

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Patent No. 11,253,572

Inter Partes Review No. IPR2023-00884

**PATENT OWNER'S OBJECTIONS TO EVIDENCE
SUBMITTED WITH THE PETITION FOR *INTER PARTES* REVIEW**

Regeneron Pharmaceuticals, Inc. (“Regeneron” or “Patent Owner”) hereby objects to the following evidence that was submitted by Samsung Bioepis Co., Ltd., (“Samsung” or “Petitioner”) with the Petition (“Pet.,” Paper 2) in the above-captioned proceeding.

**A. Exhibit 1002 (Expert Declaration of Dr. Edward Chaum in
Support of Petition for *Inter Partes* Review of Patent No.
11,253,572, dated April 27, 2023 (“Chaum Decl.”))**

Patent Owner objects to Exhibit 1002 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 fact finder, including because Paragraphs 31 and 177 are not cited in the Petition.
- FRE 801-804. The declaration constitutes hearsay to the extent that the declarant has not yet been made available for deposition.
- FRE 106 and/or FRE 1006.
 - The declaration relies on excerpts of documents identified below. In fairness, the full document ought to be considered at the same time.
 - For example, at least Paragraphs 51, 54, 109, and 111-13, rely on incomplete evidence or improper summary and/or improperly cherry-

picking selective passages of a reference, while ignoring other passages in the same reference.

- FRE 901.
 - The declaration relies on the unauthenticated evidence identified below.
 - Paragraph 180 relies on unauthenticated evidence. It is not clear where the image came from, how it was compiled, or what methods, materials, or metrics were used to arrive at the information in the image.

B. Exhibit 1005 (Press Release, “Enrollment Completed in Regeneron and Bayer Healthcare Phase 3 Studies of VEGF Trap-Eye in Neovascular Age-Related Macular Degeneration (Wet AMD) (September 14, 2009),” available at: <https://newsroom.regeneron.com/news-releases/newsrelease-details/enrollment-completed-regeneron-and-bayer-healthcarephase-3> (“2009 Press Release”))

Patent Owner objects to Exhibit 1005 under

- FRE 402 and 403. The exhibit is irrelevant, and its probative value is substantially outweighed by the danger of confusion of the issues and

misleading the fact finder, including to the extent Petitioner relies on this exhibit to show the results of a dosing regimen that it does not disclose.

- 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.

C. Exhibit 1006 (Press Release, “Regeneron and Bayer Report

Positive Results for VEGF Trap-Eye in Phase 3 Study in Central Retinal Vein Occlusion (CRVO) and in Phase 2 Study in Diabetic Macular Edema (DME),” Exhibit 99.1 to Regeneron 8-K filed on December 20, 2010, available at:

<https://yahoo.brand.edgaronline.com/displayfilinginfo.aspx?FilingID=7617341643623571&type=sect&TabIndex=2&companyid=5036&ppu=%252fdef%20E2%80%A6> (“December 2010 Press Release”)

Patent Owner objects to Exhibit 1006 under

- FRE 402 and 403. The exhibit is irrelevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder, including because Petitioner relies on it as prior art to the challenged patent, but it is not prior art.
- FRE 901. Petitioner has not demonstrated the authenticity of the exhibit.

- FRE 802. The exhibit is offered for the truth of its content without satisfying any of the hearsay exceptions, including because Petitioner relies on the reference itself for the date of publication online.

D. Exhibit 1007 (Press Release, “Bayer and Regeneron Report

Positive Top-Line Results of Two Phase 3 Studies with VEGF

Trap-Eye in Wet Age-related Macular Degeneration,” Exhibit

99.1 to Regeneron 8-K filed on November 22, 2010, available at:

[https://yahoo.brand.edgaronline.com/displayfilinginfo.aspx?Filing](https://yahoo.brand.edgaronline.com/displayfilinginfo.aspx?FilingID=7572010861126486&type=sect&TabIndex=2&companyid=5036&ppu=%252fdef%E2%80%A6)

ID=7572010861126486&type=sect&TabIndex=2&companyid=503

6&ppu=%252fdef%E2%80%A6 (“November 2010 Press

Release’))

Patent Owner objects to Exhibit 1007 under

- FRE 402 and 403. The exhibit is irrelevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder, including because Petitioner relies on it as prior art to the challenged patent, but it is not prior art.
- FRE 901. Petitioner has not demonstrated the authenticity of the exhibit.
- FRE 802. The exhibit is offered for the truth of its content without satisfying any of the hearsay exceptions, including because Petitioner relies on the reference itself for the date of publication online.

E. Exhibit 1009 (Dixon JA, Oliver SC, Olson JL, Mandava N. VEGF Trap-Eye for the treatment of neovascular age-related macular degeneration. Expert Opin Investig Drugs. 2009;18(10):1573-1580. (“Dixon”))

Patent Owner objects to Exhibit 1009 under

- FRE 402 and 403. The exhibit is irrelevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder, including because Petitioner relies on this exhibit to show the results of a dosing regimen that it does not disclose.

F. Exhibit 1010 (Major JC et al., “DA VINCI: DME and VEGF Trap-Eye: INvestigationof Clinical Impact: Phase 2 Study in Patients With Diabetic Macular Edema (DME), ARVO Annual Meeting Abstract (April 2010), Vol. 51, Issue 13, available at: <https://iovs.arvojournals.org/article.aspx?articleid=2375028> (“2010 ARVO Abstract”))

Patent Owner objects to Exhibit 1010 under

- FRE 402 and 403. The exhibit is irrelevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder, including because Petitioner relies on it as prior art to the challenged patent, but it is not prior art.

G. Exhibit 1016 (Hecht, “Ophthalmic Preparations,” Remington: The Science and Practice of Pharmacy, Volume II, 19th edition, Chapter 89 (1995). (“Hecht”))

Patent Owner objects to exhibit 1016 under

- FRE 106 and/or FRE 1006. The Exhibit appears to be an excerpt. In fairness, the full document ought to be considered at the same time.

H. Exhibit 1017 (WO 2006/047325 A1 (“Shams”))

Patent Owner objects to Exhibit 1017 under

- FRE 802. The exhibit 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.

I. Exhibit 1018 (Elman MJ, et al., Randomized trial evaluating ranibizumab plus prompt or deferred laser or triamcinolone plus prompt laser for diabetic macular edema. Ophthalmology. 2010 Jun;117(6):1064-1077.e35. (“Elman 2010”))

Patent Owner objects to Exhibit 1018 under

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

- FRE 802. The exhibit 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.

J. Exhibit 1019 (Elman MJ, et al., Randomized trial evaluating ranibizumab plus prompt or deferred laser or triamcinolone plus prompt laser for diabetic macular edema. Ophthalmology. 2010 Jun;117(6):1064-1077.e35, published April 28 2010, available at [https://www.aaojournal.org/article/S0161-6420\(10\)00243-5/fulltext](https://www.aaojournal.org/article/S0161-6420(10)00243-5/fulltext) (“Elman AAO Website))

Patent Owner objects to Exhibit 1019 under

- FRE 802. The exhibit 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, how it was compiled, or what methods, materials, or metrics were used to arrive at the information in the document.

K. Exhibit 1020 (Authenticating Affidavit and the July 13, 2010 Web Archive of the CATT Patient Eligibility Criteria, available at <https://web.archive.org/web/20100713035617/http://www.med.upe>

**nn.edu/cpob/studies/documents/CATTEligibilityCriteria_000.pdf,
attached as Exhibit B (“CATT Study”))**

Patent Owner objects to Exhibit 1020 under

- FRE 402 and 403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder, including because Petitioner has not shown it was publicly accessible as of the priority date of the challenged claims of the ’572 patent (January 13, 2011).
- FRE 802. The exhibit 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.

L. Exhibit 1021 (Regillo CD, Brown DM, Abraham P, et al.

**Randomized, double-masked, sham-controlled trial of
ranibizumab for neovascular age-related macular degeneration:
PIER Study year 1. Am J Ophthalmol. 2008;145(2):239-248.
 (“PIER Study”))**

Patent Owner objects to Exhibit 1021 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.

**M. Exhibit 1022 (Comparison of Age-related Macular Degeneration
Treatments Trials: Lucentis-Avastin Trial (NCT00593450),
available at: <https://clinicaltrials.gov/ct2/show/NCT00593450>
 (“NCT-450”))**

Patent Owner objects to Exhibit 1022 under

- FRE 802. The exhibit 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, how it was compiled, or what methods, materials, or metrics were used to arrive at the information in the document.

**N. Exhibit 1023 (Regillo CD, Brown DM, Abraham P, et al.
Randomized, double-masked, sham-controlled trial of
ranibizumab for neovascular age-related macular degeneration:
PIER Study year 1. Am J Ophthalmol. 2008;145(2):239-248,
published December 3, 2007, available at
[https://www.ajo.com/article/S0002-9394\(07\)00881-1/fulltext](https://www.ajo.com/article/S0002-9394(07)00881-1/fulltext)
 (“PIER AJO Website”))**

Patent Owner objects to Exhibit 1023 under

- FRE 901. Petitioner has not demonstrated the authenticity of the exhibit. It is not clear where the exhibit came from, how it was compiled, or what methods, materials, or metrics were used to arrive at the information in the document.

O. Exhibit 1024 (History of Changes for Study: A Study of rhuFab

V2 (Ranibizumab) in Subjects With Subfoveal Choroidal

Neovascularization Secondary to Age-Related Macular

Degeneration (AMD) (NCT00090623), available at:

https://clinicaltrials.gov/ct2/history/NCT00090623?V_1=View#StudyPageTop. (“NCT-623”))

Patent Owner objects to Exhibit 1024 under

- FRE 901. Petitioner has not demonstrated the authenticity of the exhibit. It is not clear where the exhibit came from, how it was compiled, or what methods, materials, or metrics were used to arrive at the information in the document.

P. Exhibit 1025 (ClinicalTrials.gov Background, available at:

<https://clinicaltrials.gov/ct2/about-site/background>

(“ClinicalTrials.gov Background”))

Patent Owner objects to Exhibit 1025 under

- FRE 901. Petitioner has not demonstrated the authenticity of the exhibit. It is not clear where the exhibit came from, how it was compiled, or what methods, materials, or metrics were used to arrive at the information in the document.

Q. Exhibit 1026 (ClinicalTrials.gov About the Results Database, available at: <https://clinicaltrials.gov/ct2/about-site/results> (“ClinicalTrials.gov About the Results Database”))

Patent Owner objects to Exhibit 1026 under

- FRE 901. Petitioner has not demonstrated the authenticity of the exhibit. It is not clear where the exhibit came from, how it was compiled, or what methods, materials, or metrics were used to arrive at the information in the document.

R. Exhibit 1027 (Press Release, “Regeneron Reports Positive Phase 1 Data for the VEGF TRAP in Age-Related Macular Degeneration,” Exhibit 99(a) to Regeneron 8-K filed on May 2, 2006, available at: <https://yahoo.brand.edgaronline.com/displayfilinginfo.aspx?FilingID=4380124-5423-15279&type=sect&TabIndex=2&companyid=5036&ppu=%252fd ef%E2%80%A6> (“May 2006 Press Release”))

Patent Owner objects to Exhibit 1027 under

- FRE 402 and 403. The exhibit is irrelevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder, including because Petitioner relies on this exhibit to show the results of a dosing regimen that it does not disclose.
- FRE 802. The exhibit 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, how it was compiled, or what methods, materials, or metrics were used to arrive at the information in the document.

S. Exhibit 1030 (Do DV et al., “Results of a Phase I Study of Intravitreal VEGF Trap in Subjects With Diabetic Macular Edema: The CLEAR-IT DME Study,” ARVO Annual Meeting Abstract (May 2007), Vol. 48, Issue 3, available at: <https://iovs.arvojournals.org/article.aspx?articleid=2384099> (“2007 ARVO Abstract”))

Patent Owner objects to Exhibit 1030 under

- FRE 402 and 403. The exhibit is irrelevant, and its probative value is substantially outweighed by the danger of confusion of the issues and

misleading the fact finder, including because Petitioner relies on this exhibit to show the results of a dosing regimen that it does not disclose.

- FRE 901. Petitioner has not demonstrated the authenticity of the exhibit. It is not clear where the exhibit came from, how it was compiled, or what methods, materials, or metrics were used to arrive at the information in the document.
- FRE 106 and/or FRE 1006. The Exhibit appears to be an excerpt. In fairness, the full document ought to be considered at the same time.

T. Exhibit 1031 (Do DV et al., The DA VINCI Study: phase 2 primary results of VEGF Trap-Eye in patients with diabetic macular edema. Ophthalmology. 2011 Sep;118(9):1819-26 (published online on May 5, 2011). (“Do 2011”))

Patent Owner objects to Exhibit 1031 under

- FRE 402 and 403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder because it was not published before the priority date of the challenged claims of the '572 patent (January 13, 2011).

U. Exhibit 1032 (Randolph and Jones, “Surfactant-Protein Interactions,” Rational Design of Stable Protein Formulations, edited by Carpenter and Manning, vol. 13, 2002 (“Randolph”))

Patent Owner objects to Exhibit 1032 under

- FRE 802. The exhibit is offered for the truth of its content without satisfying any of the hearsay exceptions.

V. Exhibit 1034 (Lucentis ® Original Approved Labeling (2006), available at:

https://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/125156s0000_Lucentis_Prntlbl.pdf

Patent Owner objects to Exhibit 1034 under

- FRE 402 and 403. The undated exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder to the extent it is not shown to be published before the priority date of the challenged claims of the '572 patent (January 13, 2011).
- FRE 901. Petitioner has not demonstrated the authenticity of the document. It is not clear where the exhibit came from or how it was compiled.

W. Exhibit 1038 (Heier JS, et al., Intravitreal aflibercept (VEGF trap-eye) in wet age-related macular degeneration. Ophthalmology 2012;119(12):2537-2548. (“Heier 2012”))

Patent Owner objects to Exhibit 1038 under

- FRE 402 and 403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder because it was not published before the priority date of the challenged claims of the '572 patent (January 13, 2011).
- FRE 802. The exhibit is offered for the truth of its content without satisfying any of the hearsay exceptions.

X. Exhibit 1039 (Heier JS, et al., CLEAR-IT 2 Investigators. The 1-year results of CLEAR-IT 2, a phase 2 study of vascular endothelial growth factor trapeye dosed as-needed after 12-week fixed dosing. Ophthalmology. 2011 Jun;118(6):1098-106. (“Heier 2011”))

Patent Owner objects to Exhibit 1039 under

- FRE 802. The exhibit is offered for the truth of its content without satisfying any of the hearsay exceptions.

Y. Exhibit 1040 (Pai A, El Shafei MM, Mohammed OA, Al Hashimi M., Current concepts in intravitreal drug therapy for diabetic

retinopathy. Saudi J Ophthalmol. 2010 Oct;24(4):143-9. (“Pai 2010”))

Patent Owner objects to Exhibit 1040 under

- FRE 802. The exhibit is offered for the truth of its content without satisfying any of the hearsay exceptions.

Z. Exhibit 1041 (U.S. Patent App. Pub. US 2007/0190058A1 (“Shams US App. Pub.”))

Patent Owner objects to Exhibit 1041 under

- FRE 402 and 403. The exhibit is irrelevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder, including because it is not cited in the Petition.

AA. Exhibit 1043 (WO 2012/097019A1 (“Yancopoulos PCT Application”))

Patent Owner objects to Exhibit 1043 under

- FRE 402 and 403. The exhibit is irrelevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder, including because it is not cited in the Petition.

BB. Exhibit 1044 (U.S. Dep’t Health & Human Servs., Nat’l Inst. Health, Nat’l Eye Inst., “Diabetic Retinopathy: What You Should Know (Sept. 2015),” available at:

https://www.nei.nih.gov/sites/default/files/healthpdfs/Diabetic_Retinopathy_What_You_Should_Know.pdf (“NIHDR”))

Patent Owner objects to Exhibit 1044 under

- FRE 402 and 403. The exhibit is irrelevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder, including because it is not cited in the Petition, and including because it was not published before the priority date of the challenged claims of the '572 patent (January 13, 2011).
- FRE 802. The exhibit 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 document.

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

CC. Exhibit 1045 (U.S. Dep’t Health & Human Servs., Nat’l Inst. Health, Nat’l Eye Inst., “Age-Related Macular Degeneration: What You Should Know (Sept.2015),” available at https://www.nei.nih.gov/sites/default/files/healthpdfs/WYSK_AMD_English_Sept2015_PRINT.pdf (“NIH AMD”))

Patent Owner objects to Exhibit 1045 under

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

misleading the fact finder, including because it was not published before the priority date of the challenged claims of the '572 patent (January 13, 2011).

- FRE 802. The exhibit 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 document.

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

DD. Exhibit 1046 (Halpern MT, Schmier JK, Covert D, Venkataraman K. Resource utilization and costs of age-related macular degeneration. Health Care Financ Rev. 2006;27(3):37-47. (“Halpern 2006”))

Patent Owner objects to Exhibit 1046 under

- FRE 402 and 403. The exhibit is irrelevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder, including because it is not cited in the Petition.
- FRE 802. The exhibit is offered for the truth of its content without satisfying any of the hearsay exceptions.

EE. Exhibit 1047 (Rudge JS, Holash J, Hylton D, et al. VEGF Trap complex formation measures production rates of VEGF, providing a biomarker for predicting efficacious angiogenic

blockade. Proc Natl Acad Sci U S A. 2007;104(47):18363-18370.

(“Rudge 2007”))

Patent Owner objects to Exhibit 1047 under

- FRE 402 and 403. The exhibit is irrelevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder, including because it is not cited in the Petition.

FF. Exhibit 1048 (Li E, Donati S, Lindsley KB, Krzystolik MG, Virgili G. Treatment regimens for administration of anti-vascular endothelial growth factor agents for neovascular age-related macular degeneration. Cochrane Database Syst Rev. 2020;5(5):CD012208. (“Li 2020”))

Patent Owner objects to Exhibit 1048 under

- FRE 402 and 403. The exhibit is irrelevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder, including because it is not cited in the Petition, and including because it was not published before the priority date of the challenged claims of the '572 patent (January 13, 2011).
- FRE 802. The exhibit is offered for the truth of its content without satisfying any of the hearsay exceptions.

GG. Exhibit 1049 (Brown DM, Michels M, Kaiser PK, et al.

**Ranibizumab versus verteporfin photodynamic therapy for
neovascular age-related macular degeneration: Two-year results
of the ANCHOR study. Ophthalmology.2009;116(1):57-65.e5.
 (“Brown 2009”))**

Patent Owner objects to Exhibit 1049 under

- FRE 403. The exhibit is irrelevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder, including because it is not cited in the Petition.
- FRE 802. The exhibit is offered for the truth of its content without satisfying any of the hearsay exceptions.

HH. Exhibit 1050 (Martin DF, Maguire MG, Fine SL, Ying GS,

**Jaffe GJ, Grunwald JE, et al, Comparison of Age-Related
Macular Degeneration Treatments Trial (CATT) Research
Group. Ranibizumab and bevacizumab for treatment of
neovascular age-related macular degeneration: two-year results.
Ophthalmology 2012; 119(7):1388-98 (“Martin”))**

Patent Owner objects to Exhibit 1050 under

- FRE 403. The exhibit is irrelevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact

finder, including because it is not cited in the Petition, and including because its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder because it was not published before the priority date of the challenged claims of the '572 patent (January 13, 2011).

- FRE 802. The exhibit is offered for the truth of its content without satisfying any of the hearsay exceptions.

II. Exhibit 1051 (Chakravarthy U, Harding SP, Rogers CA, Downes SM, Lotery AJ, Wordsworth S, et al, Inhibition of VEGF in Age-related choroidal Neovascularization (IVAN) Study Investigators. Ranibizumab versus bevacizumab to treat neovascular age-related macular degeneration: one-year findings from the IVAN randomized trial. Ophthalmology 2012; 119(7):1399-411 (“Chakravarthy 2012”))

Patent Owner objects to Exhibit 1051 under

- FRE 403. The exhibit is irrelevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder, including because it is not cited in the Petition, including because it was not published before the priority date of the challenged claims of the '572 patent (January 13, 2011).

- FRE 802. The exhibit is offered for the truth of its content without satisfying any of the hearsay exceptions.

JJ. Exhibit 1052 (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 (“Rosenfeld 2006”))

Patent Owner objects to Exhibit 1052 under

- FRE 403. The exhibit is irrelevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder, including because it is not cited in the Petition.
- FRE 802. The exhibit is offered for the truth of its content without satisfying any of the hearsay exceptions.

KK. Exhibit 1053 (Heimann, H. (2007). Chapter 5 Intravitreal Injections: Techniques and Sequelae. In: Holz, F.G., Spaide, R.F. (eds) Medical Retina. Essentials in Ophthalmology. Springer, Berlin, Heidelberg. (“Heimann 2007”))

Patent Owner objects to Exhibit 1053 under

- FRE 403. The exhibit is irrelevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder, including because it is not cited in the Petition.

- FRE 802. The exhibit is offered for the truth of its content without satisfying any of the hearsay exceptions.

LL. Exhibit 1054 (Jager RD, Aiello LP, Patel SC, Cunningham ET Jr. Risks of intravitreal injection: a comprehensive review. Retina. 2004;24(5):676-698. (“Jager 2004”))

Patent Owner objects to Exhibit 1054 under

- FRE 403. The exhibit is irrelevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder, including because it is not cited in the Petition.
- FRE 802. The exhibit is offered for the truth of its content without satisfying any of the hearsay exceptions.

MM. Exhibit 1056 (Pilot Study of Intravitreal Injection of Ranibizumab for Macular Telangiectasia With Neovascularization (NCT00685854) (May 24, 2008), available at: https://clinicaltrials.gov/ct2/history/NCT00685854?V_1=View#StudyPageTop (“MACTEL Study”))

Patent Owner objects to Exhibit 1056 under

- FRE 403. The exhibit is irrelevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder, including because it is not cited in the Petition.

- 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.

NN. Exhibit 1057 (Authenticating Affidavit and the November 7, 2008 Web Archive of Ranibizumab Injections to Treat Macular Telangiectasia Without New Blood Vessel Growth (NCT00685854), available at <https://web.archive.org/web/20081107014243/https://clinicaltrials.gov/ct2/show/NCT00685854>, attached as Exhibit A (“MACTEL Study Wayback Machine”))

Patent Owner objects to Exhibit 1057 under

- FRE 901. Petitioner has not demonstrated the authenticity of the exhibit.

OO. Exhibit 1058 (Using the Wayback Machine, available at: <https://help.archive.org/help/using-the-wayback-machine/>)

Patent Owner objects to Exhibit 1058 under

- FRE 403. The exhibit is irrelevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder, including because it is not cited in the Petition.
- 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.

PP. Exhibit 1059 (Eylea Label 2011 available at:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/125387lbl.pdf)

Patent Owner objects to Exhibit 1059 under

- FRE 403. The exhibit is irrelevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder, including because it is not cited in the Petition.
- FRE 901. Petitioner has not demonstrated the authenticity of the document. It is not clear where the exhibit came from or how it was compiled.

QQ. Exhibit 1060 (Glenn J. Jaffe, Paul Ashton, P. Andrew Pearson, Intraocular Drug Delivery (2006) (“Jaffe”))

Patent Owner objects to Exhibit 1060 under

- FRE 402 and 403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder, including because it is not cited in the Petition.
- FRE 802. The exhibit is offered for the truth of its content without satisfying any of the hearsay exceptions.

RR. Exhibit 1061 (Steps for a Safe Intravitreal Injection Technique (2009), available at:

[https://www.retinalphysician.com/issues/2009/July aug/steps-for-a-safe-intravitreal-injection-technique](https://www.retinalphysician.com/issues/2009/July%20aug/steps-for-a-safe-intravitreal-injection-technique)

Patent Owner objects to Exhibit 1061 under

- FRE 403. The exhibit is irrelevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder, including because it is not cited in the Petition.

To the extent the exhibits are admitted, their scope should be restricted to the purpose for which they were originally submitted. FRE 105. Should Samsung rely on an exhibit for a different purpose than the one for which it has been offered, Regeneron reserves the right to make additional objections.

In accordance with 37 C.F.R. § 42.64(b)(1), these objections are being timely filed and served within ten (10) business days of the institution of the trial by the Patent and Trial Appeal Board (“Board”), which is reflected in the Board’s Institution Decision dated November 17, 2023 (Paper 13).

IPR2023-00884

Dated: December 4, 2023

Respectfully submitted,

By /Adam R. Brausa/
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Attorney for Patent Owner

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 THE PETITION FOR *INTER PARTES* REVIEW was served as of the below date on the Petitioner via e-mail (by agreement) to the following counsel of record.

Raymond N. Nimrod (Reg. No. 31,987)
Matthew A. Traupman (Reg. No. 50,832)
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Dated: December 4, 2023

/Adam R. Brausa/
Adam R. Brausa, Reg. No. 60,287