

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD. and BIOCON BIOLOGICS INC.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Patent No. 10,888,601

Inter Partes Review No. IPR2023-00739¹

PATENT OWNER'S CORRECTED MOTION TO EXCLUDE EVIDENCE

¹ IPR2024-00201 has been joined with IPR2023-00739.

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Patent Owner Regeneron Pharmaceuticals moves to exclude certain evidence relied on by Petitioner Samsung Bioepis, Inc. 37 C.F.R. § 42.64.

The Board should exclude Exhibit 1072 (“Major”²) as not authenticated because Petitioner has not offered sufficient evidence that the document was publicly accessible as of the priority date. Petitioner’s use of Major depends on that unproven underlying assumption about public accessibility, and Major should thus be excluded.

The Board should also exclude, or at least limit Petitioner’s use of, references identified below as post-priority publications—these references cannot be used as prior art. The Board should further limit Petitioner’s use of the references identified below that Petitioner originally relied on only as to claims that have now been disclaimed. In neither case is Petitioner free to use these references for all purposes.

² Major JC et al., “DA VINCI: DME and VEGF Trap-Eye: Investigation of Clinical Impact: Phase 2 Study in Patients With Diabetic Macular Edema (DME). In the substantive briefing, the parties refer to Exhibit 1072 as “Major” or “Major 2010.” It is also sometimes referred to as the “ARVO Abstract.”

I. LEGAL STANDARD

Except as otherwise provided, the Federal Rules of Evidence govern the admissibility of evidence before the Board. 37 C.F.R. § 42.62; *see also* 37 C.F.R. § 42.64(c) (providing for motions to exclude evidence).

II. PATENT OWNER TIMELY OBJECTED TO PETITIONER'S INADMISSIBLE REFERENCES

As detailed below, Patent Owner timely objected to Exhibits 1002, 1005, 1007, 1036, 1037, 1045, 1050, and 1072 under 37 C.F.R. § 42.64(b).

March 26, 2023: Petitioner filed its Petition (Paper 1) and supporting exhibits, including Exhibits 1002, 1005, 1007, 1036, 1037, 1045, 1050. (*Id.* at vii-xii.) Exhibit 1072 was not included with the Petition.

October 20, 2023: The Board granted institution (Paper 9).

November 3, 2023: Patent Owner timely objected to Exhibits 1002, 1005, 1007, 1036, 1037, 1045, and 1050 under Fed. R. Evid. 402 and 403. (Paper 12, 1-3, 13-16.)

November 17, 2023: Petitioner made no effort to cure in response to Patent Owner's November 3, 2023 objections, failing to serve supplemental evidence within the allowable period. *See* 37 C.F.R. § 42.64(b)(2).

January 26, 2024: Patent Owner filed its Response (Paper 31).

April 26, 2024: Petitioner filed its Reply (Paper 48) and supporting evidence, including Exhibit 1072. (*Id.* at ii.) Petitioner asserted, in its Table of

Exhibits, that Exhibit 1072 was publicly accessible at the link as of April 2010.

(*See id.*)

May 3, 2024: Patent Owner timely objected to Exhibit 1072 (Paper 49).

Patent Owner objected under Fed. R. Evid. 901, explaining that Exhibit 1072 “does not have a specific date, nor does the website demonstrate when the website or article was most recently updated or made available publicly.” (*Id.* at 11.)

May 17, 2024: Petitioner again made no effort to cure in response to Patent Owner’s May 3, 2024 objections, failing to serve supplemental evidence within the allowable period. *See* 37 C.F.R. § 42.64(b)(2).

III. PETITIONER’S SUBMISSION OF THE MAJOR REFERENCE WAS UNTIMELY AND PETITIONER FAILED TO PROVE THAT MAJOR WAS PUBLICLY ACCESSIBLE BEFORE THE PRIORITY DATE

Petitioner raised Major as a prior art reference for the first time on Reply. For the reasons set forth in Patent Owner’s Sur-Reply, this was improper and untimely. (Paper 51, 21-22 (citing *Intelligent Bio-Systems, Inc. v. Illumina Cambridge, Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016)).) Exclusion of Major on this basis alone is warranted. *Intelligent Bio-Systems*, 821 F.3d at 1369; *cf.* *Axonics v. Medtronic*, 75 F.4th 1374, 1383 (Fed. Cir. 2023) (“[P]etitioner may not in reply rely on new prior art to teach a claim limitation.”).

Additionally, as the proponent of Major as alleged prior art, Petitioner had the burden to “produce evidence sufficient to support a finding that the item is

what the proponent claims it is.” Fed. R. Evid. 901(a). That burden includes proving that Major was publicly accessible before January 13, 2011—the priority date. Petitioner failed to provide any such evidence (*see* Paper 48, 17), and therefore, the Board should also exclude Major for lack of authentication as publicly accessible.

Dates listed on the publication alone are not enough. The fact that Major contains the words “April 2010” and “©2010” cannot establish that Major was accessible prior to January 2011. The Federal Circuit “has recently emphasized the need for corroboration of testimony that is used to prove a document is a printed publication.” *RPX Corp. v. Iridescent Networks, Inc.*, IPR2017-01662, at 19 (P.T.A.B. Dec. 10, 2018) (Paper 33) (collecting Federal Circuit cases); *see also Nobel Biocare Servs. AG v. Intradent USA, Inc.*, 903 F.3d 1365, 1376 (Fed. Cir. 2018), as amended (Sept. 20, 2018) (noting that a reference with “the date ‘March 2003’ on its cover . . . is not dispositive of the date of public accessibility....”).

Applying this rule, the Board has routinely excluded petitioners’ purported prior art where the evidence of a document’s availability as of a particular date is merely a statement on the face of an alleged references such as a date or copyright claim like that here. *ServiceNow, Inc. v. Hewlett-Packard Co.*, IPR2015-00716, at 16 (P.T.A.B. Aug. 26, 2015) (Paper 13). As an example, a petitioner whose evidence “amount[ed] to little more than the [] copyright date”—and lacked proof

that the POSA could have located and accessed the website ahead of the priority date—did not prove its exhibit was publicly accessible. *Schlumberger Tech. Corp., v. Integrated Drive Sys. LLC*, IPR2018-00603, at 17, 24 (P.T.A.B. Sept. 3, 2019) (Paper 40); *see also Apple Inc. v. DSS Tech. Mgmt., Inc.*, IPR2015-00373, at 10 (P.T.A.B. June 25, 2015) (Paper 8) (holding that a petitioner who “merely asserts, without any citation of evidence, that [a document] ‘was published at least as early as’” the priority date cannot adequately authenticate a prior art reference).

The Board’s decision in *TRW Auto* is on-point with the facts of this matter. In *TRW Auto. U.S. LLC v. Magna Elecs. Inc.*, IPR2014-01348 (P.T.A.B. Jan. 15, 2016) (Paper 25), the petitioner claimed in a footnote that its exhibit “was published during October 5-8 of 1999 in something called *Intelligent Transportation Systems*,” a purported periodical. *Id.* at 6. As with Petitioner’s claim in the Table of Exhibits that Major was available in “April 2010,” the *TRW Auto* petitioner “did not cite or otherwise provide any evidence of this claim.” *Id.* That the challenged exhibit contained the date “©1999” was insufficient under Fed. R. Evid. 901(a), as the Board explained, because that date “does not establish when [the] document was publicly accessible under patent law.” *Id.* at 8; *see also Microsoft Corp. v. Corel Software, LLC*, IPR2016-01300, at 8-9 (P.T.A.B. Jan. 4, 2017) (Paper 13) (copyright claims are not evidence of public accessibility). The

dates on the face of Major fare no better and do not authenticate Major as being publicly accessible for the same reasons.

No additional evidence authenticates Major as a publicly accessible reference. As the above authorities show, Petitioner needed to do something to prove that Major was publicly accessible, given that the date on the face of Major is insufficient. As a widespread treatise on IPRs explains:

If relying on non-patent literature, a petitioner must make the additional effort to ascertain the public accessibility of a document cited as prior art, and should not simply look to a date printed on the document as sufficient. A library expert or a custodian of records may provide their expert opinion on the availability of a document.

1 Patent Office Litigation § 4:14.

Petitioner, however, did not supply any such evidence. Petitioner claims to have taken Major from a website. (*See* Paper 48, *ii.*) “Printouts from a web site do not bear the indicia of reliability demanded for other self-authenticating documents under Fed. R. Evid. 902. To be authenticated, some statement or affidavit from someone with knowledge is required....” *In re Homestore.com, Inc. Sec. Litig.*, 347 F. Supp. 2d 769, 782-83 (C.D. Cal. 2004) (*cited with approval in ASM IP Holding B.V. v. Kokusai Elec. Corp.*, IPR2019-00369, at 21 (P.T.A.B. June 27, 2019) (Paper 8) (holding that a document obtained from the internet without adequate testimony from a person with knowledge is not established as a printed publication)); *Xactware Sols., Inc. v. Pictometry Int’l Corp.*, IPR2016-00594, at 11

(P.T.A.B. Aug. 24, 2017) (Paper 46) (“Printouts from websites are not self-authenticating.”); *Standard Innovation Corp. v. Lelo*, IPR2014-00148, at 10 (P.T.A.B. Apr. 23, 2015) (Paper 42) (granting motion to exclude: “When offering a printout of a webpage into evidence to prove the website’s contents, the proponent of the evidence must authenticate the information from the website itself, not merely the printout.”) (citing *Victaulic Co. v. Tieman*, 499 F.3d 227, 236 (3d Cir. 2007), as amended (Nov. 20, 2007)). Petitioner’s failure to provide any authenticating evidence cannot be excused—Major has not been authenticated as publicly accessible.

Major should be excluded. Because Petitioner did not establish that Major was publicly available prior to January 2011 with a declaration of someone with personal knowledge, and because Major itself is insufficient evidence of that fact, Petitioner has failed to meet its burden of establishing public accessibility. *ServiceNow*, IPR2015-00716, at 14. Therefore, the Board should exclude Exhibit 1072. Petitioner has not shown that it was publicly available during the relevant time. *See Spectrum Solutions L.L.C. v. DNA Genotek Inc.*, IPR2022-01347, at 26-28 (P.T.A.B. Feb. 7, 2024) (Paper 43) (granting motion to exclude as inauthentic a publication by the Center for Disease Control obtained from a U.S. government website with “2008” in the website’s URL despite an expert declaration describing the document’s provenance).

IV. PETITIONER’S REFERENCES WITH POST-PRIORITY DATES SHOULD BE EXCLUDED OR HAVE THEIR USE LIMITED

The Board should exclude references that Petitioner improperly used as prior art even though the references in question have post-priority publication dates, or at least limit Petitioner’s use of their post-priority disclosures.

“[O]bviousness is measured objectively in light of the prior art . . .,” at the time the invention was made. *Millennium Pharms., Inc. v. Sandoz Inc.*, 862 F.3d 1356, 1367 (Fed. Cir. 2017). Information made public after the priority date would not have been available to a POSA at the time of the invention. *Zoltek Corp. v. United States*, 815 F.3d 1302, 1312 (Fed. Cir. 2016) (reversing an obviousness finding due to expert’s reliance on post-priority evidence). Any prior art reference must predate the invention, and references that postdate the invention may only establish, for example, knowledge at the time of the invention. *See, e.g., Novartis Pharms. Corp. v. Teva Pharms. USA, Inc.*, No. CIV.A.05-CV-1887 DMC, 2009 WL 3754170, at *13 (D.N.J. Nov. 5, 2009); *Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.*, No. 2:15-CV-1202-WCB, 2017 WL 959592, at *5 (E.D. Tex. Mar. 13, 2017).

The Petition argued that the challenged claims are entitled to a priority date no earlier than July 12, 2013. (Paper 1, 15-16.) As Patent Owner explained in response, and as the Board found in a related IPR, the claims are entitled to a priority date in January 2011. (Paper 31, 14-16; IPR2023-00884, Paper 13, 33-34.)

Petitioner’s two-year mistake on the priority date led it to rely on post-priority evidence as prior art. For example, Petitioner relies on Heier 2012 to purportedly show that a POSA would be motivated to add loading doses “based on clinical trial experience and trial results.” (Paper 1, 43.) Yet Heier 2012 postdates the priority date by more than a year. (Ex.1007, 12.) Because Heier 2012 postdates the ‘601 Patent’s priority date, Petitioner may only use its results for a “legitimate purpose,” such as establishing the state of the art. *See Erfindergemeinschaft*, 2017 WL 959592, at *5. Petitioner goes beyond that, using the reference to discuss not the POSA’s knowledge at the time of the invention, but rather the POSA’s basis for a motivation to combine. That is impermissible. *See Amgen Inc. v. Sanofi*, No. CV 14-1317-SLR, 2016 WL 825671, at *2 (D. Del. Mar. 2, 2016) (ruling that post-priority results of experimentation are inadmissible as evidence of a POSA’s motivation to combine). For that reason, Heier 2012 should be excluded as post-priority evidence of obviousness.

Along with Heier 2012, the following references published between January 2011 (the priority date) and July 2013 (Petitioner’s asserted priority date) should be excluded under Fed. R. Evid. 402 as impermissible post-priority art, or in the alternative, should be used only for limited purposes and not as prior art:

Exhibit No.	Exhibit Description	Citation
1005	Heier 2011	Paper 1 at 43 n.15, 44 Chaum ¶¶ 59-60, 164

Exhibit No.	Exhibit Description	Citation
1007	Heier 2012	Paper 1 at 33 n.10, 43 n.15, 44 Chaum ¶¶ 60, 62, 164
1036	Martin 2012	Chaum ¶ 59
1037	Chakravarthy 2012	Chaum ¶ 59
1045	Do 2011	Paper 1 at 41, 48 Chaum ¶¶ 189, 191

V. USE OF PETITIONER’S EVIDENCE REGARDING DISCLAIMED CLAIMS SHOULD BE LIMITED

The Board should limit Petitioner’s use of Exhibits 1045 and 1050 and associated expert testimony. These exhibits form the basis for Grounds IV and V, which challenge claims 13-16, 20, 22-24, and 29-32 of the ’601 Patent. (Paper 1, 48-54.) Patent Owner has disclaimed each of these claims. (Paper 6, 1 n.1; Ex.2001; Ex.2002.) The Board should limit Petitioner’s use of evidence that Petitioner proffered solely for reasons relating to disclaimed claims.

Petitioners must “identify ‘with particularity’ the ‘evidence that supports the grounds for the challenge to each claim’” in the initial petition, while the reply may not introduce a “new theory of invalidity” or “refer[] to new evidence.” *Intelligent Bio-Systems*, 821 F.3d at 1369. The Board does not permit a petitioner to rely on “previously unidentified portions of a prior-art reference to make a meaningfully distinct contention.” *See Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1367 (Fed. Cir. 2015). When a prior art reference is absent from the instituted grounds, it is properly used to describe the state of the art only and may

not be used to render claim limitations obvious. *Cf. Genzyme Therapeutic Prods. L.P. v. Biomarin Pharm. Inc.*, 825 F.3d 1360, 1368 (Fed. Cir. 2016) (commenting that a motion to exclude is the proper avenue to remove these references).

Because Patent Owner disclaimed all claims comprising Grounds IV and V, Grounds IV and V are no longer at issue. (*See generally* Paper 48.) Petitioner thus has no relevant reason to rely on Exhibits 1045 and 1050 other than, for example, supporting the understanding of diabetic retinopathy and diabetic macular edema in the field at the time of the invention. *See* Fed. R. Evid. 401. Additionally, Patent Owner would suffer unfair prejudice if Petitioner or the Board relied on this evidence for the first time in new ways against the remaining claims. *See* Fed. R. Evid. 403. Petitioner's continued reliance on these exhibits would also confuse the issues and waste time. *See id.* Thus, the Board should limit Petitioner's use of these exhibits.

For the Board's convenience, this table recites the references that the Petition used only in relation to disclaimed claims, as well as the paragraphs of Petitioner's expert declaration relating to this evidence:

Exhibit No.	Exhibit Description	Citation
1002	Chaum Report	¶¶ 189-192
1045	Do 2011	Paper 1 at 48
1050	Eylea 2016 Label	Paper 1 at 53

VI. CONCLUSION

For the foregoing reasons, Patent Owner requests this Board grant its Motion to Exclude the above evidence.

Dated: July 3, 2024

Respectfully submitted,

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Certificate of Service (37 C.F.R. § 42.6(e)(4))

I hereby certify that the attached PATENT OWNER'S CORRECTED MOTION TO EXCLUDE EVIDENCE was served on the below date on the Petitioner via e-mail (by agreement) to the following counsel of record:

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