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. IPR2023-01069
Patent: 10,590,189

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

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Alexion respectfully submits this Sur-Reply in response to Samsung's November 10, 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 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).").

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. Culling them down to their primary references, Samsung's basic combinations mirror those at issue in the Amgen IPR:

Primary References	**IPR2023-01069 (Samsung)**	**IPR2019-00739 (Amgen)**
Bowdish & Evans	Ground 1	Ground 4 & 5
Mueller & Evans	Grounds 1 and 2	Ground 6 & 7
Bell/Hillmen/Hill	Ground 3	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 Supervisor, 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 the '189 patent and an additional patent claiming the same SEQ ID NOs:

2 and 4. (*See* POPR at 27-28.) These determinations by Examiners Rogers and Kolker should be given deference under *Adv. Bionics*. *Adv. Bionics*, Paper 6 at 9.

Further, it is undisputed that the Amgen IPRs relied on Tacken and Mueller PCT. (*See* IPR2019-00739, Paper 2 at 17, 23-24; Grounds 6-7.) Additionally, Alexion's argument that submitting the Amgen IPRs during the prosecution of the child patents "clearly influenced" Examiner Rogers' rejections in those applications also remains undisputed. (POPR at 26.) It can be concluded from these undisputed facts that Examiner Rogers did, in fact, consider Tacken and Mueller PCT as part of his review of the Amgen IPR records. (*See* Reply at 1.) That neither reference was cited in an Office Action or Notice of Allowance (Reply at 1) does not defeat this conclusion. Nor does *Bowtech*, IPR2019-00379, Paper 14, 18-19 support Samsung's contrary argument. (Reply at 1.) *Bowtech* focused on a single prior art reference. By contrast, here, the entire history, including all art, arguments, expert declarations, and testimony of the Amgen IPRs was submitted for Examiner Roger's consideration. *See BMW of N. Am. v. Stragent, LLC*, IPR2021-00426, Paper 13, 8-18 (PTAB July 19, 2021); *see also Invantis*, IPR2022-01540, Paper 14 at 10.

The facts of *Boehringer Ingelheim*, IPR2016-00409, Paper 9 (PTAB July 7, 2016), and *Fellows*, IPR2020-01435, Paper 12 (PTAB Feb. 22, 2021) are also

distinguishable. (*See* Reply at 2.) In *Boehringer*, the petitioner relied on two expert declarations and "the Examiner relied upon testimonial evidence that was not subject to cross-examination." Here, Dr. Ravetch's declaration is substantially duplicative to Dr. Balthasar's declaration in the Amgen IPRs, and all experts in the Amgen IPRs, including Dr. Balthasar, were deposed. Further, in *Fellows*, the Examiner did not have the benefit of an expert declaration but here, Examiners Rogers and Kolker had several to consider.

III. SAMSUNG FAILED TO SHOW THE EXAMINERS ERRED

There was no error during prosecution of the earlier-issued patents. Examiner Rogers reviewed the art of record, and he and Supervisory Examiner Kolker concluded that, as of March 15, 2007, no reference disclosed an antibody with SEQ ID NOs: 2 and 4. (*See, e.g.*, ALXN2101 at 1432-34; ALXN2103 at 1346-48.) The Examiners' conclusion remains accurate even with the addition of Tacken, Mueller PCT, and Bowdish, as evidenced by the Examiners allowing the claims of the '189 patent 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. (Reply at 6.) To the contrary, he issued a Rule 1.105 Request seeking detailed information on that very subject, which Alexion thoroughly answered. (EX2101 at 1227-29, 1374-80.)

Further, 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. And Samsung’s contention that Mueller PCT and Mueller 1997 do not provide the same disclosure (Reply at 5) 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, 124 (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”).

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 addressed in Alexion’s POPR. Indeed, Examiners Rogers and Kolker erred only if Samsung’s Grounds are accepted as

correct, which they are not. Namely, Tacken would not have swayed a POSA away from the consistent, clear statements in earlier and later publications that expressly identified "eculizumab" as Thomas's IgG4 antibody. (POPR at 11-12.) In fact, Tacken itself cites to Thomas. (POPR at 12.)

Nor did Examiner Rogers err with respect to Evans. (Reply at 4.) Samsung has not challenged the fact that the only full-length antibody disclosed in Evans is a mouse antibody, which is different from the uniquely-engineered full-length antibody claimed in the '189 patent. (POPR at 38-40.) It is also undisputed that Evans disclosed nine different humanized "scFv" fragments. (*Id.*) Examiner Rogers acknowledged these facts in his Notice of Allowance when discussing Evans as the "closest prior art." (EX1002 at 14874-75.) It is unclear how Samsung can contend Examiner Rogers erred when it does not dispute the very facts that Examiner Rogers found compelling when allowing the claims.

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 December 1, 2023, in their entirety on the following:

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