

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2023-00442

U.S. Patent No. 10,130,681

**PETITIONER'S OPPOSITION TO
PATENT OWNER'S MOTION TO EXCLUDE**

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TABLE OF EXHIBITS

Exhibit	Description
1001-1081	<i>Previously presented</i>
1082	Standard Affidavit (unexecuted) filed as Exhibit 1014 in <i>ASM IP Holding BV et al v. Kokusai Electric Corporation a/k/a Kabushiki-Kaisha Kokusai Electric et al.</i> , IPR2019-00369

I. INTRODUCTION

Petitioner respectfully requests the Board deny Patent Owner's Motion to Exclude.

As set out below, Patent Owner primarily seeks to exclude Ex. 1031, the CATT Study exclusion criteria. Petitioner submitted with Ex. 1031 an executed Internet Archive declaration authenticating the document and establishing its availability before the critical date of the patent. Patent Owner barely acknowledges this declaration, but the Board's precedent—including that cited in the Petition and entirely unaddressed by Patent Owner here—establishes that the declaration is sufficient to establish authenticity and public availability. *See* Pet. at 27-29 (citing *Int'l Bus. Machines Corp. v. Intellectual Ventures LLC*, No. IPR2015-00089, 2016 WL 3598306, at *28 (P.T.A.B. Apr. 25, 2016); *Sandoz Inc. v. AbbVie Biotechnology Ltd.*, No. IPR2018-00156, 2018 WL 2735468, *4-5 (P.T.A.B. June 5, 2018)). The accompanying declaration is thus sufficient to establish admissibility, and Patent Owner's other attacks are both irrelevant and premised on gross misrepresentations of the record, including Petitioner's expert's testimony.

Patent Owner also seeks to exclude Exhibits 1071 and 1072. But these exhibits are part of, and complete, two incomplete exhibits that Patent Owner itself submitted as prior art (Exhibits 2108 and 2109). Specifically, Patent Owner made a misguided argument in its POR that POSAs would look solely to the exclusion

criteria of the ANCHOR and MARINA studies, rather than those relied on by Petitioner. In alleged support of that argument, Patent Owner cited Exhibits 2108 and 2109, which are ANCHOR and MARINA papers. Those exhibits are incomplete, however, and expressly reference “a complete list of eligibility criteria” which they state are listed in a “Supplementary Appendix,” but which Patent Owner did not provide the Board. *See, e.g.* Ex. 2109 at 1421. Exhibits 1071 and 1072 are the Supplemental Appendices for these papers, as Patent Owner should know having submitted the ANCHOR and MARINA papers. And as Petitioner pointed out in its Reply (at 16-17), the complete list of exclusion criteria reflected in Exhibits 1071 and 1072 undermines Patent Owner’s arguments. Patent Owner should not be heard to challenge the admissibility of material directly referenced by—and indeed part of—exhibits that Patent Owner submitted as prior art.

Finally, Patent Owner contends that Petitioner did not cite Exhibit 1029, which is U.S. Patent No. 9,669,069 (the “’069 patent). But Petitioner discussed the ’069 patent directly throughout its Petition, including in the discussion of related cases, as well as in discussion the ’681 patent’s prosecution history. *See* Petition at 6, 9, 14. The ’069 patent is useful context for the Board in considering the related cases and prosecution history, and the fact Patent Owner inadvertently omitted a *in haec verba* citation to “Exhibit 1029” should not result in its exclusion.

II. ARGUMENT

A. Exhibit 1031 Is Admissible and Was Authenticated by Executed Declaration Establishing Its Authenticity and Public Availability¹

Ex. 1031 is an online publication listing the exclusion criteria associated with the CATT clinical trial, which evaluated the efficacy and safety of intravitreal injections of Avastin relative to Lucentis. Ex. 1031, CATT Study; Ex. 1035; Ex. 1002, ¶¶ 101-103. Ex. 1031 contains an authenticating affidavit from the Internet Archive, showing the CATT Study document was available to a POSA as of at least July 13, 2010. Petitioner cited cases in its Petition (at 27-29) finding that the same type of affidavits as submitted here have been routinely accepted by the Board as evidence of authenticity and public availability.

Patent Owner argues that Ex. 1031 should be excluded because it is insufficiently authenticated. But Patent Owner's motion barely acknowledges that Ex. 1031 is expressly authenticated by executed declaration. And it nowhere addresses the Board's cases finding that Internet Archive declarations can be used

¹ As noted in Petitioner's Petition (at 26, n.3), even without the CATT Study, "the MACTEL Study and PIER Study's disclosure of the recited exclusion criteria are sufficient alone or in combination" to render obvious the challenged claims, and so even if the Board were to grant Patent Owner's motion (it should not), the challenged claims are still obvious over MACTEL and PIER.

to authenticate and establish public availability of prior art. *See, e.g., Int’l Bus. Machines Corp v. Intellectual Ventures LLC*, IPR2015-00089, 2016 WL 3598306, at *28 (P.T.A.B. Apr. 25, 2016). The use of Internet Archive affidavit to authenticate a prior art document is well established and routinely accepted by the Board. *Id.*; *see also Merck Sharp & Dohme Corp. v. Wyeth LLC*, 2016 WL 9410454 (P.T.A.B. December 1, 2016) (accepting an archived copy on the ‘Internet Archive’ website as prior art, and the authenticity of prior art based on the affidavit of [the office manager of the Internet Archive]”); *Servicenow, Inc. v. Hewlett-Packard Co.*, No. IPR2015-00707, 2015 WL 5117886, at *5 (P.T.A.B. Aug. 26, 2015) (same).

Ignoring these cases, Patent Owner instead relies on *ASM IP Holding B.V. v. Kokusai Electric Corporation*, No. IPR2019-00369, 2019 WL 2711249 (P.T.A.B. June 27, 2019). But ASM supports Petitioner here. In ASM, the party proffering the exhibit submitted a webpage print out and—unlike here—an ***unexecuted***, form declaration. *Id.*, at *8; *see also* Ex. 1082. This, of course, raised concerns about the authenticity of the document, as the proffering party was apparently unable to obtain an executed declaration. *Id.* Without any further information showing authenticity, the Board excluded the document. *Id.*

ASM supports admissibility of Exhibit 1031. As the Board explained, “[t]o authenticate printouts from a website, the party proffering the evidence must produce some statement or affidavit from someone with knowledge of the website . . . for

example a web master or someone else with personal knowledge would be sufficient.” *Id.* This is precisely what Petitioner did here. Exhibit 1031 includes an **executed** declaration by Nathaniel E Frank-White, a Records Request Processor at the Internet Archive, attesting to his personal knowledge of the content on the Internet Archive, its operation, and how the Wayback Machine archives websites and files, and when the CATT Study document was captured by the Wayback Machine and made publicly available. Ex. 1031, 1-4. Exhibit 1031 is therefore admissible under the evidentiary rules and was properly authenticated by the executed declaration. *See U.S. v. Bansal*, 663 F.3d 634, 667-68 (3d. Cir. 2011) (finding Internet Archive images authenticated under Federal Rule of Evidence 901(b)(1) by a witness with personal knowledge of its contents).

Patent Owner’s other cases (at 5-6) similarly are inapposite. None of them involve a document supported by an executed declaration establishing the authenticity and public availability of the document. Instead, they include cases addressing documents offered with no supporting testimony at all, or testimony that expressly established that the document may not have been authentic or publicly available. *See Riverbed Tech., Inc. v. Realtime Data LLC*, No. IPR2016-00978, 2017 WL 4925393, at *17 (P.T.A.B. Oct. 30, 2017) (excluding publication under FRE 901 because no evidence of authentication or supporting testimony); *Ingenico Inc. v. IOENGINE, LLC*, IPR2019-00929, 2020 WL 5637098, at *43- 44 (P.T.A.B.

Sept. 21, 2020) (excluding letter because it was “not accompanied by testimony attesting to its authenticity”); and *Linear Tech. Corp. v. Micrel, Inc.*, 275 F.3d 1040, 1055-56 (Fed. Cir. 2001) (affirming exclusion of letters lacking signature or letterhead and based on testimony casting doubt letters were actually mailed).

Because Exhibit 1031 is authenticated by a witness with personal knowledge of the content relied upon, Patent Owner’s assertion that Petitioner’s expert Dr. Chaum “made no independent investigation into its authenticity or provenance” of Exhibit 1031 is irrelevant. Motion to Exclude, 4-5. Patent Owner’s assertion that Exhibit 1031 should be excluded under FRE 702 and 703 also fails on this basis.

Patent Owner further faults Petitioner for not providing the “indicia of reliability” for Ex. 1031, but as Patent Owner admits, Exhibit 1031 clearly shows “CATT Patient Eligibility Criteria” and “CATT: Lucentis-Avastin Trial” on the face of the document, which was published by University of Pennsylvania—the institution that was known to be responsible for conducting and reporting the CATT clinical trial. See Ex. 1031 (URL reciting www.med.upenn.edu); Ex. 1035 (listing University of Pennsylvania as “Responsible Party” for providing information for the CATT clinical trial). Patent Owner relies on testimony from Dr. Chaum that University of Pennsylvania was not the “sponsoring” university; but Dr. Chaum’s testimony was correct—the University of Pennsylvania was the **coordinating** center, not the sponsor. See <https://www.med.upenn.edu/cpob/catt.html> (Center for

Preventive Ophthalmology and Biostatistics (CPOB) at UPenn “is home to ... the CATT<https://www.med.upenn.edu/cpob/center-coordinating.html> Coordinating Center”).

Patent Owner additionally argues that Exhibit 1031 is hearsay and should be excluded. Motion to Exclude, 6. But it is not offered for the truth of the matters asserted therein as Patent Owner contends—e.g. that the disclosed exclusion criteria were actually adopted by the CATT clinical trial. Rather, Exhibit 1031 was offered to show what it would teach to a POSA concerning the relevant exclusion criteria known at the time. Pet., 26-28, 42-44.

Consistent with this understanding, Dr. Chaum also testified that POSAs would be led to University of Pennsylvania’s website for the CATT Study document (Ex. 1031), and that he considered it, because it is “material...in the literature that’s available and resources that [Dr. Chaum or a POSA] can tap to understand what the state of the art was, what the concerns were and what other clinical trials were doing.” Ex. 2384, 198:8-14; *see also* Ex. 1035 (showing the CATT clinical trial “First Posted” date of January 15, 2008). Ex. 1031 is therefore not hearsay.

For the foregoing reasons, Exhibit 1031 should not be excluded.

B. Exhibits 1071 and 1072 Are Admissible and Form Part of Patent Owner's Own Incomplete Exhibits

Patent Owner (at 7-10) also seeks to exclude Exhibits 1071 and 1072. Petitioner submitted these exhibits solely in rebuttal to Patent Owner's misguided argument that POSAs would look solely to the exclusion criteria of two other studies—particularly the MARINA and ANCHOR studies—and that the criteria for these studies would not motivate a POSA to adopt the relevant exclusion criteria. POR at 36-52.

Specifically, Patent Owner argued in its POR that a POSA would have looked to the MARINA and ANCHOR studies and adopted their exclusion criteria. In alleged support of that argument, Patent Owner cited Exhibits 2108 and 2109, which are papers published regarding ANCHOR and MARINA. The ANCHOR and MARINA papers submitted by Patent Owner, however, are incomplete. Those papers expressly reference “a complete list of eligibility criteria” which they state are listed in a “Supplementary Appendix,” but which Patent Owner did not provide the Board. *See, e.g.* Ex. 2109 at 1421; Ex. 2108 at 1435.

Exhibits 1071 and 1072, which Patent Owner seeks to exclude, are the Supplemental Appendices for these papers. As Petitioner pointed out in its Reply (at 16-17), the exclusion criteria provided in these exhibits—and conveniently omitted by Patent Owner—undermine Patent Owner's arguments in two ways. First, they are different from the criteria adopted in later studies, showing that POSAs

would not solely rely on the ANCHOR and MARINA studies as Patent Owner contends. See Reply (comparing Ex. 1001, 10:57-12:15 (later study criteria) with Ex. 1071 and Ex. 1072). Second, the exclusion criteria they do list teach to exclude patients with diseases or conditions—such as the exclusion criteria here—that “render the subject at high risk for treatment complications.” See, e.g. Ex. 1072. They are thus consistent with Petitioner’s arguments, and undermine Patent Owner’s position. They should have been submitted by Patent Owner in the first place.

It should go without saying that offering the complete set of exclusion criteria, which were missing from the incomplete exhibits that Patent Owner itself submitted as part of the prior art, should not present an authenticity, hearsay, or public availability issues. Exhibits 1071 and 1072 reflect, on their face, that they are the “Supplementary Appendi[ces]” to Exhibits 2108 and 2109, which are the ANCHOR and MARINA papers submitted by Patent Owner. They both list the title and publication information corresponding to Exhibits 2108 and 2109 on their face, which match that of the information reflected on Exhibits 2108 and 2109.² And both

² Patent Owner argues there is nothing on the face of Exhibits 1071 and 1072 indicating when they are publicly available. Their availability is established on the face of Exhibits 2108 and 2019, which were themselves publicly available, and

were downloaded as expressly directed in Exhibits 2108 and 2109. *See* Exhibit 2108 at 1435; Exhibit 2109 at 1421.

Accordingly, these documents are as authentic and were as accessible as Exhibits 2108 and 2109, which Patent Owner submitted as prior art—indeed, they are properly considered part of those exhibits. Accordingly, Exhibits 2108 and 2109, submitted by Patent Owner itself, along with the information on the face of the exhibits themselves, establish the authenticity and public availability of Exhibits 1071 and 1072. Patent Owner should not be heard to argue otherwise, given its contention that Exhibits 2108 and 2109 are authentic and publicly available.

Patent Owner also adds a last ditch argument that Exhibits 1071 and 1072 are hearsay. But neither exhibit is offered for the truth of the matters asserted therein—e.g. that patients were actually excluded from the relevant trials based on the criteria. Instead, both exhibits were offered only to show what they would teach to a POSA and to directly contradict Patent Owner’s argument about what the ANCHOR and MARINA papers themselves teach POSAs. They are thus not hearsay.

which reference these Exhibits 1071 and 1072 directly, including instructing on how to access them along with the papers.

C. Exhibit 1029 Was Discussed in Multiple Places in the Petition and Is Admissible Here

Finally, Patent Owner (at 10-11) contends that Petitioner did not cite Exhibit 1029, which is the '069 patent. Patent Owner contends the exhibit should be excluded on that basis. Petitioner, however, discussed the '069 patent directly throughout its Petition, including in the discussion of related cases, as well as in discussion the '681 patent's prosecution history. See Petition at 6, 9, 14. Specifically, the Board previously issued a FWD invalidating the challenged '069 patent claims, rejecting many of the same arguments made by Patent Owner here. And Patent Owner terminally disclaimed the '681 patent claims over the '069 patent during prosecution. Thus, the '069 patent is useful context for the Board in considering the related cases and prosecution history.

The fact that Petitioner inadvertently omitted a *in haec verba* citation to “Exhibit 1029” should not result in its exclusion, given Petitioner clearly and directly discussed the '069 Patent in the Petition. Nor does Patent Owner's sole authority suggest it should. At 10, Patent Owner cites *One World Techs., Inc. v. Chamberlain Grp., Inc.*, IPR2017-00126, Paper 56, at 16-17 (P.T.A.B. Oct. 24, 2018) for the proposition that “exhibits that are not cited in the pleadings have no bearing on any fact that is of consequence in determining the outcome of the proceeding.” But in *One World Tech*, the only reference to the challenged exhibit was in the Patent Owner's expert's report. The Board expressly noted that the Patent Owner did not

make any arguments discussing the document, and did not even cite the paragraph of the expert's report that cited the exhibit. That is a far cry from here, where all this is missing is an *in haec verba* citation to "Exhibit 1029." Such a small ministerial issue should not result in exclusion.

II. CONCLUSION

For the foregoing reasons, Petitioner respectfully requests the Board deny Patent Owner's Motion to Exclude.

DATED: April 5, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

In accordance with 37 C.F.R. § 42.6(e), I hereby certify that on April 5, 2024, true and correct copies of Petitioner's Opposition to Patent Owner's Motion to Exclude were served via electronic mail to Patent Owner at the following email addresses of record:

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