

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
Patent No. 10,130,681 B2

PATENT OWNER'S MOTION TO EXCLUDE

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Pursuant to 37 C.F.R. § 42.64, Patent Owner Regeneron Pharmaceuticals, Inc. (“Patent Owner”) hereby moves to exclude (i) Exhibit 1031 and portions of Petitioner’s Petition, Reply, and expert declaration relying on that exhibit; (ii) Exhibits 1071 and 1072, and portions of Petitioner’s Reply relying on those exhibits; and (iii) Exhibit 1029.¹ The exhibits and portions of Petitioner’s pleadings and expert declaration that Patent Owner seeks to exclude are irrelevant under Federal Rules of Evidence (“FRE”) 401 and 402; are unfairly prejudicial under FRE 403; constitute improper expert testimony under FRE 702 and 703; constitute improper hearsay under FRE 802; and/or are not authenticated under FRE 901. Pursuant to 37 C.F.R. § 42.64, Patent Owner timely raised its objections to these materials on August 2, 2023, and January 23, 2024 (Paper Nos. 17 and 41).

I. INTRODUCTION

Petitioner’s challenge to the ’681 Patent depends on exhibits and testimony that run afoul of the FRE. First, Petitioner relies in its grounds on Exhibit 1031, a document that Petitioner claims contains exclusion criteria for the CATT clinical study. Exhibit 1031, however, lacks indicia of reliability, and Petitioner’s expert was unable to answer basic questions regarding its provenance. Petitioner’s Exhibits

¹ For ease of reference, a table listing specific locations of the Petitioner submissions that are the subject of this motion to exclude is included *infra* at 12.

1071 and 1072, documents that purport to be supplemental appendices from the MARINA and ANCHOR clinical studies, are similarly problematic. Petitioner has failed to establish the authenticity of these exhibits and has, therefore, failed to establish they are relevant prior art as opposed to unauthenticated hearsay. Finally, Petitioner has submitted Exhibit 1029, which is not cited nor relied upon in its pleadings. Patent Owner respectfully requests that the Board exclude these submissions.

II. PETITIONER’S IMPROPER EXHIBITS AND ARGUMENTS SHOULD BE EXCLUDED

A. Exhibit 1031 Is Unauthenticated Hearsay and Should Be Excluded Under FRE 401-03, 702-03, 802 and/or 901-02

Petitioner relies on an unauthenticated document, Exhibit 1031, as part of its Ground I challenge. The Petition and accompanying papers provide no evidence or explanation to establish that Exhibit 1031 is what Petitioner purports it to be—*i.e.*, a disclosure of exclusion criteria from the CATT clinical trial. Petitioner incorrectly refers to Exhibit 1031 as the “CATT Study.” Pet. (Paper 2), 26-27. But Exhibit 1031 is not a study protocol, ClinicalTrials.gov entry, or scientific publication. Rather, it appears to be an excerpt from a larger document of unknown origin and authorship—it contains no indication that its listed “eligibility criteria,” were in fact included in the CATT study protocol, or in any other document on which the POSA would have relied. Patent Owner timely noted these failings in its post-institution briefing and

objections to Petitioner's exhibits.²

FRE 901(a) is clear: "To satisfy the requirement of authenticating or identifying an item of evidence, the proponent must produce evidence sufficient to support a finding that the item is what the proponent claims it is." Authentication may be shown by the "appearance, contents, substance, internal patterns, or other distinctive characteristics of the item, taken together with all the circumstances." Fed. R. Evid. 901(b)(4). However, documents "lack[ing] authenticating indicia" should be excluded under FRE 901. See *Xactware Sols. Inc. v. Pictometry Int'l Corp.*, IPR2016-00594, 2017 WL 3671031, at *4-6 (P.T.A.B. Aug. 24, 2017), *aff'd per curiam*, 742 F. App'x 509 (Fed. Cir. 2018) (mem.).

Exhibit 1031 comprises an affidavit from an Internet Archive custodian (pages 1-2) and a document posted on the University of Pennsylvania ("UPenn") website with the heading "CATT Patient Eligibility Criteria" (pages 5-8). Beyond

² See POR (Paper 26), 35 & n.21; Paper 17, 1-2, 8-9. Patent Owner also provided sufficient particularity in its objections. *Id.* Specifically, Patent Owner objected to Exhibit 1031 under FRE 401-03, 802, and 901 and objected to Dr. Chaum's testimony relying on Exhibit 1031 (Ex.1002, ¶¶ 99-103, 130-58) under FRE 401-03, 702-03, 802, and 901. *Id.*

its isolated headings,³ however, the “CATT” excerpt does not contain any identifying information or connection to a complete source document, much less any “indicia of reliability,” such as a periodical name, publication date, author information, copyright date, etc. that would prove that it is in fact what Petitioner says it is—*i.e.*, the exclusion criteria used in the CATT study. *See ASM IP Holding B.V. v. Kokusai Elec. Corp.*, IPR2019-00369, 2019 WL 2711249, at *8 (P.T.A.B. June 27, 2019) (“Printouts from a web site do not bear the indicia of reliability demanded for other self-authenticating documents under [Federal Rule of Evidence] 902.” (alteration in original) (quoting *Victaulic Co. v. Tieman*, 499 F.3d 227, 236 (3d Cir. 2007))). And while the Internet Archive affidavit (Ex.1031, 1-2) indicates that Exhibit 1031 was posted online, it does nothing to establish that the document is what it purports to be.

Petitioner’s expert, Dr. Chaum, relied on Exhibit 1031 (*see* Ex.1002, §§ IX.A.2, B.2), but admitted that he had never seen the document before it was

³ The headings “CATT Patient Eligibility Criteria” and “CATT: Lucentis-Avastin Trial,” are, at best, hearsay statements and do not establish the authenticity of Exhibit 1031. *Cf. Standard Innovation Corp. v. Lelo, Inc.*, IPR2014-00148, Paper 42, at 13-16 (P.T.A.B. Apr. 23, 2015) (dates printed on face of document inadmissible to prove publication date).

provided to him by Petitioner’s counsel, and that he made no independent investigation into its authenticity or provenance. Ex.2384, 190:1-8; 192:4-17; 196:10-197:11; 198:16-19. Dr. Chaum was unable to provide any information regarding the authorship or original source of Exhibit 1031, and could not verify whether the document was final or complete, let alone whether it was actually part of the CATT protocol. Ex.2384, 189:10-25; 190:18-191:4; 198:16-199:6. Nor has Petitioner explained why the POSA would look to a posting on the UPenn website, when Dr. Chaum acknowledged that the National Eye Institute (not UPenn) sponsored the study. *See* POR, 35 & n.21; *see also* Ex.2384, 199:7-11.

Petitioner has made no attempt to address the deficiencies of Exhibit 1031—through submission of supplemental evidence, proffer of an authenticated document for comparison, or otherwise—and has not otherwise responded to Patent Owner’s timely objections. Given this lack of authenticating evidence, and because Petitioner has failed to meet its burden under the Federal Rules of Evidence, the Board should exclude Exhibit 1031, and should likewise exclude all portions of Petitioner’s papers, including its expert declaration, that rely on it.⁴ *See Riverbed Tech., Inc. v. Realtime Data LLC*, IPR2016-00978, 2017 WL 4925393, at *17 (P.T.A.B. Oct. 30,

⁴ Specifically, Pet., §§ VI.B.1, VII.B; Exhibit 1002 (Chaum Decl.), ¶¶ 99-103, 130-58; Reply (Paper 40), § III.A.

2017) (excluding purported publication under FRE 901 where expert was unable to provide source and authenticating information), *aff'd per curiam*, 742 F. App'x 505 (Fed. Cir. 2018) (mem.); *Linear Tech. Corp. v. Micrel, Inc.*, 275 F.3d 1040, 1055-56 (Fed. Cir. 2001) (affirming exclusion of letters on authenticity grounds due to lack of signature, letterhead, or other identifying information); *TRW Automotive U.S. LLC v. Magna Elecs. Inc.*, IPR2014-01348, 2016 WL 212791, at *1-5 (P.T.A.B. Jan. 15, 2016) (excluding non-self-authenticating document under FRE 901 when proffering party failed to provide any supplemental evidence as to authenticity); *see also Ingenico Inc. v. IOENGINE, LLC*, IPR2019-00929, 2020 WL 5637098, at *43-44 (P.T.A.B. Sept. 21, 2020).

Because Petitioner has failed to authenticate Exhibit 1031, this exhibit should also be excluded as irrelevant under FRE 401-03, and as hearsay under FRE 802. Petitioner uses Exhibit 1031 to show the truth of the matter asserted—*i.e.*, that its listed “eligibility criteria” reflect the exclusion criteria actually employed in the CATT clinical study. *See* Pet., 26. But with no sponsoring witness or applicable hearsay exception, Exhibit 1031 cannot properly be used for that purpose, and should be excluded. *See Mylan Pharms., Inc. v. Bausch Health Ir. Ltd.*, IPR2022-00722, 2023 WL 6161595, at *24-28 (P.T.A.B. Sept. 8, 2023).

Exhibit 1031 should further be excluded under FRE 702 and 703. While experts may rely on unauthenticated hearsay in some circumstances, here

Dr. Chaum’s testimony on Exhibit 1031 makes clear that he “did not analyze his source materials so much as repeat their contents.” *Wi-Lan Inc. v. Sharp Elecs. Corp.*, 992 F.3d 1366, 1374-75 (Fed Cir. 2021) (quoting *United States v. Mejia*, 545 F.3d 179, 198 (2d Cir. 2008)); *see* Ex.2384 (Chaum Tr.), 190:1-8; 192:4-17; 196:10-197:11; 198:16-199:6. Petitioner cannot use its expert “as a conduit for introducing hearsay under the guise that the testifying expert used the hearsay as the basis of his testimony.” *Id.* at 1375 (quoting *Marvel Characters, Inc. v. Kirby*, 726 F.3d 119, 136 (2d Cir. 2013)). In addition, because Petitioner has failed to establish that Exhibit 1031 is the type of document reasonably relied on by experts in the field, a conclusory statement to the contrary is “not sufficient.” *Id.* at 1376; *see also id.* (affirming exclusion of “unauthenticated source code printouts” because proponent had made no showing that source code experts would reasonably rely them).

B. Exhibits 1071 and 1072 Are Unauthenticated Hearsay and Should Be Excluded Under FRE 401-03, 802, and 901-02

Petitioner relies on Exhibits 1071 and 1072 for their purported disclosure of exclusion criteria for the MARINA and ANCHOR clinical studies. *See* Reply, 16-17. But Petitioner has not established that either exhibit was published in the prior art. Indeed, both of Exhibits 1071 and 1072 are unauthenticated hearsay. Patent Owner timely objected to these exhibits as irrelevant under 401-03 and as hearsay and unauthenticated under FRE 802 and 902. Paper 41, 1-2. Exhibits 1071 and 1072, and the portions of Petitioner’s papers that rely on them, should be excluded.

Petitioner submitted Exhibits 1071 and 1072 for the first time on Reply, attempting to use these documents as if they were prior art printed publications. Reply, 16-17.⁵ But, to rely on a document as prior art, a petitioner must prove that it was “sufficiently accessible to the public interested in the art” before the critical date. *In re Lister*, 583 F.3d 1307, 1311 (Fed. Cir. 2009) (quoting *In re Cronyn*, 890 F.2d 1158, 1160 (Fed. Cir. 1989)). In other words, a petitioner must show that the document 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.” *Acceleration Bay, LLC v. Activision Blizzard Inc.*, 908 F.3d 765, 772 (Fed. Cir. 2018) (citation omitted); *see also C.R. Bard, Inc. v. AngioDynamics, Inc.*, 748 F. App’x 1009, 1013-15 (Fed. Cir. 2018).

Exhibits 1071 and 1072 share a substantially similar form: a cover page labeled “Supplementary Appendix” with a citation to a separate publication, followed by pages with substantive content in a different font. Ex.1071; Ex.1072. There is no information on the face either “Supplementary Appendix” indicating

⁵ Petitioner’s attempt to present Exhibits 1071 and 1072 as new prior art references on Reply should also be rejected as procedurally improper. *Ford Motor Co. v. Safe Driving Techs. LLC*, IPR2021-01446, 2023 WL 2605067, at *20 (P.T.A.B. Mar. 10, 2023); *see also* Consol. Trial Prac. Guide 73 (Nov. 2019).

where the appendix itself was published or when (or if) it became publicly available. *Id.* Exhibits 1071 and 1072 do not, for example, include a web address, copyright stamp, or any indication of the date on which either exhibit was accessed, let alone published. *See Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, 2019 WL 7000067, at *3-4 (P.T.A.B. Dec. 20, 2019) (precedential). Nor has Petitioner provided any supplemental evidence purporting to establish that either “Supplementary Appendix” was available in the prior art.

Petitioner’s only purported use of Exhibits 1071 and 1072 is as prior art. Reply, 16-17. Because Petitioner has failed to establish that Exhibits 1071 and 1072 are in fact prior art “printed publications” under 35 U.S.C. § 311(b), they are not relevant to this proceeding. *See In-Depth Geophysical, Inc. v. ConocoPhillips Co.*, IPR2019-00849, 2019 WL 4239627, at *2-7 (P.T.A.B. Sept. 6, 2019) (failure of petitioner to prove reference was patented publication dooms patentability challenged based on said reference). Accordingly, Exhibits 1071 and 1072 should be excluded from evidence under at least FRE 401-403.

Exhibits 1071 and 1072 are also hearsay subject to exclusion under FRE 802. On Reply, Petitioner purports to use both exhibits to show the truth of the matter asserted—*i.e.*, that Exhibit 1071 and 1072 reflect the exclusion criteria actually employed in the MARINA and ANCHOR clinical studies. Reply, 16. On that basis, Exhibits 1071 and 1072 are unquestionably hearsay, and with no sponsoring witness,

applicable hearsay exception, or expert testimony supporting their inclusion, should, for that reason also, be excluded. *See Mylan Pharms., Inc. v. Bausch Health Ir. Ltd.*, IPR2022-00722, 2023 WL 6161595, at *24-28 (P.T.A.B. Sept. 8, 2023).

Exhibits 1071 and 1072 should also be excluded under FRE 901 and 902, as neither has been authenticated by Petitioner. Exhibits 1071 and 1072 do not contain indicia of reliability that would make the exhibits self-authenticating.⁶ And despite Patent Owner’s timely objections, Petitioner did not submit supplemental evidence to authenticate Exhibits 1071 and 1072. On that basis, they should be excluded. *See Linear Tech. Corp. v. Micrel, Inc.*, 275 F.3d 1040, 1055-56 (Fed. Cir. 2001).

C. Petitioner’s Exhibit Not Cited in the Pleadings Should Be Excluded as Irrelevant

Exhibits that are not cited in the pleadings “ha[ve] no bearing on any fact that is of consequence in determining the outcome of the proceeding” and should be

⁶ *See* FRE 902. As described above, both exhibits have a cover page that is in a different font from the remainder of the document, and it is not clear what, if any, connection those cover pages have to the rest of the documents. And neither Exhibit 1071 nor Exhibit 1072 contains sufficient identifying information to establish its authenticity. *See TRW Automotive US LLC v. Magna Elecs. Inc.*, IPR2014-01348, 2016 WL 212791, at *1-5 (P.T.A.B. Jan. 15, 2016).

excluded pursuant to FRE 401 and 402. *One World Techs., Inc. v. Chamberlain Grp., Inc.*, IPR2017-00126, Paper 56, at 16-17 (P.T.A.B. Oct. 24, 2018).

Exhibit 1029 was not cited in Petitioner's pleadings. Patent Owner timely objected to Exhibit 1029, and provided sufficient particularity in its objections, specifically arguing that Exhibit 1029 is inadmissible pursuant to FRE 401-03. Paper 17, 8.⁷ This uncited exhibit was not relied upon by Petitioner and should therefore be excluded as irrelevant.

III. CONCLUSION

For the reasons presented herein, Patent Owner respectfully requests that the Board exclude the following Exhibits and argument:

⁷ Patent Owner also objected to Exhibit 1029 as inadmissible under FRE 401-03 because it is not prior art and is thus irrelevant. Paper 17, 8. Because Petitioner has not relied on this exhibit, Patent Owner does not address this additional objection. However, to the extent that Petitioner seeks to rely on this exhibit in the future, it should also be excluded under FRE 401-03.

Material for Exclusion	Location
Unauthenticated Exhibit and Related Argument	• Exhibit 1031 • Petition (Paper 2), §§ VI.B.1, VII.B • Reply (Paper 40), § III.A • Exhibit 1002 (Chaum Decl.), ¶¶ 99-103, 130-58
Irrelevant (as non-Prior Art), Unauthenticated Hearsay Exhibits	• Exhibits 1071, 1072
Uncited Exhibit	• Exhibit 1029

Dated: March 29, 2024

Respectfully Submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that on March 29, 2024, a true and entire copy of this **PATENT OWNER'S MOTION TO EXCLUDE** was served via e-mail to the Petitioners at the following email addresses:

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