Decision, which relies on the prior-art status of Voswinckel JESC and Voswinckel JAHA. Final Dec. 12–35.

H. Remaining Grounds

Petitioner argues that claims 1–8 would have been obvious over the combination of the '212 patent and Voswinckel JESC. Pet. 46–50. We do not disturb the determination in the Final Written Decision that we need not reach this ground “[b]ecause Petitioner has shown by a preponderance of the evidence that all of the challenged claims would have been obvious over the similar combination of the '212 patent, Voswinckel JESC, and Voswinckel JAHA.” Final Dec. 36.

Petitioner argues that claim 1 was anticipated by Ghofrani; that claims 1, 3, and 8 would have been obvious over the combination of Voswinckel JAHA and Ghofrani; that claims 1 and 3 were anticipated by Voswinckel 2006; and that claims 2 and 4–8 would have been obvious over the combination of Voswinckel 2006 and the '212 patent. Pet. 50–64. These grounds fail for the reasons discussed in the Final Written Decision. Final Dec. 36–41.

CONCLUSION¹

For the reasons discussed above, Patent Owner has shown that we overlooked its argument regarding the date of availability of the research aids that Petitioner argued showed that Voswinckel JESC and Voswinckel JAHA qualified as prior art. A proper consideration of that argument shows that the research aids do not establish the prior-art status of Voswinckel JESC and Voswinckel JAHA, but there is no change to the outcome with respect to Petitioner's asserted grounds of unpatentability, because the distribution of Voswinckel JESC and Voswinckel JAHA at professional conferences proves the prior-art status of those references. Accordingly, we deny Patent Owner's request for rehearing.

When all arguments are properly considered, Petitioner has shown by a preponderance of the evidence that claims 1–8 of the '793 patent are unpatentable.

Outcome of Decision on Rehearing:

Claims	35 U.S.C §	Reference(s)/Basis	Denied	Granted
1–8	103(a)	'212 patent, Voswinckel JESC, Voswinckel JAHA	1–8	
Overall Outcome			1–8	

¹ Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this Decision, we draw Patent Owner's attention to the April 2019 Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. §§ 42.8(a)(3), (b)(2).

Final Outcome of Final Written Decision after Rehearing:

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–8	103(a)	'212 patent, Voswinckel JESC, Voswinckel JAHA	1–8	
1–8	103(a)	'212 patent, Voswinckel JESC ²		
1	102(a)	Ghofrani		1
1, 3, 8	103(a)	Voswinckel JAHA, Ghofrani		1, 3, 8
1, 3	102(a)	Voswinckel 2006		1, 3
2, 4–8	103(a)	Voswinckel 2006, '212 patent		2, 4–8
Overall Outcome			1–8	

ORDER

It is hereby

ORDERED that Patent Owner's Request for Rehearing is denied;

FURTHER ORDERED that the determination in the Final Written Decision that the research aids relied on by Petitioner show the prior-art status of Voswinckel JESC and Voswinckel JAHA is overturned and replaced with the determination in the present decision that the distribution

² Neither the Final Written Decision nor this Rehearing Decision reaches this ground because Petitioner has proven all challenged claims are unpatentable based on obviousness over the combination of the '212 patent, Voswinckel JESC, and Voswinckel JAHA.

IPR2021-00406
Patent 10,716,793 B2

of Voswinckel JESC and Voswinckel JAHA at professional conferences establishes the prior-art status of those references;

FURTHER ORDERED that, based on the preponderance of the evidence, claims 1–8 of the '793 patent have been shown to be unpatentable;

FURTHER ORDERED that all other rulings in the Final Written Decision remain undisturbed; and

FURTHER ORDERED that parties to this proceeding seeking judicial review of this Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

IPR2021-00406
Patent 10,716,793 B2

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IPR2021-00406
Patent 10,716,793 B2

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