UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AJINOMOTO CO., INC.
Petitioner

v.

ABTIS CO., LTD.
Patent Owner

IPR2025-00283
Patent No. 11,896,675

DECLARATION OF DR. TATSUYA OKUZUMI IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW

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I, Tatsuya Okuzumi, Ph.D., declare as follows:

I. INTRODUCTION

1. I have personal knowledge of the facts and information set forth in this declaration, believe them to be true, and if asked to do so, would testify competently thereto. I am not being reimbursed for my time spent preparing this declaration.

2. I understand that this declaration will be submitted on behalf of Ajinomoto Co., Inc. ("Ajinomoto") in the above-captioned proceeding concerning a petition for *inter partes* review of U.S. Patent No. 11,896,675 ("the '675 Patent"), owned by AbTis Co., Ltd. ("AbTis").

3. I have provided this declaration to address two issues : (i) a presentation slide deck entitled "Technology of Site Specific Conjugation for Next Generation ADCs" (EX1007) that I presented at the 18th annual PepTalk conference on January 16, 2019, and (ii) a poster entitled "Development of a Novel Chemical Site-Specific Conjugation Platform for ADCs – AjiCap™ Technology" that was also displayed at the 18th annual PepTalk conference on January 16, 2019 (EX1006), and on which I am listed as a corresponding author.

II. BACKGROUND

4. I am currently the General Manager of Material and Technology Solution Laboratories at Ajinomoto. I have worked from Ajinomoto for over 24 years. Prior to my current role, I served as the General Manager of Planning Group

in Bio-Pharma Services Department for the Contract Development and Manufacturing Organization (CDMO) Business at Ajinomoto (July 2023 – September 2024), the General Manager of Business Development Group in Bio-Pharma Services Department for the CDMO Business (July 2022 – June 2023), an Associate General Manager in Research and Business Department as Business Development and R&D Project Management (August 2017 – June 2022) for the CDMO Business, a Manager in R&D Planning Department for Company-Wide R&D Strategy (July 2014 – July 2017), a Project Manager on pharmaceutical R&D projects (July 2009 – June 2014), and a Scientific Researcher focusing on small molecule drug discovery (April 2000 – June 2009). A copy of my curriculum vitae is attached to this Declaration as Appendix A.

5. In 1998, I received a bachelor's degree in Chemistry from Department of Chemistry, Tokyo Institute of Technology, and in 2005, I obtained my Ph.D. in Chemistry from Tokyo Institute of Technology, where my research focused on development of an Efficient Synthetic Method for Quinazoline-Related Heterocyclic Compounds on Solid Phase.

6. I spent 2 years performing post-doctoral research at the University of California, San Francisco in the laboratory of Kevan Shokat, where my research focused on protein kinases.

7. I have also served in several leadership roles for professional societies, including as a conference steering committee member for The Society of Synthetic Organic Chemistry, Japan (April 2009 – March 2013), an editing committee member of the scientific bulletin for The Pharmaceutical Society of Japan (April 2011 – March 2017), and a steering committee member for the Japanese Society for Chemical Biology (April 2009 – Present).

8. I possess over 30 years of expertise and experience that span the areas of organic chemistry, medicinal chemistry, chemical biology, biochemistry, cell biology, targeted drug delivery, bioconjugate, bioanalysis, antibody-drug-conjugate ("ADC") design, antibody metabolism, and site-specific conjugation chemistry.

9. As a normal practice, Ajinomoto employees regularly attend scientific and technical conferences attended by other companies and researchers participating in the same field of research. For example, some Ajinomoto employees attend the PepTalk conference every year. In most cases Ajinomoto employees send a follow-up e-mail to conference attendees who they met at the conference, and sometimes they receive an e-mail from the attendees. At conferences such as PepTalk, Ajinomoto employees have a chance to talk, discuss and exchange business cards with conference attendees directly at a poster session or before or after an oral presentation.

10. For purposes of this declaration and the above-referenced proceeding, I understand that I should consider a person of ordinary skill in the art ("POSA") in the 2019-2023 timeframe to be an individual with specialized knowledge in the field of antibody-drug conjugates, which would entail (1) a Ph.D. degree in organic chemistry, biochemistry, medicinal chemistry, and/or pharmacology, along with at least 1-2 years of relevant applied research and/or industry experience in the field of antibodies or antibody-drug conjugates, or, alternatively, (2) a Master's or Bachelor's degree in one of the aforementioned fields with at least 3-5 years, or 5-7 years, respectively, of relevant applied research and/or industry experience in the field of antibodies or antibody-drug conjugates. That person would have familiarity, gained through study, training, and/or experience, with the design and development of antibody-drug conjugates and antibody modifications.

III. PEPTALK 2019 CONFERENCE

11. Peptalk 2019 was held in San Diego, California on January 14-18, 2019. According to the conference program, PepTalk 2019 was "one of the largest annual gatherings of protein science researchers in the world" and "feature[d] renowned speakers from academia, biotech and pharma who bring global expertise and perspective to the forefront." EX1013, 2. The conference included more than 150 research posters and more than 1,300 participants. *Id.* 1, 2. In addition to research posters and presentations, PepTalk 2019 also included training seminars, short

courses, keynote addresses, and luncheon presentations. *Id.* 6-8. Posters were presented daily throughout the conference.

12. The PepTalk 2019 conference included a track directed to "Antibody Therapeutics," with two days (January 15-16, 2019) specifically focused on Antibody-Drug Conjugates, including presentations by sixteen presenters . EX1013, 27, 31-33. The Antibody Therapeutics track was described in the PepTalk 2019 conference agenda as "The weeklong Antibody Therapeutics pipeline reveals the exciting developments in next-generation antibody therapeutics, including Antibody-Drug Conjugates, Bispecific Antibody Therapeutics, and Cancer Immunotherapies." *Id.*, 27. The poster session for the Antibody-Drug Conjugates section of the conference was held on January 15-16, 2019, and posters were displayed in an exhibit hall without limitation on attendee entrance during a predetermined timeslot and during breaks. *Id.*, 31-33.

13. To my knowledge, there was no expectation of confidentiality with respect to materials—either posters or presentations—presented during the 2019 PepTalk conference, and all disclosures of such materials were made without limitation on the conference attendees able to view the materials.

IV. "Technology of Site Specific Conjugation for Next Generation ADCs" Slide Deck Presentation at PepTalk 2019 (PepTalk Presentation)

14. On January 16, 2019, I presented the slide deck entitled "Technology of Site Specific Conjugation for Next Generation ADCs" (EX1007) at a luncheon presentation at the PepTalk 2019 conference. This luncheon presentation was open to all attendees of the conference, and did not require any additional registration or cost beyond that of attending the PepTalk conference.

15. The presentation lasted for approximately 30 minutes, and to the best of my recollection, there were at least dozens of people (approximately 30-50) in attendance. I provide herewith photographs taken during my presentation showing some of the attendees at my talk. *See* EX1015.

16. I recall that Dr. Rakesh Dixit, who provided the keynote presentation on January 15, 2019 during the "Fighting Cancer with Antibody-Drug Conjugates" session of the Antibody-Drug Conjugates track (*see* EX 1013, 31), asked a question in my luncheon presentation.

17. While hard copies of the presentation were not provided during the presentation, I did provide copies of the presentation—without limitation—to conference attendees with whom I communicated at the conference. For example, after the PepTalk conference, I provided copies of the same slide deck that I presented to at least five individuals, including Dr. Igor D'Angelo, Dr. Bernhard

Valldorf, Dr. Michael Szardenings, Susan Lee, and Professor Rolf G. Werner. I sent each of these individuals a separate email with a copy of the slide deck on February 9, 2024. *See* EX1017-EX1021. In addition to providing a copy of the same slide deck from the PepTalk conference, my emails to each of these individuals noted, among other things, that the AJICAP™ technology offered "Wide drug-linker compatibility:" with "reactive group compatibility includes thiol, alkyne, azide, etc." *Id.*

18. At the time I sent the slide deck to Dr. D'Angelo, he had the title Senior Research Scientist at Amgen Inc. *See* EX1017. I have reviewed Dr. D'Angelo's LinkedIn profile (EX1022), which indicates that he obtained a bachelor's degree in biological sciences from Università di Pavia and a Ph.D. from Heidelberg University in biochemistry. He then held a post-doctoral position at the University of British Colombia for 4 years. At the time the slide deck was sent, Dr. D'Angelo had worked in several roles in the pharmaceutical industry over nearly 11 years. Accordingly. I believe he fits the standard for a person of ordinary skill in the art discussed above (i.e., "a Ph.D. degree in organic chemistry, biochemistry, medicinal chemistry, and/or pharmacology, along with at least 1-2 years of relevant applied research and/or industry experience in the field of antibodies or antibody-drug conjugates").

19. At the time I sent the slide deck to Dr. Valldorf, he had the title Principal Scientist at EMD Serono, Inc. (a subsidiary of Merck KGaA). *See* EX1018. I have

reviewed Dr. Valldorf's LinkedIn profile (EX1023), which indicates that he obtained a bachelor's degree and a master's degree, both in molecular biology, from Goethe University Frankfurt and a Ph.D. from Technishe Universität Darmstadt in biochemistry. At the time the slide deck was sent, Dr. Valldorf had worked as a Principle Scientist for over 1 year. Accordingly. I believe he fits the standard for a person of ordinary skill in the art discussed above (i.e., "a Ph.D. degree in organic chemistry, biochemistry, medicinal chemistry, and/or pharmacology, along with at least 1-2 years of relevant applied research and/or industry experience in the field of antibodies or antibody-drug conjugates"). In an email response received from Dr. Valldorf on February 11, 2019, he confirmed that he "forwarded it [the slide deck] to my ADC conjugation colleagues."

20. At the time I sent the slide deck to Dr. Szardenings, he was the Head of the Ligand Development Unit of the Fraunhofer Institute for Cell Therapy and Immunology. *See* EX1019. I specifically remember that Dr. Szardenings attended my January 16, 2019, presentation at PepTalk 2019 in person, and I recall discussing the presentation with him after it was completed. Dr. Szardenings responded to my email the following day, on February 10, 2019, stating: "I like your technology." *Id.*

21. Additionally, I have reviewed Dr. Szardenings' LinkedIn profile (EX1024), which indicates that he obtained a bachelor's degree in chemistry from University of Hamburg and a Ph.D. from Technishe Universität Braunschweig in

biochemistry, protein design, and mutagenesis. He then held a post-doctoral position at the University of Uppsala in the Institute of Molecular Biology for 4 years. At the time the slide deck was sent, Dr. Szardenings had worked in various roles in academia and the pharmaceutical industry for 36 years. Accordingly. I believe he fits the standard for a person of ordinary skill in the art discussed above (i.e., "a Ph.D. degree in organic chemistry, biochemistry, medicinal chemistry, and/or pharmacology, along with at least 1-2 years of relevant applied research and/or industry experience in the field of antibodies or antibody-drug conjugates").

22. At the time I sent the slide deck to Ms. Lee, she had the title Senior Research Associate at Seagen, Inc. (*see* EX1020.), which focuses on developing antibody based therapies. I have reviewed Ms. Lee's LinkedIn profile (EX1025), which indicates that she obtained a bachelor's degree in biology with an emphasis on molecular cell biology from the University of California, Davis. At the time the slide deck was sent, she had worked in various scientist roles within the pharmaceutical industry for nearly 14 years. Accordingly. I believe she fits the standard for a person of ordinary skill in the art discussed above (i.e., "a Master's or Bachelor's degree in one of the aforementioned fields with at least 3-5 years, or 5-7 years, respectively, of relevant applied research and/or industry experience in the field of antibodies or antibody-drug conjugates").

23. At the time I sent the slide deck was sent to Prof. Werner, he was a professor at the University of Tübingen. *See* EX1021. I understand that he received his Ph.D. from the University of Tübingen and that he has working in various roles in academia and the pharmaceutical industry for decades. Accordingly. I believe Prof. Werner fits the standard for a person of ordinary skill in the art discussed above (i.e., "a Ph.D. degree in organic chemistry, biochemistry, medicinal chemistry, and/or pharmacology, along with at least 1-2 years of relevant applied research and/or industry experience in the field of antibodies or antibody-drug conjugates").

24. Finally, my January 16, 2019, presentation at PepTalk 2019 was also summarized and reported on in the March 2019 issue of *Drugs of the Future*. *See* EX1014. In particular, page 244 of this journal states:

> A new technology for site-specific conjugation for next-generation ADCs was described by Tatsuya Okuzumi (Ajinomoto). The technology is based on a highly specific 13-amino acid peptide that binds to the hinge region of the Fc-domain of human IgG at an affinity of 20 nM. Further improvement and the addition of 4 amino acids improved the affinity to 4 nM. The peptide with the conjugated linker is called AJICAP reagent and can be directly utilized for site-specific conjugation to the IgG at lysine 248. The resulting ADC displays an ideal DAR of 2. AJICAP is compatible with IgGl, 2 and 4. Variants of

> trastuzumab and rituximab have been used as material for proof-of-concept studies with a wide range of different payloads. Conjugated antibodies still show a normal FcRn binding that supports long half-life. Dosing of 5 mg/kg inhibited tumors in a similar way to trastuzumab emtansine but with an at least 2-fold higher maximum tolerated dose.

25. I believe this discussion in *Drugs of the Future* further shows that my January 16, 2019, presentation at PepTalk 2019 was understood by and of interest to individuals that were of ordinary skill in the art.

V. "Development of a Novel Chemical Site-Specific Conjugation Platform for ADCs," Poster Presentation at PepTalk 2019 (PepTalk Poster)

26. I am one of the named authors on the poster titled "Development of a Novel Chemical Site-Specific Conjugation Platform for ADCs," which was displayed at the PepTalk 2019 conference. EX1006.

27. The poster was displayed in the Exhibit Hall of the Hilton San Diego Bayfront in San Diego, CA, which hosted the PepTalk 2019 conference. The poster was displayed during the Antibody-Drug Conjugate session on January 16, 2019. EX1013, 32. Accordingly, attendees of the conference had uninhibited access to the poster at various times throughout January 16, 2019. For example, the Antibody-Drug Conjugate session included three specific poster viewing periods during the day: one from 9:50 AM to 10:35 AM, one from 3:05 PM to 4:00 PM, and one from

6:05 PM to 7:00 PM. I provide herewith photographs taken during 9:50 AM to 10:35 AM poster session showing me interacting with conference attendees in relation to the poster. *See* EX1016.

28. I attended the poster viewing sessions and stood with the poster to discuss it with any conference attendees that were interested. I had hard copies of the poster with me and I provided these hard copies to several conference attendees that viewed the poster and discussed it with me. I do not recall the precise number of conference attendees I provided with a copy of the poster, but I recall providing copies to at least dozens of people.

VI. CONCLUSION

29. I conclude, based on my review of the materials referenced in this declaration, as well as based on my own personal knowledge, that the subject matter described in both the presentation and poster that I presented at PepTalk 2019 was publicly available as of at least January 16, 2019, to persons of ordinary skill in the art, specifically including those involved in the design and development of antibody-drug conjugates and antibody modifications.

30. I hereby declare that all statements made herein on my knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false

statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Tatsuya Okuzumi, Ph.D.

Dated: Dec 17th, 2024

Appendix A

CURRICULUM VITAE
Tatsuya Okuzumi, Ph.D.

- Personal Information
  - ✓ Date of Birth: February 28, 1976
  - ✓ Place of Birth: Kanagawa, Japan

- Education
  - ✓ Department of Chemistry, Tokyo Institute of Technology - B.S. March 1998 – Organic Chemistry / Biochemistry
  - ✓ Department of Chemistry and Materials Science, Tokyo Institute of Technology - M.S. March 2000 – Organic Chemistry, Biochemistry
  - ✓ Department of Chemistry and Materials Science, Tokyo Institute of Technology - Ph.D. May 2006 – Organic Chemistry

- Job History
  - ✓ April 2000 — Joined Ajinomoto Co., Inc. Assigned as a researcher in Pharmaceutical Research laboratory
  - ✓ July 2007 — Transferred to University of California, San Francisco as a research fellow
  - ✓ July 2009 — Returned to Pharmaceutical Research laboratory as a researcher
  - ✓ July 2013 — Promoted to Manager
  - ✓ April 2014 — Transferred to R&D Planning Department
  - ✓ October 2017 — Promoted to Associate General Manager
  - ✓ April 2018 — Transferred to Bio-Fine Laboratory with joint appointment to R&D Planning Department
  - ✓ July 2020 — Promoted to Group Leader in Bio-Fine Laboratory with joint appointment to Research & Business Planning Department
  - ✓ July 2021 — Transferred to Research & Business Planning Department with joint appointment to Bio-Pharma Services Department
  - ✓ July 2022 — Transferred to Bio-Pharma Services Department and promoted to General Manager, Business Development Group. Appointed as BoD member in GeneDesign Inc., an affiliate company of Ajinomoto Co., Inc.
  - ✓ July 2023 — Assigned to General Manager, Planning Group in Bio-Pharma Services Department and an outside director in GeneDesign Inc.
  - ✓ Dec 2023 — Appointed as Chief Global Coordination Officer at Forge Biologics Inc., an affiliate company of Ajinomoto Co., Inc. with joint appointment to General Manager, Planning Group in Bio-Pharma Services Department
  - ✓ Oct 2024 — Appointed as General Manager, Material & Technology Solution Labs

- Committees
  - ✓ Apr 2009 - Present — Steering Committee Member, Japanese Society for Chemical Biology
  - ✓ Apr 2011 - Mar 2017 — Editorial Committee Member of Scientific Bulletin, Pharmacia

✓ Apr 2009 - Mar 2013 Conference Steering Committee Member, The Society of Synthetic Organic Chemistry, Japan

EOD