

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Patent No. 11,253,572

Inter Partes Review No. IPR2023-00884¹

**PATENT OWNER'S OBJECTIONS TO EVIDENCE SUBMITTED WITH
PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE**

¹ IPR2024-00260 and IPR2024-00298 are joined with IPR2023-00884.

Patent Owner Regeneron Pharmaceuticals, Inc. hereby objects to the following evidence that was submitted by Petitioner Samsung Bioepis Co., with the Petitioner's Reply to Patent Owner's Response (Papers 63 and 64). These objections are timely filed and served within five business days of service Petitioner's June 10, 2024 Reply. 37 C.F.R. § 42.64(b)(1)

A. Exhibit 1076 Deposition Transcript of Michael W. Stewart, M.D. (May 30, 2024) in IPR2023-00884

Patent Owner objects to Exhibit 1076 for each of the reasons noted in the objections made during the underlying deposition.

B. Exhibit 1077 Stewart MW, Rosenfeld PJ. Predicted biological activity of intravitreal VEGF Trap. Br J Ophthalmol. 2008 May;92(5):667-8

Patent Owner objects to Exhibit 1077 under:

- FRE 402-403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the factfinder.
- FRE 802. The exhibit is hearsay because it is offered for the truth of its content without satisfying any of the hearsay exceptions.
- FRE 901. Petitioner has not demonstrated the authenticity of the exhibit.

It is not clear where the exhibit came from or how it was compiled.

Patent Owner further objects to Exhibit 1077 as being improperly submitted in Petitioner's Reply for the first time. Petitioner could have raised Exhibit 1077

with its argument in the Petition. “Petitioner may not submit new evidence or argument in reply that it could have presented earlier” U.S. Patent Trial and Appeal Board, Consolidated Practice Guide 73 (Nov. 2019) (“Practice Guide”); *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369–70 (Fed. Cir. 2016) (precluding the introduction of new evidence to support a new theory of invalidity); *see also Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1367 (Fed. Cir. 2015) (rejecting a reply even for reliance on new portions of previously submitted prior art).

C. Exhibit 1078 Brown DM, Kaiser PK, Michels M, Soubrane G, Heier JS, Kim RY, Sy JP, Schneider S; ANCHOR Study Group. Ranibizumab versus verteporfin for neovascular age-related macular degeneration. N Engl J Med. 2006 Oct 5;355(14):1432-44 (“ANCHOR Study”)

Patent Owner objects to Exhibit 1078 under:

- FRE 402-403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the factfinder. The exhibit presents clinical results using a different compound than the one in the claimed regimens, which is substantially more prejudicial than probative.
- FRE 802. The exhibit is hearsay because it is offered for the truth of its content without satisfying any of the hearsay exceptions.
- FRE 901. Petitioner has not demonstrated the authenticity of the exhibit.

It is not clear where the exhibit came from or how it was compiled.

Patent Owner further objects to Exhibit 1078 as being improperly submitted in Petitioner's Reply for the first time. Petitioner could have raised Exhibit 1078 with its argument in the Petition. "Petitioner may not submit new evidence or argument in reply that it could have presented earlier" Practice Guide at 73; *Intelligent Bio-Sys.*, 821 F.3d at 1369–70; *see also Ariosa*, 805 F.3d at 1367.

D. Exhibit 1079 Rosenfeld PJ, Brown DM, Heier JS, Boyer DS, Kaiser PK, Chung CY, et al. Ranibizumab for neovascular age-related macular degeneration. New England Journal of Medicine 2006; 355(14):1419-31 ("MARINA Study")

Patent Owner objects to Exhibit 1079 under:

- FRE 402-403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the factfinder. The exhibit presents clinical results using a different compound than the one in the claimed regimens, which is substantially more prejudicial than probative.
- FRE 802. The exhibit is hearsay because it is offered for the truth of its content without satisfying any of the hearsay exceptions.
- FRE 901. Petitioner has not demonstrated the authenticity of the exhibit. It is not clear where the exhibit came from or how it was compiled.

Patent Owner further objects to Exhibit 1079 as being improperly submitted in Petitioner's Reply for the first time. Petitioner could have raised Exhibit 1079 with its argument in the Petition. "Petitioner may not submit new evidence or

argument in reply that it could have presented earlier” Practice Guide at 73; *Intelligent Bio-Sys.*, 821 F.3d at 1369–70; *see also Ariosa*, 805 F.3d at 1367.

E. Exhibit 1080 Deposition Transcript of George D. Yancopoulos, M.D., Ph.D. (April 12, 2024)

Patent Owner objects to Exhibit 1080 for each of the reasons noted in the objections made during the underlying deposition.

F. Exhibit 1081 Samsung Bioepis Petition for IPR filed in *Samsung Bioepis Co., Ltd. v. Regeneron Pharmaceuticals, Inc.*, PTAB-IPR2023-00739 (Paper 1) (“Samsung 601 Petition”)

Patent Owner objects to Exhibit 1081 under:

- FRE 402-403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the factfinder.
- FRE 611 and 37 CFR § 42.24 because Petitioner’s submission of an 83-page petition from another proceeding violates the requirements of FRE 611 that the Board “exercise reasonable control over the mode and order of . . . presenting evidence.” The exhibit contains attorney argument that exceeds the scope of direct examination questioning. Likewise, Petitioner’s submission of additional petitions in this proceeding flouts the word limit established by 37 CFR § 42.24(c)(1). Patent Owner further objects to Exhibit 1081 under FRE 403 because the consideration of the 83-page document, to the extent it has any probative value, is

substantially outweighed by the danger of unfair prejudice, confusing the issues, wasting time, and needlessly presenting cumulative evidence.

- 37 CFR § 42.53. Patent Owner is attempting to introduce testimony in an unauthorized form and in a manner that is unfairly prejudicial to Patent Owner.

Patent Owner further objects to Exhibit 1081 as being improperly submitted in Petitioner's Reply for the first time. Petitioner could have raised individual arguments and evidence contained within Exhibit 1081 with its argument in the Petition. "Petitioner may not submit new evidence or argument in reply that it could have presented earlier" Practice Guide at 73; *Intelligent Bio-Sys.*, 821 F.3d at 1369–70; *see also Ariosa*, 805 F.3d at 1367.

G. Exhibit 1082 Deposition Transcript of Karen Chu (April 11, 2024)

Patent Owner objects to Exhibit 1082 for each of the reasons noted in the objections made during the underlying deposition.

H. Exhibit 1083 RGN-EYLEA-MYLAN-00526220 – RGN-EYLEA-MYLAN-00526223

Patent Owner objects to Exhibit 1083 under:

- FRE 901. Petitioner has not introduced evidence or testimony to properly authenticate the exhibit.

- FRE 402-403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the factfinder.
- FRE 802. The exhibit is hearsay because it is offered for the truth of its content without satisfying any of the hearsay exceptions.
- 37 CFR § 42.53. Patent Owner is attempting to introduce testimony in an unauthorized form and in a manner that is unfairly prejudicial to Patent Owner.

I. Exhibit 1084 Deposition Transcript of Richard Manning, Ph.D. (March 27, 2024) in *Samsung Bioepis Co., Ltd. v. Regeneron Pharmaceuticals, Inc.*, PTAB-IPR2023-00739 and -00884

Patent Owner objects to Exhibit 1084 for each of the reasons noted in the objections made during the underlying deposition.

J. Exhibit 1085 (Deposition Transcript of Michael W. Stewart, M.D. (March 29, 2024) in *Samsung Bioepis Co., Ltd. v. Regeneron Pharmaceuticals, Inc.*, PTAB-IPR2023-00739)

Patent Owner objects to Exhibit 1085 under:

- FRE 402-403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the factfinder. The exhibit presents a deposition from a different proceeding with different arguments.

- 37 CFR § 42.53. The rule requires that compelled testimony be submitted in the form of a deposition transcript and that uncompelled testimony must be submitted in the form of an affidavit. The rule further imposes time limits of: “[s]even hours for cross-examination, four hours for redirect examination, and two hours for re-cross examination.” Petitioner has already exhausted its cross-examination allowance with the witness at deposition, and thus Petitioner vastly exceeds its limit on allowable testimonial time that it may present to the Board. Petitioner rejected Patent Owner’s offer to consolidate the -00739 deposition with the -00884 deposition, and using both depositions in this proceeding unfairly prejudices Patent Owner. *See* 3/2/24 10:21 a.m. Z. Summers Email to A. Brausa.
- FRE 802. The exhibit is hearsay because it is offered for the truth of its content without satisfying any of the hearsay exceptions.

Patent Owner further objects to Exhibit 1085 for each of the reasons noted in the objections made during the underlying deposition.

K. Exhibit 1086 Memorandum Opinion and Order Following Bench Trial, *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, No. 22-cv-00061-TSK (N.D.W. Va. January 31, 2024) (ECF No. 692) (REDACTED) (“Mylan Litigation”)

Patent Owner objects to Exhibit 1086 under:

- FRE 802. The exhibit is hearsay because it is offered for the truth of its content without satisfying any of the hearsay exceptions.
- 37 CFR § 42.53. Patent Owner is attempting to introduce testimony in an unauthorized form and in a manner that is unfairly prejudicial to Patent Owner.

L. Exhibit 1087 Nguyen QD, Tatlipinar S, Shah SM, Haller JA, Quinlan E, Sung J, Zimmer-Galler I, Do DV, Campochiaro PA. Vascular endothelial growth factor is a critical stimulus for diabetic macular edema. Am J. Ophthalmol. 2006 Dec;142(6):961-9

Patent Owner objects to Exhibit 1087 under:

- FRE 402-403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the factfinder. The exhibit presents clinical results using a different compound than the one in the claimed regimens, which is substantially more prejudicial than probative.
- FRE 802. The exhibit is hearsay because it is offered for the truth of its content without satisfying any of the hearsay exceptions.
- FRE 901. Petitioner has not demonstrated the authenticity of the exhibit. It is not clear where the exhibit came from or how it was compiled.

Patent Owner further objects to Exhibit 1087 as being improperly submitted in Petitioner's Reply for the first time. Petitioner could have raised Exhibit 1087

with its argument in the Petition. “Petitioner may not submit new evidence or argument in reply that it could have presented earlier” Practice Guide at 73; *Intelligent Bio-Sys.*, 821 F.3d at 1369–70; *see also Ariosa*, 805 F.3d at 1367.

M. Exhibit 1088 Institution Decision issued in *Samsung Bioepis Co., Ltd. v. Regeneron Pharmaceuticals, Inc.*, PTAB-IPR2023-00739 (Paper 9) (“’601 IPR ID”)

Patent Owner objects to Exhibit 1088 under:

- FRE 402-403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the factfinder. The exhibit presents an opinion from a different proceeding with different arguments.
- FRE 802. The exhibit is hearsay because it is offered for the truth of its content without satisfying any of the hearsay exceptions.
- 37 CFR § 42.53, including to the extent Patent Owner is attempting to introduce testimony in an unauthorized form and in a manner that is unfairly prejudicial to Patent Owner.

N. Exhibit 1089 Declaration of Michael W. Stewart, M.D. submitted as Exhibit 2027 in *Samsung Bioepis Co., Ltd. v. Regeneron Pharmaceuticals, Inc.*, PTAB-IPR2023-00739 (“Stewart ’601 IPR Decl.”)

Patent Owner objects to Exhibit 1089 under:

- FRE 402-403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and

misleading the factfinder. The exhibit presents a declaration from a different proceeding with different arguments.

- 37 CFR § 42.53. First, the rule requires that compelled testimony be submitted in the form of a deposition transcript and that un compelled testimony must be submitted in the form of an affidavit. Petitioner thus improperly relies on Exhibit 1089 as un compelled testimony from an expert in the form of an expert declaration, which as explained below is prejudicial to Patent Owner. Second, the rule imposes time limits of: “[s]even hours for cross-examination, four hours for redirect examination, and two hours for re-cross examination.” Petitioner has already exhausted its cross-examination allowance with the witness at deposition, and thus Petitioner vastly exceeds its limit on allowable testimonial time that it may present to the Board.
- FRE 802. The exhibit is hearsay because it is offered for the truth of its content without satisfying any of the hearsay exceptions.

O. Exhibit 1091 RGN-EYLEA-MYLAN-00631182

Patent Owner objects to Exhibit 1091 under:

- FRE 402-403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the factfinder.

- FRE 802. The exhibit is hearsay because it is offered for the truth of its content without satisfying any of the hearsay exceptions.
- 37 CFR § 42.53, including to the extent Patent Owner is attempting to introduce testimony in an unauthorized form and in a manner that is unfairly prejudicial to Patent Owner.

P. Exhibit 1092 Responsive Expert Declaration of Dr. Edward Chaum, dated June 10, 2024 (“Chaum Resp. Decl.”)

Patent Owner objects to Exhibit 1092 under:

- FRE 402-403. The declaration is irrelevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the factfinder.
- FRE 106 and/or FRE 1006. The declaration relies on excerpts of documents identified in these Objections. In fairness, the full document ought to be considered at the same time. For example, at least Paragraphs 14, 19–27, 30, 32, 37–39, and 41–42 rely on incomplete evidence, improperly summarize exhibits, and/or cherry-pick selective passages of a reference, while ignoring other passages in the same reference.
- FRE 702, 703, and 705. The responsive declaration is not based on sufficient facts or data, is not the product of reliable principles and

methods, and has not applied the proper principles to the facts of this proceeding.

- FRE 901. The declaration relies on the unauthenticated evidence identified in these Objections. For example, at least Paragraphs 14, 19-27, 32, and 38–39 rely on Exhibit 2047, which is unauthenticated evidence. Petitioner has not introduced corroborating evidence or testimony to demonstrate Exhibit 2047’s authenticity, nor has it shown that Exhibit 2047 was publicly available as of the priority date.

Patent Owner further objects to Exhibit 1092 as being improperly submitted in Petitioner’s Reply for the first time. Petitioner could have raised the expert testimony in Exhibit 1092 with its declaration in the Petition. “Petitioner may not submit new evidence or argument in reply that it could have presented earlier” Practice Guide at 73; *Intelligent Bio-Sys.*, 821 F.3d at 1369–70; *see also Ariosa*, 805 F.3d at 1367.

Q. Exhibit 2047 VEGF Trap-Eye in Wet AMD - CLEAR-IT 2: Summary of One- Year Key Results, Presented at 2008 Retina Society Meeting, Scottsdale, Arizona (Sep. 28, 2008)

Patent Owner objects to Exhibit 2047 under:

- FRE 402-403. As offered by Petitioner, the exhibit is irrelevant, and its probative value on the issue as to which Petitioner seeks to use the Exhibit is substantially outweighed by the danger of confusion of the

issues and misleading the factfinder. Patent Owner's limited and different use of this Exhibit in its Preliminary Response did not render this Exhibit relevant and admissible for all purposes.

- FRE 802 and 805. As offered by the Petitioner, the exhibit is hearsay because it is offered for the truth of its content without satisfying any of the hearsay exceptions. The exhibit is further hearsay within hearsay to the extent the presentation contains statements of others, without both statements satisfying any of the hearsay objections.
- FRE 901. Petitioner has not demonstrated the authenticity or public availability of the exhibit for the purpose of the exhibit as offered by Petitioner. Petitioner has not provided corroborating evidence or testimony to prove that Exhibit 2047 is what Petitioner purports it to be. Patent Owner's limited and different use of the Exhibit did not address these issues.
- FRE 1002 and 1004. The exhibit is not an original version of the underlying clinical study or any of the grounds, so it may not be used to prove the contents of that clinical study or of an alleged prior art reference.
- 37 C.F.R. § 42.120. The exhibit is inadmissible because it addresses matters outside of the instituted grounds in this proceeding.

IPR2023-00884

Date: June 17, 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 OBJECTIONS TO EVIDENCE SUBMITTED WITH PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE was served as of the below date on the Petitioner via e-mail (by agreement) to the following counsel of record:

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Dated: June 17, 2024

/Adam R. Brausa/
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