**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.

ALEXION PHARMACEUTICALS, INC.
Patent Owner.

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Case No. IPR2023-00999
Patent: 9,725,504

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# PATENT OWNER'S SUR-REPLY TO PETITIONER'S REPLY TO PRELIMINARY RESPONSE

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Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
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Alexion respectfully submits this Sur-Reply in response to Samsung's October 5, 2023 Reply (Paper 7). (*See* EX3001.)

## I. INTRODUCTION

Samsung's Reply both overly limits and misapplies the *Adv. Bionics* framework. Namely, according to Samsung, *Adv. Bionics* is limited to art or arguments "presented ***during the original prosecution***." (Reply at 1 (emphasis added).) But the correct rule of *Adv. Bionics*, consistent with Section 325(d), is whether the same or substantially the same art or arguments were "***previously presented to the Office***." *Adv. Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential); 35 U.S.C. § 325(d) (referring to "the same or substantially the same prior art or arguments ***previously were presented to the Office***."). In fact, the Board has also rejected positions attempting to limit the scope of its discretion under Section 325(d). *Invantis, Inc. et al. v. Sight Sciences, Inc.*, IPR2022-01540, Paper 14 at 10 (PTAB Mar. 22, 2023) (citing *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017) (precedential-in-part)) (agreeing "with the patent owner that prior art considered during prosecution of the parent application constitutes prior art previously presented to the Office under § 325(d)."); *see also BMW of N. Am. v. Stragent, LLC*, IPR2021-00426, Paper 13

(PTAB July 19, 2021). Samsung also acknowledges the broader scope of *Adv. Bionics* by addressing the prosecution of the related child patent—the '189 patent—in both its Petition and Reply. If the inquiry were limited to "original prosecution" as Samsung now contends, then there would have been no reason for Samsung to twice address the prosecution of a related patent. Further, such a limitation would be a poor use of the Board's time and resources if it were required to repeat the Examiners' efforts from prosecuting related patents.

## II. SAMSUNG REPEATS AMGEN'S BASIC COMBINATIONS

Samsung's Reply, like its Petition, focuses mostly on Bowdish, Mueller PCT, Tacken, and Evans, and the relationship (if any) each reference has to the claimed SEQ ID NOs: 2 and 4—the common elements in all claims of all five Alexion patents challenged by Samsung. Culling them down to their primary references, Samsung's basic combinations mirror those at issue in the Amgen IPR:

| **Primary References** | **IPR2023-00999 (Samsung)** | **IPR2019-00739 (Amgen)** |
|---|---|---|
| Bowdish & Evans | Grounds 1 & 2 | Ground 4 & 5 |
| Mueller & Evans | Grounds 3 & 4 | Ground 6 & 7 |
| Bell/Hillmen/Hill | Ground 5 | Ground 1, 2, & 3 |

Tossing in Tacken does not differentiate Samsung's positions from Amgen's at least because Samsung uses Tacken identically to the way Amgen used it. (*See*

IPR2019-00739, Paper 2 at 17.) And in response Alexion, like here, responded that Tacken and the rest of the art before March 15, 2007 all pointed to Thomas's IgG4 antibody (*see* IPR2019-00739, Paper 10 at 27, 38). Examiner Rogers and his Supervising Examiner Kolker subsequently considered the entire Amgen IPR records, including Tacken, and Alexion's counter-arguments, and characterized Evans and Bowdish as the closest and second closest prior art, respectively, before allowing two additional patents claiming the same SEQ ID NOs: 2 and 4. (*See* POPR at 29.) These determinations by Examiners Rogers and Kolker should be given deference under *Adv. Bionics*. *Adv. Bionics*, Paper 6 at 9 ("At bottom, this framework reflects a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown.").

## III. SAMSUNG MISAPPLIES THE LAW ON SECTION 325

### A. Samsung's Analysis of *Adv. Bionics*, Part 1, Is Incorrect.

Bowdish and Mueller PCT were previously presented to the Office on an IDS during the prosecution of the '880, '504, and '149 patents as U.S. Patent No. 7,482,435/U.S. Pub No. 2003/0049683 and Mueller 1997, respectively. Samsung's only reply to this undisputed fact is that "mere citation of the reference itself on an IDS is often insufficient," citation of a counterpart "in an IDS is even more insufficient," and "[n]either reference was cited, discussed, or relied on as the basis for any rejection." (Reply at 1.) But Samsung is mistaken on the law. In

fact, the decision Samsung relies on reaches the opposite conclusion. (Reply at 1 (citing *CODE200, UAB v. Bright Data Ltd.*, IPR2022-00353, Paper 8 (PTAB July 1, 2022)).) In *CODE200*, the Board found Part 1 satisfied when three references were cited on an IDS but not used in a rejection. *CODE200*, Paper 8 at 7 (citing "Pet. 64" (pointing to the face of patent where the references were cited) and "Prelim. Resp. 7" (starting Patent Owner's argument that each was cited on an IDS)). This is consistent with the Board's precedent. *See Adv. Bionics*, Paper 6 at 7-8; *see also Invantis,* Paper 14 at 8. Samsung also fails to address Alexion's case law on this issue (POPR at 21), and further fails to address Alexion's contention that Samsung's arguments are the same as those presented during prosecution (POPR at 23-24).

Samsung's contention that Mueller PCT and Mueller 1997 do not provide the same disclosure is also incorrect and contradicted by its own expert, Dr. Ravetch, who acknowledges that Mueller PCT is a "***companion*** patent application describing the ***same work*** published in the Mueller 1997 article." (EX1003 at ¶¶ 62, 102 (emphasis added).) *See Palo Alto Networks, Inc. v. Finjan, Inc.*, IPR2015-01974, Paper 13 (PTAB May 18, 2016) ("the statute does not require a complete overlap of these implementations for us to deem their disclosures (or arguments presented regarding those disclosures) substantially the same").

Samsung's case, *Cisco Sys., Inc. v. Netsocket, Inc.*, IPR2023-00607, Paper 11 (PTAB Sept. 26, 2023), is also distinguishable. In *Cisco*, the Patent Owner failed to establish any overlap between the petitioner's references (Schelen-1 and -2) and the reference cited during prosecution (the Schelen IEEE paper). And though the Schelen IEEE paper was cited on an IDS, the Examiner crossed it out and refused to consider it. *Cisco*, Paper 11 at 22. No such facts exist here.

### B. Samsung Failed in Its Burden to Show the Examiners Erred

There was no error during prosecution of the '504 patent. Examiner Rogers reviewed the art of record and concluded that, as of March 15, 2007, no reference disclosed an antibody with SEQ ID NOs: 2 and 4. Examiner Rogers' conclusion remains accurate even with the addition of Tacken, Mueller PCT, and Bowdish, as evidenced by the Examiners allowing similar claims in the '189 and '809 child patents after considering the Amgen IPRs. Samsung also fails to explain how Examiner Rogers supposedly erred in his conclusion that eculizumab and its unique sequence were not accessible to the public. To the contrary, he issued a Rule 1.105 Request seeking detailed information on that very subject, which Alexion thoroughly answered. (EX1002 at 1123-24, 1301.) And Samsung's contention that the Examiners failed to appreciate Mueller PCT and "Bowdish and Evans" is speculation unsubstantiated by Dr. Ravetch's Declaration (EX1003 at

¶ 178). *Ivantis*, Paper 14 at 10; *Adv. Bionics*, Paper 6 at 9 ("If reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability"). Finally, if there was an error (there was not), then it was cured during prosecution of the child '189 and '809 patents when Examiner Rogers considered the entire Amgen IPR records, including these same art and arguments, and continued to grant patents covering the same SEQ ID NOs: 2 and 4.

There was no error during prosecution of the child patents. Notably, Samsung's inference that Examiner Rogers was unaware that the claimed SEQ ID NO: 2 reflects a hybrid IgG2/4 heavy chain (Reply at 5) would mean that he ignored the entire Amgen IPR records before him and their repeated statements that SEQ ID NO: 2 is a hybrid IgG2/4 sequence. The record reflects the opposite.

The remaining purported errors are the same flawed arguments Samsung asserts in its Petition, which are fully accounted for in Alexion's POPR. This also renders Samsung's statement that Alexion provided no substantive response to Samsung's Error 2, 3, and 4 incorrect. Indeed, Examiners Rogers and Kolker erred only if Samsung's Grounds are accepted as correct, which they are not.

Further, under Section 325(d), differing expert opinions on how an examiner may have erred should be given little weight. *Adv. Bionics*, Paper 6 at 9.

Respectfully submitted,

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**CERTIFICATION OF SERVICE**

The undersigned hereby certifies that the foregoing **PATENT OWNER'S SUR-REPLY TO PETITIONER'S REPLY TO PRELIMINARY RESPONSE** were served via electronic mail on October 20, 2023, in their entirety on the following:

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