

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Patent No. 10,888,601

Inter Partes Review No. IPR2023-00739¹

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

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

Regeneron Pharmaceuticals, Inc. (“Regeneron” or “Patent Owner”) hereby objects to the following evidence that was submitted by Petitioner Samsung Bioepis Co. Ltd., (“Samsung” or “Petitioner”) with the Reply (Paper 48) in the above-captioned proceeding.

Exhibit 1061 (Deposition Transcript of Michael W. Stewart, M.D. (March 29, 2024))

Patent Owner objects to Exhibit 1061 for each of the reasons noted in the objections made during the underlying deposition.

Exhibit 1062 (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))

Patent Owner objects to Exhibit 1062 under FRE 106, FRE 403, and FRE 611. Petitioner has submitted a heavily redacted version of what it contends is the District Court’s opinion in *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, No. 22-cv-00061-TSK (N.D.W. Va. January 31, 2024) (“Mylan Litigation”), with sentences and pages missing throughout the exhibit. (*See, e.g.*, Ex. 1062, at 99-105). The remainder of this document has not been provided by Petitioner, but in fairness ought to be considered at the same time as the portions of the opinion Petitioner introduced. The document, however, is under seal and cannot be provided to the Board by Patent Owner. Therefore, it is unfairly prejudicial for the Board to rely on Petitioner’s submission.

Patent Owner objects to Exhibit 1062 under FRE 901. Petitioner offers that Exhibit 1062 as the court's final decision in the Mylan Litigation. Petitioner, however, submitted a heavily redacted version with sentences and pages missing throughout the exhibit. The parties to the Mylan litigation, including the Petitioner in IPR2024-00201, agree that the Mylan litigation has not been fully resolved, which means Exhibit 1062 is not the final decision in the Mylan Litigation.

Patent Owner objects to Exhibit 1062 under 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 objects to Exhibits 1062 under 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.

Exhibit 1063 (Final Written Decision in *Mylan Pharmaceuticals Inc. v. Regeneron Pharmaceuticals, Inc.*, IPR2022-01226 [Paper 101] (“601 FWD”))

Patent Owner objects to Exhibit 1063 under FRE 402-403 to the extent 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; while the Board may consider prior decisions if appropriate, those prior decisions are not admissible evidence on the merits of Patent Owner's arguments. Petitioner also

fails to identify with specificity what portions, if any, of Exhibit 1063 that purportedly support its arguments.

Patent Owner objects to Exhibit 1063 under 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 objects to Exhibits 1062 under 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.

Exhibit 1064 (Final Written Decision in *Mylan Pharmaceuticals Inc. v. Regeneron Pharmaceuticals, Inc.*, IPR2022-01225 [Paper 96] (“’681 FWD”))

Patent Owner objects to Exhibit 1064 under FRE 402-403 to the extent 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 over a different patent; while the Board may consider prior decisions if appropriate, those prior decisions are not admissible evidence on the merits of Patent Owner’s arguments. Petitioner also fails to identify with specificity the portions, if any, of Exhibit 1064 that purportedly support its arguments.

Patent Owner objects to Exhibit 1064 under 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 objects to Exhibits 1062 under 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.

Exhibit 1065 (Order on Claim Construction, *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, No. 22-cv-00061-TSK (N.D.W. Va. April 19, 2023) (ECF No. 427))

Patent Owner objects to Exhibit 1065 under FRE 402-403 to the extent 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 tribunal over proceeding with different standards, arguments, discovery, and evidence; while the Board may consider prior decisions if appropriate, those prior decisions are not admissible evidence on the merits of Patent Owner's arguments. Petitioner also fails to identify with specificity the portions, if any, of Exhibit 1065 that purportedly support its arguments.

Patent Owner objects to Exhibit 1065 under 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 objects to Exhibits 1065 under 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.

Exhibit 1066 (Bench Trial Transcript (Vol. 1), *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, No. 22-cv-00061-TSK (N.D.W. Va. April 19, 2023) (June 12, 2023) (“Yanco Trial Transcript”))

Patent Owner objects to Exhibit 1066 under FRE 106, FRE 403, and FRE 611. Petitioner has submitted an incomplete version of what it contends is the “Yanco Trial Transcript,” in the Mylan Litigation, with pages missing from the exhibit. (*See, e.g.*, Ex. 1066, at 10). The remainder of this document has not been provided by Petitioner, but in fairness ought to be considered at the same time as the portions of the opinion Petitioner introduced. The document, however, is under seal and cannot be provided to the Board by Patent Owner. Therefore, it is unfairly prejudicial for the Board to rely on Petitioner’s submission.

Patent Owner further objects to Exhibit 1066 under FRE 611 because Petitioner’s submission of a 252-page transcript from another proceeding violates the requirements of FRE 611 that the Board “exercise reasonable control over the mode and order of examining witnesses and presenting evidence.” The exhibit contains attorney argument and testimony that exceeds the scope of direct examination questioning.

Patent Owner further objects to Exhibit 1066 under FRE 403 because the consideration of the 252 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.

Patent Owner objects to Exhibit 1066 because Petitioner is using the 252-page exhibit to introduce attorney-argument in the form of opening statements beyond the allowable scope and limits of this proceeding, including 37 CFR § 42.24.

Patent Owner objects to Exhibit 1066 under 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 objects to Exhibit 1066 under 37 CFR § 42.53. First, 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. Petitioner thus improperly relies on Exhibit 1066 as testimony in the form of a District Court trial transcript, 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. By introducing Exhibit 1066, Petitioner vastly

exceeds its limit on allowable testimonial time that it may present to the Board and deprives Patent Owner the opportunity to re-direct on the relevant issues raised in Exhibit 1066's testimony.

Exhibit 1067 (Bench Trial Transcript (Vol. 8), *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, No. 22-cv-00061-TSK (N.D.W. Va. April 19, 2023) (June 22, 2023) (“Csaky Trial Transcript”))

Patent Owner objects to Exhibit 1067 under FRE 402-403. The exhibit is not relevant to the extent Petitioner relies upon it in its Reply, and the exhibit's probative value is substantially outweighed by the danger of confusion of the issues and misleading the factfinder.

Patent Owner objects to Exhibit 1067 under 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 1067 under FRE 611 because Petitioner's submission of the 246-page transcript from another proceeding violates the requirements of FRE 611 that the Board “exercise reasonable control over the mode and order of examining witnesses and presenting evidence.” The exhibit contains attorney argument and testimony that exceeds the scope of direct examination questioning.

Patent Owner objects to Exhibit 1067 under 37 CFR § 42.53. First, 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. Petitioner thus improperly relies on Exhibit 1067 as testimony in the form of a District Court trial transcript, 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. By introducing Exhibit 1067, Petitioner vastly exceeds its limit on allowable testimonial time that it may present to the Board and deprives Patent Owner the opportunity to re-direct on the relevant issues raised in Exhibit 1067’s testimony.

Exhibit 1068 (Bench Trial Transcript (Vol. 4), *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, No. 22-cv-00061-TSK (N.D.W. Va. April 19, 2023) (June 15, 2023) (“Albini Trial Transcript”))

Patent Owner objects to Exhibit 1068 under FRE 402-403. The exhibit is not relevant to the extent Petitioner relies upon it in its Reply, and the exhibit’s probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder.

Patent Owner objects to Exhibit 1068 under FRE 702-703. Petitioner’s cited testimony is not based on sufficient facts or data, is not the product of reliable principles and methods, and the expert has not applied the proper principles to the facts of this proceeding.

Patent Owner objects to Exhibit 1068 under 37 CFR § 42.53. First, 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. Petitioner thus improperly relies on Exhibit 1068 as uncompelled testimony from an expert in support of the Petitioner the form of a District Court trial transcript, 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. By introducing Exhibit 1068, as uncompelled testimony Petitioner has violated the requirement to provide an affidavit, which has deprived Patent Owner of the ability to depose and cross-examine the witness in this proceeding. Petitioner vastly exceeds its limit on allowable testimonial time that it may present to the Board.

Patent Owner objects to Exhibit 1068 under FRE 802. The exhibit is hearsay because it is offered for the truth of its content without satisfying any of the hearsay exceptions.

Exhibit 1069 (U.S. Patent No. 7,303,747)

Patent Owner objects to Exhibit 1069 under FRE 402-403. The exhibit is not relevant to the extent Petitioner relies upon it in its Reply, and the exhibit’s probative value is substantially outweighed by the danger of confusion of the

issues and misleading the factfinder. Petitioner also fails to identify with specificity the portions of Exhibit 1069 that purportedly support its arguments. Petitioner relies on Exhibit 1069 only to the extent referenced by Exhibit 1068, which is inadmissible for the reasons explained above.

Patent Owner further objects to Exhibit 1069 as being improperly submitted in Petitioner's Reply for the first time. Petitioner could have raised Exhibit 1069 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"); cf. *Caterpillar Inc. v. Wirtgen America, Inc.*, IPR2022-01264, 2024 WL 230734, at *22 (P.T.A.B. 2024) (permitting additional evidence because Petitioner's reply arguments were mere logical extensions of arguments from the Petition).

Exhibit 1070 (Deposition Transcript of Richard Manning, Ph.D. (March 27, 2024))

Patent Owner objects to Exhibit 1070 for each of the reasons noted in the objections made during the underlying deposition.

Exhibit 1071 (Deposition Transcript of David Brown, M.D. (April 3, 2024))

Patent Owner objects to Exhibit 1071 for each of the reasons noted in the objections made during the underlying deposition.

Exhibit 1072 (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), ARVO Annual Meeting Abstract (April 2010), Vol. 51, Issue 13, allegedly available at: <https://iovs.arvojournals.org/article.aspx?articleid=2375028>)

Patent Owner objects to Exhibit 1072 under 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. For example, the document does not have a specific date, nor does the website demonstrate when the website or article was most recently updated or made available publicly. Petitioner has not shown that Exhibit 1072 was available as of the alleged publication date.

Patent Owner objects to Exhibit 1072 under 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 1072 as being improperly submitted in Petitioner’s Reply for the first time. Petitioner could have raised Exhibit 1072 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; *cf. Caterpillar*, 2024 WL 230734, at *22 (permitting additional evidence because Petitioner’s reply arguments were mere logical extensions of arguments from the Petition).

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

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