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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ANTONIO J. GRILLO-LOPEZ

Appeal 2018-006082
Application 13/524,837
Technology Center 1600

Before JEFFREY N. FREDMAN, TAWEN CHANG, and DAVID COTTA, *Administrative Patent Judges*.

CHANG, *Administrative Patent Judge*.

DECISION ON REQUEST FOR REHEARING

Appellant[1] requests rehearing of the decision entered August 28, 2019 ("Decision"), which affirmed the Examiner's rejections of claims 15–17 as obvious but designated the affirmance as a new ground of rejection.

We deny the requested relief.

DISCUSSION

In the Decision, we found that the transcript of the July 25, 1997 meeting of FDA's Biological Response Modifiers Advisory Committee ("FDA Transcript") was made sufficiently accessible to the public interested

[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42.

in the art so as to render it a printed publication within the meaning of § 102(b). Appellant contends that the Decision "is contrary to the previous board decisions finding that this very FDA Transcript was not a printed publication." Req. Reh'g 4. We are not persuaded.

A. Examination and IPR Proceedings have Different Standards for Establishing a Printed Publication

As an initial matter, the previous board decisions involving the FDA Transcript were in IPR proceedings,[2] where "a petitioner is required to present evidence and arguments sufficient to show that it is reasonably likely that it will prevail in showing the unpatentability of the challenged claims." *Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, Paper 29 at 13 (PTAB Dec. 20, 2019) (precedential) (citing 35 U.S.C. §§ 312(a)(3), 314(a)).

In contrast, the examination context involves a burden-shifting framework under which the USPTO can shift the burden to the applicant to come forward with rebuttal evidence or argument to overcome a prima facie case. *Ex Parte Albert*, 18 USPQ 2d 1325 (BPAI 1984) ("[T]he examiner met his burden of proof by setting forth the nominal publication date. . . . The Patent and Trademark Office is in no position to establish any thing beyond that. The burden is clearly upon appellants to disprove the prima facie publication date established by the examiner."); *see also In re Antor Media Corp.*, 689 F.3d 1282, 1287–89 (Fed. Cir. 2012) (establishing a burden-shifting framework regarding presumptive enablement of a prior art printed publication cited by an examiner); *In re Jung*, 637 F.3d 1356, 1362

[2] *Celltrion, Inc. v. Biogen, Inc.*, IPR2017-01094, IPR2017-01230, IPR2017-01227, and IPR2017-01229.

(Fed. Cir. 2011) (establishing that the prima facie case is a procedural device that shifts the burden of production to the applicant and that the USPTO sets forth a prima facie case when its rejection satisfies the notice requirement of 35 U.S.C. § 132); *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993) (establishing a burden-shifting framework regarding prima facie cases of obviousness); *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977) (establishing a burden-shifting framework regarding rejections based on findings of inherency). Given the different legal frameworks and burdens for establishing a reference as prior art in IPR proceedings and examination, the Decision is not contrary to the Board decisions finding that a petitioner failed to meet its burden of showing that the FDA transcript is a printed publication. In other words, the framework set forth in the *Hulu* decision for IPR proceedings does not apply to examination.

B. The Examiner Sufficiently Established That the FDA Transcript is a Printed Publication

More importantly, as the Decision notes, the petitioner in those IPR proceedings "did not cite to publication of the Notice of Hearing in the Federal Register, attendance of the hearing by an interested member of the public pursuant to the notice, or the requirements of FACA [Federal Advisory Committee Act] in support of the public accessibility of the FDA Transcript." Dec. 15, fn. 12. As the predecessor to our reviewing court has explained, "[e]ach [printed publication] case must be decided on the basis of its own facts." *In re Wyer*, 655 F.2d 221, 227 (CCPA 1981).

Appellant contends that the Decision nevertheless does not "lay out a *prima facie* case that 'persons interested and ordinarily skilled in the subject

matter or art exercising reasonable diligence' would have been able to obtain a copy of the actual FDA Transcript."[3] Req. Reh'g 3.

Appellant first contends that the Decision "conflat[es] the concept of the hearing itself being public with the question of whether the FDA Transcript is a printed publication." *Id.* Appellant contends that the Decision "does not articulate any reason an ordinarily skilled person would have read the Federal Register." *Id.* at 5. Appellant further contends that "notification of a *public hearing* is not evidence that a later *printed publication* was made sufficiently available to an ordinarily skilled person exercising reasonable diligence," that "there is no evidence that an ordinarily skilled person would have learned anything about the transcript from the notice," and that "attendance at the oral hearing by an 'interested member of the public' is not evidence that a later printed publication was made sufficiently available to an ordinarily skilled person exercising reasonable diligence." *Id.*

We are not persuaded. As to Appellant's argument that the Decision does not explain why an ordinarily skilled person would have read the Federal Register, the Decision notes that publication of the notice of the advisory committee meeting is intended to "insure that all interested persons are notified of such meeting prior thereto." Dec. 13. A person of ordinary skill in the art, such as an oncologist or medical researcher of ordinary skill,

[3] Appellant asserts that "[t]he alleged evidence [of public accessibility] that the Board identifies did not appear until the Examiner's Answer and the Board's decision" and that "the evidence presented in the Examiner's Answer was presented only in the context of *public use*." Req. Reh'g 3. We are not persuaded: As noted in the Decision, our affirmance was designated as a new ground of rejection under 37 C.F.R. § 41.50(b), and such a rejection need not be based solely on the reasoning set forth in the Answer.

would have been such an "interested person." Given the intent behind publishing the notice of meeting, we find that a prima facie case exists that an interested artisan would have been aware of the notice of meeting published in the Federal Register.

Likewise, contrary to Appellant's apparent understanding, the Decision does not suggest that either the public notice of meeting, the public meeting, and/or attendance of an interested member of the public at the meeting render the transcript of the hearing publicly accessible, whether together or by themselves. Dec. 13–14. Rather, the Decision explains that the notice and the hearing establishes a prima face case that "an ordinarily skilled artisan for purposes of the claimed invention (e.g., an oncologist or a medical researcher of average experience) would have been aware of the Biological Response Modifiers Advisory Committee meeting regarding rituximab." *Id.* The Decision then explains that, given that "there is a reasonable expectation, if not a legal requirement, that transcripts of FDA advisory committee meetings would be publicly available at a designated place at the agency," a prima facie case also exists that, once an ordinarily skilled artisan is aware of the meeting regarding rituximab, he or she also would have known of the existence of the transcript and been able to obtain a copy with the exercise of reasonable diligence. *Id.* at 14–15. In short, there is no conflation between the public nature of the meeting and whether a subsequent transcript of the meeting was sufficiently publicly accessible.[4]

[4] The cases cited by Appellant are inapposite. *AT&T Corp. v. Microsoft*, 2004 WL 292321, No. 01 Civ 4872 (WHP), 2004 WL 292321 (S.D.N.Y. Feb. 17, 2004), merely stands for the proposition that oral presentation of a paper, without more, does not constitute, or transform the paper into, a "printed publication." *Id.* at *6. Here, we do not suggest that the advisory

Appellant also misunderstands the Decision when it argues that presence of an interested member of the public at the advisory committee meeting is not evidence that the transcript of the meeting was made sufficiently available to an ordinarily skilled artisan exercising reasonable diligence, because there is no evidence that the interested member of the public was an ordinarily skilled artisan and because, even if an ordinarily skilled artisan had been present at the meeting and even if such a person had known about the existence of the transcript, knowledge of a single individual is not sufficient to establish public accessibility. Req. Reh'g 5–6.

As discussed above, the intent of the notice of the advisory committee meeting is to "insure that all interested persons are notified of such meeting prior thereto." Dec. 13. The presence of an interested member of the public at the meeting, even if he or she is not an ordinarily skilled artisan for

committee meeting, without more, transforms the transcript of the meeting into a printed publication.

In *In re Cronyn*, the Court held that three student theses were not accessible to the public where cards listing the theses are filed alphabetically by the author's name, because the only "research aid" (i.e., the author's name) "bears no relationship to the subject of the student's thesis." *Id.* at 1159, 1161. Similarly, the court in *In re Bayer*, 568 F.2d 1357 (CCPA 1978), held that "[a]ccessibility to appellant's thesis by the three members of the graduate committee . . . does not raise . . . a presumption" that "'the public concerned with the art would know of (the invention).'" *Id.* at 1361. In this case, in contrast to the facts of *In re Bayer* and *In re Cronyn*, the FDA advisory committee meeting as well as the topic of the meeting (i.e., Rituximab as treatment for patients with relapsed or refractory low grade or follicular B-cell non-Hodkin's Lymphoma) was announced in the Federal Register, with the intent of "insur[ing] that all interested persons are notified of [the] meeting prior thereto." Dec. 13.

purposes of the claimed invention,[5] suggests that the notice achieved that goal, and thus supports a prima facie case that ordinarily skilled artisans (who are also interested persons) would have been aware of the advisory committee meeting. Neither are we persuaded by Appellant's argument that knowledge of a single individual is not sufficient to establish public accessibility of the transcript and its citation to *Bayer*, 568 F.2d at 1358–1359, and *SRI Int'l, Inc. v. Internet Sec. Sys., Inc.*, 511 F.3d 1186, 1195–96 (Fed. Cir. 2008), for support. As explained above, our finding of public accessibility in the Decision is not based solely, or even primarily, on the fact that a member of the public was present at the advisory committee meeting. This factual point does, however, tend to support a finding of public availability.

Appellant contends that, "assuming an ordinarily skilled person might have known about the oral hearing . . . , and . . . assuming a copy of the FDA Transcript was publicly available," there is no evidence that such a person "would have known of the existence and accessibility of the transcript." Req. Reh'g 4. Appellant contends that "a law . . . requiring a transcript of a hearing be made, and be made available, is not evidence that the transcript was made sufficiently available to an ordinarily skilled person exercising reasonable diligence." *Id.* at 6.

We are not persuaded. Appellant has not disputed that the FACA requires the creation of a transcript of the FDA committee meeting at issue and to make such a transcript publicly available; instead, Appellant argues

[5] The member of the public who attended and spoke at the meeting was Kathryn Adams, Vice President of the Cure for Lymphoma Foundation in 1997. FDA Transcript 8:10–12.

only that "[a]n ordinarily skilled person in this case is not a lawyer" and that the Decision "presents no explanation or proof that a person with ordinar[y] skill in the pertinent art would have been aware of the FACA requirements." Req. Reh'g.

We disagree with Appellant's apparent suggestion that only lawyers would be aware of the requirements set forth in FACA.[6] As discussed above and in the Decision, an ordinarily skilled artisan in this case includes an oncologist or medical researcher of average experience.[7] Dec. 13–14. It does not matter that such individuals are not lawyers, but that they are able to obtain pertinent information relating to the work of FDA advisory committees regarding cancer drugs such as rituximab, because they work in an industry whose products are regulated by the FDA and/or because they prescribe such products.

CONCLUSION

We have carefully reviewed the original decision in light of Appellant's request, but we find no point of law or fact which we overlooked or misapprehended in arriving at our decision. Therefore, Appellant's request is denied with respect to making any modifications to the Decision.

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[6] Appellant asserts that FACA "was enacted to cure specific ills, above all the wasteful expenditure of public funds for worthless committee meetings and biased proposals." Req. Reh'g 6 (internal quotation marks and citation omitted). Appellant does not provide any reasoning for its apparent position that this goal is incompatible with an intent to make documents related to advisory committee meetings publicly accessible, particular to ordinarily skilled artisans in the field(s) to which the subject matter of the meetings pertain.

[7] Appellant has neither disputed this characterization of the ordinarily skilled artisan nor proposed different qualifications for such an individual.

Outcome of Decision on Rehearing:

Claims	35 U.S.C §	Reference(s)/Basis	Denied	Granted
15–17	103(a)	FDA Transcript	15–17	

Final Outcome of Appeal after Rehearing:

Claims	35 U.S.C. §	Reference(s) / Basis	Affirmed	Reversed	New Ground
15–17	102(b)	Prescribing information for Rituxan®, dated November 1997		15–17	
15–17	103(a)	FDA Transcript	15–17		15–17
Overall Outcome			15–17		15–17

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

REHEARING DENIED