

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 IPR2023-00739

U.S. Patent No. 10,888,601

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

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I. INTRODUCTION

Petitioner respectfully requests the Board deny Patent Owner's ("PO") Motion to Exclude.

As set out below, PO primarily seeks to exclude Ex. 1072, a 2010 Abstract describing the results of the Phase II DA VINCI trial involving intravitreal injection of aflibercept in DME patients published by the Association for Research in Vision and Ophthalmology ("ARVO"). PO contends that Ex. 1072 is new evidence not raised in the Petition and calls for exclusion on that basis. But Ex. 1072 is directly responsive to the issues PO raised in the POR – in particular PO's new claim construction argument concerning efficacy and "fixed" dosing, as well as PO's expert's testimony that the same data in Ex. 1072, if available in the prior art, would have provided a POSA a motivation and reasonable expectation of success for the five loading doses as claimed. Ex. 1072 is thus admissible as responsive new evidence.

PO also seeks to exclude Ex. 1072 for lack of authentication. However, PO fails to inform the Board that its own expert, Dr. David Brown, testified in this proceeding about his authorship and presentation of Ex. 1072 at the 2010 ARVO annual meeting. *See, e.g.*, Ex. 1071, 28:24-29:12, 30:14-38:25, 159:1-162:11; *see also* Ex. 1073, ¶¶ 40-47. In fact, Dr. Brown submitted a declaration describing his involvement in drafting and presenting Ex. 1072 at the 2010 ARVO annual meeting

in IPR2023-00884 (“572 IPR”).¹ *Id.* This fact alone is sufficient to render Ex. 1072 admissible under the rules. PO should not be heard to challenge the admissibility of material it alleges was authored by its own expert, who extensively testified as to his authorship and the provenance of that material.

Moreover, even if that evidence is ignored, Ex. 1072 additionally includes the “indicia of reliability” sufficient for self-authentication under FRE 902. Specifically, Ex. 1072 identifies J.C. Major, D.M. Brown, and DA VINCI Study Group as the authors of the abstract, and further specifies that it was published in April 2010 as part of the Investigative Ophthalmology & Visual Science journal. And Ex. 1072 includes the copyright date of 2010 attributed to ARVO, which PO’s expert acknowledges as “the biggest peer scientific meeting in visual sciences” where basic science and clinical data are routinely presented and discussed. Ex.1071, 35:4-14. Ex. 1072 therefore “bears indicia of reliability . . . with sufficient publication dates and other indicia bearing status of a well-known publication” and is admissible. *Funai Elec. Co., Ltd. v. Gold Charm Ltd.*, Case IPR2015-01468, slip op. at 50-52 (PTAB December 27, 2016) (Paper 40).

¹ The deposition of Dr. Brown was consolidated between the instant proceeding and 572 IPR, and his testimony concerning Ex. 1072 is equally relevant and applicable in both proceedings.

Additionally, PO contends Exs. 1005, 1007, 1036-37, and 1045 and associated expert testimony should be excluded because they postdate the critical date of the '601 patent. However, as detailed below, these exhibits were introduced to demonstrate the state of anti-VEGF dosing strategies at the time of the invention and to provide context for a POSA's motivation to adopt the extended dosing regimen as claimed. As PO does not dispute, such use of post-priority evidence is permitted under controlling Federal Circuit law. The Board is capable of weighing these materials appropriately.

Finally, the Board need not exclude Exs. 1045 and 1050 and associated expert testimony as PO contends. There is no prejudice in maintaining these exhibits because the invalidity grounds they are associated with are no longer at issue due to PO's prior disclaimer of claims 13-16, 20, 22-24 and 29-32. Accordingly, PO's motion to exclude should be denied in its entirety.

II. ARGUMENT

A. Ex. 1072 Is Responsive to POR and Self-Authenticating

Ex. 1072 is an abstract published online by ARVO describing the partial results of the Phase II DA VINCI trial, which evaluated the efficacy and safety of intravitreal injections of aflibercept in comparison to laser photocoagulation in DME patients. Ex. 1072 specifies J.C. Major, D.M. Brown, and DA VINCI Study Group as the authors of the abstract, and further includes that it was published in

Investigative Ophthalmology & Visual Science in April 2010. Ex. 1072 additionally shows an ARVO copyright date of 2010.

PO (at 3-7) first complains that Ex 1072 should be excluded because it is new evidence raised for the first time on Reply. But, “there is no blanket prohibition against the introduction of new evidence during an IPR.” *Anacor Pharms., Inc. v. Iancu*, 889 F.3d 1372, 1380–82 (Fed. Cir. 2018) (explaining that the petitioner “may introduce new evidence after the petition stage if the evidence is a legitimate reply to evidence introduced by the patent owner”); *see also, Rembrandt Diagnostics, LP v. Alere, Inc.*, 76 F.4th 1376, 1384-1385 (Fed. Cir. 2023). In fact, “the introduction of new evidence in the course of the trial is to be expected in [IPR] trial proceedings” and permissible “as long as the opposing party is given notice of the evidence and an opportunity to respond to it.” *Genzyme Therapeutic Prods. Ltd. P'ship v. Biomarin Pharm. Inc.*, 825 F.3d 1360, 1366 (Fed. Cir. 2016).

Ex. 1072 is responsive to the issues raised in the POR. Specifically, Ex. 1072 was cited in the Reply to address PO’s new claim construction argument, raised for the first time in its POR, that the claims require efficacy and a “fixed” dosing. Reply, 9, 17; POR, 16-22. It was also cited in response to PO’s expert’s testimony that the same Phase II DME data (Table 2) described in Example 5 of the ’601 patent, if available in the prior art, would have provided a motivation and reasonable expectation of success for the dosing regimen with five loading doses as claimed.

Reply, 17; Ex. 1061, 30:24-32:19, 107:11-109:6. And PO had the opportunity to, and did respond to Ex. 1072 in its sur-reply. Sur-Reply, 21-22. Accordingly, the content and basis for the introduction of Ex. 1072 are “perfectly permissible” under controlling Federal Circuit law. *See, e.g., Genzyme* at 1366; *Rembrandt* at 1384-1385. Ex. 1072 should not be excluded.

PO (at 3-7) further seeks to exclude Ex. 1072 for lack of authentication as publicly accessible under FRE 901. However, Ex. 1072 unambiguously shows that it was authored by J.C. Major, D.M. Brown, and DA VINCI Study Group, and was presented at the 2010 ARVO Annual Meeting. And as PO admits (at 4-6), Ex. 1072 on its face specifies the April 2010 publication date and includes the copyright date of 2010 attributed to ARVO, which PO’s own expert acknowledges as “the biggest scientific meeting, peer scientific meeting in visual sciences.” Ex 1071, 35:4-11. Indeed PO’s expert Dr. Brown was a clinical investigator in the DA VINCI trial and testified that he and Dr. Major submitted and presented Ex. 1072 at the 2010 ARVO Annual Meeting, further confirming its authenticity and public availability as of the alleged invention date. Ex. 1071, 28:24-29:12, 30:14-38:25, 159:1-162:11; *see also* Ex. 1073, ¶¶ 40-47.

Ignoring these facts and PO’s own expert testimony supporting authenticity, PO (at 6-7) contends that an authenticating declaration is required for Ex. 1072 to be admissible. That is incorrect. Where, as here, an article is accompanied with a

copyright date and corroborating publication information from a widely recognized and trustworthy source, it is self-authenticated at a minimum under FRE 902(6) (periodicals), 902(7) (trade inscriptions and the like), or 901(b)(4) (circumstantial evidence).

First, Ex. 1072 qualifies as a self-authenticating printed publication under FRE 902(6) because it is part of the ARVO periodicals. *See* FRE 902(6) (“Printed material purporting to be a newspaper or periodical.”). As noted above, Ex. 1072 specifies that it was published in the Investigative Ophthalmology & Visual Science journal by ARVO in April 2010. The Board has routinely found such periodical articles self-authenticating prior art under FRE 901(6).² *See e.g., Liberty Mutual Ins. Co. v. Progressive Casualty Ins. Co.*, Case CBM2012-00010, Paper No. 59 at p. 37 (holding that an IEEE article is self-authenticating under FRE 902(6))³; *see also*

² PO has submitted dozens of self-authenticating journal articles and publications in support of its position here and in the other IPRs on related patents. *See, e.g.,* Exs. 2021, 2023, 2041-2042 2057-62, 2090, 2092-95, 2103-2105. The exclusionary rule PO seeks would require unnecessary authentication and hinder the goal of efficiency in IPRs.

³ The Board often cites well-known periodical publications (e.g., IEEE) *sua sponte* without questioning the publication/copyright information provided on the face of

Ericsson Inc. v. Intellectual Ventures, Case IPR2014–00527, slip op. at 10–13 (PTAB May 18, 2015) (Paper 41)

Second, Ex. 1072 is self-authenticating under FRE 902(7) because it contains the ARVO trade name inscriptions, copyright symbol, and official journal publication citation. See FRE 902(7) (“An inscription, sign, tag, or label purporting to have been affixed in the course of business and indicating origin, ownership, or control.”).

Courts routinely find a trade name inscription and label adequate authentication under FRE 902(7). See *ACCO Brands, Inc.*, 592 F. Supp. 2d at 1219; *Alexander v. CareSource*, 576 F.3d 551, 561 (6th Cir. 2009) (job description on a company letterhead was self-authenticating under Fed. R. Evid. 902(7) because it contained a trade inscription indicating the source of origin of the document); *Pass & Seymour, Inc. v. Hubbell Inc.*, 532 F. Supp. 2d 418, 438 (N.D.N.Y. 2007) (self-promoting advertising for Snap Connect Devices and press materials containing a company logo were self-authenticating); *Milton H. Greene Archives, Inc. v. BPI Commc’ns, Inc.*, 378 F. Supp. 2d 1189, 1195 n.3 (C.D. Cal. 2005) (advertising campaign books bearing trade inscriptions were self-authenticating); *Fenton v.*

such documents. See, e.g., *Liberty Mutual Ins. Co. v. Progressive Casualty Ins. Co.*, CBM2012-00010, Paper No. 59, p. 9 (P.T.A.B. Feb. 24, 2014).

Sterling Plumbing Gp., Inc., 21 F.3d 1113, at *2 n.2 (9th Cir. 1994) (videotape with Kohler logo and mark was self-authenticating under Fed. R. Evid. 902(7)) (unpublished); *Byrne v. CSX Transportation, Inc.*, Case No. 14-3791, 2015 WL 3916450, at *4 (6th Cir. June 26, 2015) (invoices with Conrail logos were self-authenticating under Fed. R. Evid. 902(7)).

Lastly, Ex. 1072 is further authenticated under FRE 901(b)(4) based on the totality of the circumstances. See FRE 901(b)(4) (“The appearance, contents, substance, internal patterns, or other distinctive characteristics of the item, taken together with all the circumstances.”). For instance, in addition to the ARVO trade name, the official copyright symbol, journal citation, publication date, and authorship specified on the front page reliably authenticate Ex. 1072 as a publicly accessible reference before the priority date. This is further reinforced by Dr. Brown’s testimony as to his authorship and provenance of Ex. 1072 as discussed above. PO has proffered no evidence to the contrary showing that Ex. 1072 has been altered, or that Ex. 1072 was unavailable at the ARVO website. Additionally, the data reported in Ex. 1072 matches that which was subsequently reported. See Ex. 1045. Accordingly, all circumstantial evidence taken together satisfies the authentication standard under FRE 901(b)(4).

PO’s reliance on *TRW Auto. U.S. LLC v. Magna Elecs. Inc.*, IPR2014-01348 (P.T.A.B. Jan. 15, 2016) (Paper 25) is misplaced. There, the Board excluded an

article that the petitioner claimed was published between October 5-8, 1999 in an IEEE journal. *Id.*, 6. However, the article included no evidence matching the publication date and identity of the journal as asserted by the petitioner.

Here, to the contrary, Ex. 1072 explicitly identifies its source, publication date, and copyright associated with ARVO. Such information in combination with PO's expert testimony confirming his authorship of Ex. 1072 and public availability is more than sufficient for self-authentication under the rules. *See, e.g., Ericsson* at 10–13 (accepting the publication information on the IEEE copyright line in exhibit as evidence of its date of publication and public accessibility because “members in the scientific and technical communities who both publish and engage in research rely on the information published on the copyright line of IEEE publications.”); *see also Silver Peak Sys., Inc. v. Riverbed Technology, Inc.*, Case IPR2014–00149, slip op. at 28 (PTAB May 2, 2014) (Paper 7) (identification of publication and revision dates, assigned sponsor, and document number shown in exhibit sufficient to establish authenticity).

For the forgoing reasons, the Board should find Ex. 1072 admissible.

B. Exs. 1005, 1007, 1036-37, and 1045 Show the State of the Art at the Time of the Priority Date and Are Admissible

PO (at 8-10) argues that Exs. 1005, 1007, 1036-37, and 1045 should be excluded based solely on publication date. PO contends that since these exhibits

postdate the alleged priority date of the '601 patent, they are “improperly used as prior art.” *Id.*

PO’s argument is baseless. As an initial matter, PO does not dispute that there is no sweeping prohibition against post-priority evidence. To the contrary, such evidence can be relevant in assessing patent validity, which is at issue here. For instance, “later-issued patents and publications may be used to show the state of the art existing on the date of the application in question.” *In re Koller*, 613 F.2d 819, 824 & n.5 (C.C.P.A. 1980); *see also Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1373 (Fed. Cir. 2017).

That is exactly what Petitioner did here. Contrary to PO’s assertion, these exhibits were not used as prior art, but were offered to show the state of the art that informed the motivation of a POSA to move forward with an extended dosing regimen at the time of the invention.

For example, Exs. 1005 and 1007 summarize pre-priority clinical trials of anti-VEGF agents, the established superiority of aflibercept, and explain the consequent motivation for a POSA to test and implement a less frequent dosing regimen based on these pre-priority results and the known complications associated with monthly intravitreal injections at the time of the invention. Pet. 1-2, 43-44.

Similarly, Exs. 1036-37 describe clinical trials of other anti-VEGF agents (e.g., ranibizumab and bevacizumab) and the rationale underlying the tested dosing

regimens at the time of the invention. *See* Ex. 1002, ¶59. Likewise, Ex. 1045 summarizes a POSA's motivation underlying a Phase II trial of aflibercept in DME patients based on pre-priority anti-VEGF clinical trials. *See* Pet., 40-41.

Accordingly, the use of Exs. 1005, 1007, 1036-37, and 1045 in Petitioner's briefing falls squarely within the permitted use of post-priority evidence. That should end the analysis, and the Board should deny PO's motion to exclude these exhibits and associated expert testimony on this basis. *See, e.g., In Re: Copaxone Consol. Cases*, 906 F.3d 1013, 1020 (Fed. Cir. 2018) (affirming district court's admission of post-priority evidence used to show the state of the art and analysis of motivation of POSA at the time of the invention). The Board is more than capable of giving appropriate weight to this evidence.

C. Exs. 1045 and 1050 Do Not Prejudice PO and Should Not Be Excluded

PO (at 10-11) objects that Exs. 1045 and 1050 and associated expert testimony should be excluded under FRE 401 and 403 because they are directed to addressing the invalidity of claims 13-16, 20, 22-24 and 29-32, which PO disclaimed. There is no prejudice to PO or confusion from maintaining the exhibits to keep the complete record of the proceeding. *See, e.g., Boehringer Ingelheim Animal Health Usa Inc. v. Kansas State Univ. Rsch. Found.*, Case PGR2020-00076, slip op. at 44-45 (PTAB Jan. 31, 2022) (Paper 42) (denying motion to exclude because the Board "[did] not

find that maintaining the exhibits in this proceeding results in any unfair prejudice to Petitioner, or that they have confused the issues”).

II. CONCLUSION

For the foregoing reasons, Petitioner respectfully requests the Board deny PO’s Motion to Exclude.

DATED: July 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 July 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 address of record:

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DATED: July 5, 2024

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