

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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SAMSUNG BIOEPIS CO., LTD.,  
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,  
Patent Owner.

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Case IPR2023-00566

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

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**PETITION FOR *INTER PARTES* REVIEW  
OF U.S. PATENT NO. 10,888,601**

**DECLARATION OF DR. BENJAMIN H. BLOOM**

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| <b>Exhibit</b> | <b>Description</b>                                                                                                                                                                                                                                                                                                                                                               |
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| 1001           | U.S. Patent No. 10,888,601 B2 (“’601 patent”)                                                                                                                                                                                                                                                                                                                                    |
| 1002           | Expert Declaration of Dr. Thomas A. Albini in Support of Petition for Inter Partes Review of Patent No. 10,888,601 B2, dated June 30, 2022 (“Albini”), filed in IPR2022-01226                                                                                                                                                                                                    |
| 1003           | Expert Declaration of Mary Gerritsen, Ph.D. in Support of Petition for Inter Partes Review of U.S. Patent No. 10,888,601 B2, dated June 30, 2022 (“Gerritsen”), filed in IPR2022-01226                                                                                                                                                                                           |
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| 1005           | Quan Dong Nguyen et al., A Phase I Study of Intravitreal Vascular Endothelial Growth Factor Trap-Eye in Patients with Neovascular Age-Related Macular Degeneration, 116 OPHTHALMOLOGY 2141 (2009) (“Nguyen-2009”)                                                                                                                                                                |
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| 1008           | U.S. Patent No. 7,531,173 B2 (“’173 patent”)                                                                                                                                                                                                                                                                                                                                     |
| 1009           | U.S. Patent No. 7,396,664 B2 (“’664 patent”)                                                                                                                                                                                                                                                                                                                                     |
| 1010           | U.S. Patent No. 7,374,758 B2 (“’758 patent”)                                                                                                                                                                                                                                                                                                                                     |
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| 1012           | Press Release, Regeneron, Regeneron and Bayer HealthCare Announce Encouraging 32-Week Follow-Up Results from a Phase 2 Study of VEGF Trap-Eye in Age-Related Macular Degeneration (Apr. 28, 2008), <a href="http://investor.regeneron.com/releasedetail.cfm?releaseid=394066">http://investor.regeneron.com/releasedetail.cfm?releaseid=394066</a> (“Regeneron (28-April-2008)”) |
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| 1014 | Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW1), NCT00509795, ClinicalTrials.gov (Apr. 28, 2009), <a href="https://clinicaltrials.gov/ct2/show/NCT00509795">https://clinicaltrials.gov/ct2/show/NCT00509795</a> (“NCT-795”) |
| 1015 | VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2), NCT00637377, ClinicalTrials.gov (Mar. 17, 2008), <a href="https://clinicaltrials.gov/ct2/show/NCT00637377">https://clinicaltrials.gov/ct2/show/NCT00637377</a> (“NCT-377”)                                                                        |
| 1016 | IPR2021-00881 Ex.1109, Diana V. Do Deposition Transcript (April 21, 2022) (“IPR2021-00881 Ex.1109”)                                                                                                                                                                                                                        |
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| 1094 | ClinicalTrials.gov, 1997: Congress Passes Law (FDAMA) Requiring Trial Registration, U.S. NAT’L LIBRARY MED. (Oct. 2020), <a href="https://clinicaltrials.gov/ct2/about-site/history">https://clinicaltrials.gov/ct2/about-site/history</a> (“History-ClinicalTrials.gov”)                                                                                                                                                                                      |
| 1095 | Affidavit of Duncan Hill (Internet Archive Records Request Processor) Regarding Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW1), NCT00509795, ClinicalTrials.gov (Apr. 28, 2009) and VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2), NCT00637377, ClinicalTrials.gov (Mar. 17, 2008), dated January 27, 2021 (“Wayback-Affidavit-601”) |
| 1096 | File History of U.S. Patent No. 10,130,681 B2 (“’681 FH”)                                                                                                                                                                                                                                                                                                                                                                                                      |
| 1098 | Curriculum Vitae of Dr. Benjamin J. Bloom                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 1099 | <i>Mylan Pharmaceuticals, Inc. v. Regeneron Pharmaceuticals, Inc.</i> PTAB-IPR2022-01226, Mylan’s Petition, Paper 2.                                                                                                                                                                                                                                                                                                                                           |
| 1100 | <i>Mylan Pharmaceuticals, Inc. v. Regeneron Pharmaceuticals, Inc.</i> PTAB-IPR2022-01226, Institution Decision, Paper 22.                                                                                                                                                                                                                                                                                                                                      |
| 1101 | <i>Mylan Pharmaceuticals Inc. v. Regeneron Pharmaceuticals, Inc.</i> PTAB-IPR2021-00881, Final Written Decision, Paper 94.                                                                                                                                                                                                                                                                                                                                     |

## **I. INTRODUCTION**

1. I have been retained by the law firm Quinn Emanuel Urquhart & Sullivan on behalf of Samsung Bioepis Co., Ltd., (hereinafter “Samsung Bioepis” or “Petitioner”) to provide expert opinions concerning antagonists of Vascular Endothelial Growth Factor (“VEGF”) used as intravitreal injection for the treatment of angiogenic disorders such as age related macular degeneration, diabetic retinopathy, diabetic macular edema, central retinal vein occlusion (CRVO), branch retinal vein occlusion, and corneal neovascularization.

2. I have been asked to provide my opinions related to U.S. Patent No. 10,888,601 (“the ’601 patent”) (Ex. 1001) and the scientific and technical knowledge regarding the subject matter of the ’601 patent. I understand that Mylan Pharmaceuticals Inc. (“Mylan”) filed an *inter partes* review petition (“Mylan’s petition”) against claims 1-9, 34-39, 41-43, and 45 of the ’601 patent, and the Patent Trial and Appeal Board instituted Mylan’s petition on January 11, 2023. *See* Ex. 1099, *Mylan Pharmaceuticals Inc., v. Regeneron Pharmaceuticals, Inc.*, IPR2022-01226, Paper 22 (“Mylan IPR”). I understand that Samsung Bioepis petitions for *inter partes* review of the same claims of the ’601 patent as the Mylan IPR on the same grounds, and Samsung Bioepis requests to join the Mylan IPR. I submit this declaration in support of Samsung Bioepis’s petition for *inter partes* review.

3. My opinions in this declaration are based on the documents I cite along with my professional training, experience and knowledge that I have acquired working in the field of ophthalmology over the past 45 years. I am being compensated for my services as an expert at my standard consulting rate of \$600 per hour. My compensation is in no way contingent on the substance of my opinions or the outcome of this case.

## **II. BACKGROUND AND QUALIFICATIONS**

4. I am an ophthalmologist with over 45 years of experience in the research, diagnosis, treatment, and analysis of vitreoretinal eye disorders. I received a Bachelor of Science degree in Electrical Engineering from Northeastern University College of Engineering with High Honors in 1968. After I completed graduate courses in Biomedical Instrumentation at Massachusetts Institute of Technology between 1968 and 1970, I obtained my M.D. from Tufts University School of Medicine in 1974. After medical school, I completed an internship at Newton-Wellesley Hospital in 1975, and a PHS Traineeship in Electrophysiology and ophthalmology residency at Tufts-New England Medical Center Hospital between 1975-1979. After my residency, I completed Retina/Vitreous Surgery Fellowships at Manhattan Eye, Ear and Throat Hospital and New York Hospital.

5. My clinical practice is focused on the diagnosis and treatment of patients suffering from all diseases of the retina, including age-related macular

degeneration, diabetic retinopathy, diabetic macular edema, and related disorders, as well as uveitis. I have experience with surgical interventions as well as the prescription and administration of various intravitreally-administered anti-angiogenesis agents.

6. 1980 to 1983, I held the position of Assistant Clinical Professor of Ophthalmology at Hahnemann University. I served as an ophthalmology consultant for Philadelphia Geriatric Center between 1980 and 1983 and Friends Hospital in Pennsylvania between 1980 and 2000. I was an assistant attending ophthalmic surgeon at Manhattan Eye, Ear and Throat Hospital in New York between 1980 and 1981 and an attending surgeon at Frankford Hospital in Pennsylvania between 1980 and 1993. I was also an attending surgeon at Rolling Hill Hospital in Pennsylvania between 1980-1991 and an attending ophthalmologist at Germantown Hospital and Medical Center in Pennsylvania between 1982 and 2010. I have been an attending surgeon at Albert Einstein Medical Center in Pennsylvania since 1985, an examining ophthalmologist for the Family Eye Disease Study of the Massachusetts Eye & Ear Infirmary and Harvard Medical School since 1998, an assistant clinical professor at Lankenau Institute for Medical Research since 2021, and a deputy director of Jefferson Center for Injury Research and Prevention in the Division of Trauma at Sidney Kimmel Medical College Thomas Jefferson University in Philadelphia since 2018. Since 2005, I have been an instructor in ophthalmology at Sidney Kimmel

Medical College Thomas Jefferson University in Philadelphia. Since 2019, I have been an attending ophthalmologist at the Lankenau Medical Center Ophthalmology Clinic and a faculty at Philadelphia College of Osteopathic Medicine.

7. In my current and prior positions, I have been involved in the teaching and training of medical students, fellows, and residents in the area of ophthalmological surgical techniques, including injection protocols for the administration of therapeutics for the treatment of age-related macular degeneration, diabetic macular edema, diabetic retinopathy, and other vitreoretinal eye disorders. More recently, I have served as an educational staff at Wills Eye Hospital in Pennsylvania teaching residents during the Cataract and Primary Eye Care Service clinic and in the operating rooms at Einstein Medical Center.

8. I was and/or currently am a member in several Professional and Academic Societies, including American Academy of Ophthalmology, American College of Surgeons, American Society of Retina Specialists, European Vitreoretinal Society, Philadelphia County Medical Society, Pennsylvania Medical Society, the College of Physicians of Philadelphia, and Greater Philadelphia Ophthalmic Society, among others. Between 1982 and 1984, I was on the editorial board for Medical Ultrasound. I have authored or co-authored numerous publications, including book chapters, peer-reviewed scientific papers, abstracts, and other published works on ophthalmic disorders.

9. In sum, I have over 45 years of hands-on clinical and research experience specializing in treating vitreoretinal disorders and the prescription and intravitreal administration of VEGF antagonists. I have included a copy of my *curriculum vitae* in support of my opinions. Ex. 1098, Bloom CV.

### **III. INFORMATION RELIED UPON AND OPINIONS REGARDING THE '601 PATENT**

10. In addition to my general knowledge gained as a result of my education and experience as an ophthalmologist, I have reviewed and considered, among other things, the '601 patent, the prosecution history of the '601 patent, and the prior art of record discussed herein.

11. I also considered the Final Written Decision ("FWD") issued by the Patent Trial and Appeal Board ("Board") in IPR2021-00881 ("the '338 IPR") concerning U.S. Patent No. 9,254,338 ("'338 patent"), finding all challenged claims there unpatentable. *See* Ex. 1101, IPR2021-00881, Final Written Decision, Paper 94.

12. I also reviewed the Institution Decision issued by the Board in IPR2022-01226 instituting *inter partes* review of the same challenged claims of the '601 patent with respect to all grounds in Mylan's petition. *See* Ex. 1100, IPR2022-01226, Institution Decision, Paper 22. I agree with the Board's reasoning in its Institution Decision, which concerns the same claims of the same patent challenged here.

13. Moreover, I also reviewed and considered the declarations of Drs. Thomas A. Albini (Ex. 1002) and Mary E. Gerritsen (Ex. 1003) submitted in connection with Mylan's petition for *inter partes* review of the '601 patent, including materials and exhibits cited therein. See Ex. 1099, IPR2022-01226, Mylan's Petition, Paper 2. I agree with, and hereby adopt and incorporate by reference, the opinions set forth in the declarations of Drs. Albini and Gerritsen.

#### IV. CONCLUSION

14. This declaration is based on my present assessment of material and information currently available to me.

15. I hereby declare that all statements made herein of my own knowledge are true and that all statements made herein on information and belief are believed to be true. Further, these statements were made with the knowledge that willful false statements and the lie so made are punishable by fine, imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-identified patent.

February 7, 2023

Date

Benjamin H. Bloom

Benjamin H. Bloom