

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

TABLE OF AUTHORITIES

Page(s)

Cases

<i>ASM IP Holding B.V. v. Kokusai Elec. Corp.</i> , IPR2019-00369, 2019 WL 2711249 (P.T.A.B. June 27, 2019)	4
<i>Ingenico Inc. v. IOENGINE, LLC</i> , IPR2019-00929, 2020 WL 5637098 (P.T.A.B. Sept. 21, 2020)	2
<i>Wi-LAN Inc. v. Sharp Elecs. Corp.</i> , 992 F.3d 1366 (Fed. Cir. 2021)	2
<i>Xactware Sols., Inc. v. Pictometry Int’l Corp.</i> , IPR2016-00594, 2017 WL 3671031 (P.T.A.B. Aug. 24, 2017).....	2

Other Authorities

37 C.F.R. § 42.64(b)(2).....	1
Fed. R. Evid. 401	1, 5
Fed. R. Evid. 402	1, 5
Fed. R. Evid. 403	1, 5
Fed. R. Evid. 702	1, 4
Fed. R. Evid. 703	1, 4
Fed. R. Evid. 802	1, 4, 5
Fed. R. Evid. 901	1, 2, 5
Fed. R. Evid. 902	1, 5

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

PO has moved to exclude Ex.1031 as unauthenticated under FRE 901 and as inadmissible hearsay under FRE 401-03, 702-03, and 802. Paper 46 (“Mot.”), § II.A. Specifically, Petitioner has failed to establish that Ex.1031 is what Petitioner purports it to be—*i.e.*, “a document (‘the CATT study’) listing exclusion criteria for CATT as of July 13, 2010.” Paper 2 (Pet.), 26; Mot., 2-6.

Petitioner spends its opposition arguing that Ex.1031 was a printed publication—*i.e.*, a printout of a document posted on UPenn’s website as of the cited date. Paper 48 (“Opp.”), § II.A. Petitioner’s argument and evidence¹—including its Internet Archive affidavit—go to this point. But Ex.1031’s printed publication status is not the basis for PO’s objections to this document—indeed, that Ex.1031 was posted on UPenn’s website is one of the multiple problems with that reference that ***casts doubt*** on its authenticity. Mot., 5. It is axiomatic that FREs 901-02 are not satisfied by a mere showing that a reference was published. Rather FREs 901-02

¹ Petitioner did not serve ***any*** supplemental evidence in response PO’s timely objections to Ex.1031, and its belated attempt to present such evidence (*e.g.*, Ex.1082 and citation to a newly relied-upon URL at Opp. 4, 6-7) for the first time now should be rejected. 37 C.F.R. § 42.64(b)(2). In any event, this improper new evidence has no bearing on whether Ex.1031 is what Petitioner purports it to be.

require a finding that “the appearance, contents, substance, internal patterns, or other distinctive characteristics of the item, taken together with all the circumstances support a finding that the item is what the proponent claims it is.” *Wi-LAN Inc. v. Sharp Elecs. Corp.*, 992 F.3d 1366, 1373 (Fed. Cir. 2021) (cleaned up) (quoting FRE 901). And it is Petitioner’s burden to establish the authenticity of its asserted references even when printed publication status is not at issue. *See, e.g., Ingenico Inc. v. IOENGINE, LLC*, IPR2019-00929, 2020 WL 5637098, at *43-45 (P.T.A.B. Sept. 21, 2020); *Xactware Sols., Inc. v. Pictometry Int’l Corp.*, IPR2016-00594, 2017 WL 3671031, at *4-5 (P.T.A.B. Aug. 24, 2017).

Petitioner has failed to meet its burden here. Petitioner’s single invalidity ground relies on Ex.1031 being “a document (the ‘CATT study’) listing exclusion criteria for CATT as of July 13, 2010.” Pet., 26. Petitioner’s own expert, Dr. Chaum, concedes that Ex.1031 is not a study protocol, ClinicalTrials.gov entry, or scientific publication; that he did not know if the exclusion criteria listed in Ex.1031 were actually employed in the CATT study; and that he would have to compare Ex.1031 with the clinicaltrials.gov listing for CATT—which is inconsistent—to verify its accuracy. Mot., 4-5; *see also* Ex.2384, 189:10-25, 196:10-24, 198:16-199:14. Instead, Ex.1031 appears to be an excerpt from an unknown source document that bears no authenticating information or “indicia of reliability” to indicate that it lists the actual CATT exclusion criteria, or that the POSA would have reason to believe

it did. Mot., 3-4. The headings Petitioner points to (Opp., 6) do not remedy this problem—they are isolated hearsay statements and do not show that Ex.1031 is a credible source let alone that it reflects actual CATT exclusion criteria (Mot., 4 n.3). Nor does Ex.1031’s presence on the UPenn website bolster its authenticity. Mot., 5. Petitioner now concedes that its assertion in the Petition that “[t]he University of Pennsylvania was the sponsor of the [CATT] study” was **wrong**. Pet., 26; Opp., 6. While Petitioner attempts to link UPenn to the CATT study through improper citation to new evidence (*see* Opp., 6-7), it still cites no pre-priority support for its revised assertion that UPenn was “the institution that was known to be responsible” for CATT, or that the POSA would look to the UPenn website or credit it as an authoritative source for the CATT exclusion criteria. Opp., 6-7.

The Internet Archive affidavit relied on by Petitioner (Opp., 5) also does not establish that Ex.1031 reflects the exclusion criteria used in the CATT study. The Internet Archive custodian has no “personal knowledge” of the content of Ex.1031, so cannot speak to the evidentiary objections at issue here. *U.S. v. Bansal*, cited by Petitioner (Opp., 5), does not hold otherwise. The *Bansal* court merely found that Internet Archive testimony established that a disputed exhibit was sourced from the defendant’s own website. Here, PO has not disputed that Ex.1031 is from UPenn’s website—that fact **undermines** its authenticity.

Petitioner’s case law addressing printed publication status (Opp., 1, 4) is likewise inapposite,² and its attempts to distinguish PO’s cases fail (Opp., 4-6). In *ASM v Kokusai Electric*, as here, Petitioner failed to provide testimonial evidence of a witness with “personal knowledge of the *content*” of the disputed website exhibits—testimony on the source and generation of the exhibits was found insufficient. IPR2019-00369, 2019 WL 2711249, at *8 (P.T.A.B. June 27, 2019) (emphasis added).

Ex.1031 should also be excluded as inadmissible hearsay under FRE 802 and 702-03. Mot., 6-7. Petitioner’s claim that Ex.1031 was not offered for the truth of the matter is belied by its own statements in the Petition—*e.g.*, that Ex.1031 “describe[s] exclusion criteria for the CATT study involving bevacizumab (Avastin[®]) and ranibizumab (Lucentis[®])” and “list[s] exclusion criteria for CATT as of July 13, 2010.” Pet., 25, 26. This is textbook hearsay, and cannot be rehabilitated (or imported) by the conclusory testimony of an expert that admittedly made no independent investigation into Ex.1031. Mot. 4-5, 6-7; Ex.2384, 189:10-22, 192:4-13; 198:16-199:14.

² Petitioner’s citation to *Merck* is to an IPR petition, not a Board decision.

II. Exhibits 1071 and 1072 Are Unauthenticated Hearsay and Should Be Excluded Under FRE 401-03, 802, and 901-02³

Petitioner has failed to show that Exs.1071-72 were publicly available in the prior art, let alone that they are what they purport to be. Mot., § II.B. Petitioner's attempt to divert attention from these failings by belatedly pointing to PO's exhibits is improper. Opp., 8-9. Petitioner filed no objections to PO's exhibits, and they are not germane to the admissibility of Exs.1071-72. Petitioner's suggestion that PO omitted MARINA and ANCHOR exclusion criteria from the record is unfounded. PO's briefing cites to Ex.2347, which includes the MARINA and ANCHOR study protocols and exclusion criteria. Ex.2347 shows that Petitioner's Exs.1071-72 omit a key disclosure that contradict Petitioner's rebuttal arguments. Paper 45, 17 n.11 (Petitioner's reply incorrectly points to an exclusion criteria directed to historic *systemic* conditions as relating to exclusion of historic *ocular* conditions.). Further, Petitioner's cross-references from other exhibits (Opp., 9-10) only show supplemental appendices existed, not that Exs.1071-72 are the referenced appendices. Petitioner's unverifiable assertions that Ex.1071-72 "were downloaded as expressly directed" (*id.*) lack evidentiary support, and thus should be ignored.

³ PO also moves to exclude Ex.1029 as irrelevant under FREs 401-03. Mot., § II.C. Petitioner concedes that Ex.1029 (Opp., 11-12) is not cited for its obviousness arguments, and is of limited relevance.

Dated: April 12, 2024

Respectfully Submitted,

/Deborah E. Fishman/

Deborah E. Fishman (Reg. No. 48,621)
3000 El Camino Real #500
Palo Alto, CA 94304

**Counsel for Patent Owner,
Regeneron Pharmaceuticals, Inc.**

CERTIFICATE OF SERVICE

The undersigned certifies that on April 12, 2024, a true and entire copy of this
**PATENT OWNER'S REPLY TO PETITIONER'S OPPOSITION TO
PATENT OWNER'S MOTION TO EXCLUDE** was served via e-mail to the
Petitioners at the following email addresses:

qe-samsungbioepis@quinnemanuel.com
raynimrod@quinnemanuel.com
matthewtraupman@quinnemanuel.com
elliotochoi@quinnemanuel.com
zachsummers@quinnemanuel.com
sarahcork@quinnemanuel.com
landonsmith@quinnemanuel.com

/Deborah E. Fishman/

Deborah E. Fishman (Reg. No. 48,621)
3000 El Camino Real #500
Palo Alto, CA 94304

**Counsel for Patent Owner,
Regeneron Pharmaceuticals, Inc.**