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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD.,
Petitioner,

v.

ALEXION PHARMACEUTICALS, INC.
Patent Owner.

Case No. IPR2023-00998
Patent: 9,718,880

DECLARATION OF ARTURO CASADEVALL, M.D., PH.D.

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I, Arturo Casadevall, M.D., Ph.D., hereby declare and say as follows:

I. INTRODUCTION

1. I am over the age of eighteen (18) and otherwise competent to make this declaration.

2. I have been retained by Alexion Pharmaceuticals, Inc. ("Alexion") as an independent expert consultant in this proceeding against Samsung Bioepis Co. Ltd. ("Samsung") before the U.S. Patent and Trademark Office's Patent Trial and Appeal Board ("PTAB"). Although I am being compensated at my normal consulting rate of $600/hr for the time I spend on this matter, no part of my compensation is dependent on the outcome of this proceeding, and I have no other interest in this proceeding.[1]

3. I was first retained by Alexion in 2019 as an independent expert consultant in proceedings before the PTAB involving three instituted *Inter Partes* Review ("IPR") trials brought by petitioner Amgen, Inc.: IPR2019-00739 regarding U.S. Pat. No. 9,725,504 (the "'504 patent"); IPR2019-00740 regarding U.S. Pat. No. 9,718,880 (the "'880 patent"); and IPR2019-00741 regarding U.S.

[1] All opinions expressed and implied in this Declaration are solely my own and do not represent or reflect the views of my employer.

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Pat. No. 9,732,149 (the "'149 patent") (collectively, "the Amgen IPRs"). I submitted a declaration in each of the Amgen IPRs, which I signed on November 22, 2019 (the "2019 Casadevall Decl."), and provided testimony via deposition on January 24, 2020. My 2019 Casadevall Decl. submitted in the Amgen IPRs contains an overview of my experience and qualifications, which have not changed significantly in the past five years. A more recent version of my curriculum vitae is attached here as **Appendix A**.

4. I have also been retained by Alexion to again act as an independent expert consultant in five IPRs brought by petitioner Samsung: IPR2023-00933 regarding the '149 patent; IPR2023-00998 regarding the '880 patent; IPR2023-00999 regarding the '504 patent; IPR2023-01069 regarding U.S. Pat No. 10,590,189 (the "'189 patent"); and IPR2023-01070 regarding U.S. Pat. No. 10,703,809 (the "'809 patent") (collectively, "the Samsung IPRs"). More specifically, I have been retained by Alexion to again opine on whether, from the perspective of a person of ordinary skill in the art ("POSA") before March 15, 2007, the claims of the '880 patent would have been unpatentable in view of, among other references, Bowdish (EX1004), Evans (EX1005), Bell (1007), Tacken (EX1008), Mueller PCT (EX1009), and Wang (EX EX1044).

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5. I am also aware that the PTAB has issued Institution Decisions in each of the Samsung IPRs granting Samsung's petitions and instituting trials. I understand that the PTAB's Institution Decisions do "not reflect a final determination on the patentability of the claim." (IPR2023-00998, Paper No. 9 at 68.)

6. I have reviewed and considered Samsung's IPR petition regarding the '149 patent (IPR2023-00933, Paper No. 2), the Ravetch Decl. (*id*. at EX1003) and the Ippoliti Decl. (*id*. at EX1062) regarding the '880 patent, the Institution Decision regarding the '880 patent (*id*. at Paper No. 9), and the other documents cited therein. As already mentioned, it is my opinion that Samsung's "Grounds" in its IPR regarding the '880 patent consist of substantially the same core art and arguments presented in the Amgen IPRs. Accordingly, the opinions I provided in the 2019 Casadevall Decl. are equally applicable to Samsung's IPR regarding the '880 patent. None of the opinions I presented in the 2019 Casadevall Decl. have changed since its original execution.

7. For these reasons, I expressly adopt and reassert all of my opinions presented in my 2019 Casadevall Decl. for the purposes of Samsung's IPR against the '880 patent. I understand that my 2019 Casadevall Decl. from IPR2019-00740 has been submitted to the PTAB as ALXN2022 for use in these proceedings.

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8. For the reasons explained in my 2019 Casadevall Decl. (IPR2023-00998, ALXN2022), it is my opinion that the claims of the ’880 patent are valid over all of the art (for example, Bowdish (EX1004), Evans (EX1005), Mueller 1997 (EX1006), Bell (EX1007), Tacken (EX1008), Mueller PCT (EX1009), Thomas (EX1010), Hillmen 2004 (EX1011), Hill 2004 (EX1012), Hill 2005 (EX1013), Hillmen 2006 (EX1014), and, where applicable, Wang (EX1044)) and arguments presented by Samsung in its IPR regarding the ’880 patent. More specifically, I disagree with Dr. Ravetch’s opinions set forth in the Ravetch Decl. (IPR2023-00933, EX1003) and with Dr. Ippoliti’s opinions set forth in the Ippoliti Decl. (*id*. at EX1062), and it is my opinion that:

- Claim 2 of the ’880 patent is not anticipated by Bowdish (EX1004) (Ground 1);
- Claim 2 of the ’880 patent is not rendered obvious over Bowdish, Evans (EX1005) in view of Bell (EX1007), Tacken (EX1008), and Mueller PCT (EX1009) (Ground 2);
- Claim 2 of the ’880 patent is not rendered obvious over Evans and Mueller PCT in view of Bell and Tacken (Ground 3);

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- Claims 1 and 3 of the ’880 patent are not rendered obvious over Bowdish, Evans, and Wang in view of Bell, Tacken, and Mueller PCT (Ground 4);
- Claims 1 and 3 of the ’880 patent are not rendered obvious over Evans, Mueller PCT, and Wang in view of Bell and Tacken (Ground 5); and
- Claim 2 is not anticipated by Bell (Ground 6).

In my opinion, none of these references disclosed each and every element recited in the claims of the ’880 patent as arranged in the claim, whether expressly or inherently.

9. In my opinion, a person having ordinary skill in the art (“POSA”) without the benefit of hindsight, and with the benefit of the full scope of prior art available as of March 15, 2007, would not have found the claimed invention obvious. To the contrary, the art would have led a POSA in a direction divergent to the path taken by the claimed invention. It is also my opinion that a POSA, without the benefit of hindsight, would not have been motivated to combine the teachings of any of these references because there was no teaching, motivation, suggestion, or other reason to do so, and that a POSA would not have had a reasonable expectation of success with respect to the claimed invention.

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10. It is also my opinion that "objective indicia" further support the non-obviousness of the invention recited in the '880 patent, including at least the fulfillment of a long-felt, unmet need; commercial success, failure of others; copying; and industry praise, as set forth in my 2019 Casadevall Decl.

11. I expressly reserve my right to present additional or supplemental opinions as these Samsung IPRs progress.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that I made these statements 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.

Date: 3/8/2024 | 12:15:20 PM PST

DocuSigned by:
Arturo Casadevall, M.D., Ph.D.
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Arturo Casadevall, M.D., Ph.D.