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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER, INC. and
SAMSUNG BIOEPIS CO., LTD.,
Petitioners,
v.
GENENTECH, INC.,
Patent Owner.

Case IPR2017-01488[1]
U.S. Patent 6,407,213

PATENT OWNER'S MOTION FOR OBSERVATIONS ON CROSS-EXAMINATION OF JEFFERSON FOOTE, PH.D.

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[1] Case IPR2017-02139 has been joined with this proceeding.

Pursuant to the Joint Notice of Stipulation to Revise Schedule (Paper 53), Patent Owner Genentech, Inc. ("Patent Owner") submits the following observations on cross-examination of Jefferson Foote, Ph.D. with respect to his testimony in support of Petitioner's reply (Paper 56). The complete transcript of this cross-examination is submitted herewith as Exhibit 2059.

1. In Exhibit 2059 at 21:1-4, 22:12-23:5, and 27:11-22, Dr. Foote admitted that Ex. 1069, a paper by Dr. Lutz Riechmann et al., "is not one of the references that Pfizer relies on as grounds for invalidity in its petition." Dr. Foote further admitted that the humanized antibodies described in Ex. 1069 include substitutions at 27H and 30H, and that the claims of the '213 patent do not recite substitutions at either of these positions. This testimony is generally relevant to Petitioners' argument that a person of ordinary skill in the art would create a humanized antibody with substitutions that are recited in the claims of the '213 patent. (Paper 56, Petitioner Reply at 12-14.) In particular, this testimony is relevant to Dr. Foote's testimony in paragraph 47 of his Reply Declaration (Ex. 1202) in which he asserts that both the '213 patent and the Riechmann paper (Ex. 1069) state that candidates for FR substitution include those that may interact with CDRs.

2. In Exhibit 2059 at 30:13-31:2 and 31:15-32:3, Dr. Foote admitted that the experimental example in Queen 1990 (Ex. 1050) "did not mention substitutions

that are recited in the '213 patent claims," and that the particular substitutions made in Queen 1990 did not "overlap with the positions substituted in – or claimed in the '213 [patent]." This testimony is generally relevant to Petitioners' argument that a person of ordinary skill in the art following the teachings of the prior art would arrive at a humanized antibody with substitutions that are recited in the claims of the '213 patent. (Paper 56, Petitioner Reply at 12-14, 18-21.) In particular, this testimony is relevant to Dr. Foote's testimony in paragraphs 130-134 of his Reply Declaration (Ex. 1202) in which he disagrees with Dr. Wilson's assertion that the Queen 1990 criteria are far too general and vague to disclose or suggest a specific humanized antibody with substitutions recited in the '213 patent claims.

3. In Exhibit 2059 at 33:10-35:3, Dr. Foote admitted that he did not provide a specific example of how a person of ordinary skill in the art would humanize a particular antibody using the techniques of Queen 1989 (Ex. 1034), Queen 1990 (Ex. 1050), or Kurrle (Ex. 1071) to identify the substitutions recited in the '213 patent claims. According to Dr. Foote, "[t]hat might have been a good idea, but I didn't do that." This testimony is generally relevant to Petitioners' argument that a person of ordinary skill in the art would create a humanized antibody with substitutions that are recited in the claims of the '213 patent. (Paper 56, Petitioner Reply at 12-14, 18-21.) In particular, this testimony is relevant to

Dr. Foote's testimony in paragraphs 126-134 of his Reply Declaration (Ex. 1202) in which he disagrees with Dr. Wilson's assertion that the Kurrle and Queen 1990 criteria are far too general and vague to disclose or suggest a specific humanized antibody with substitutions recited in the '213 patent claims.

4. In Exhibit 2059 at 45:4-22 and 47:6-14, Dr. Foote admitted that Queen 1990 reported that the humanized anti-TAC antibody it describes had "approximately the same affinity" as the native murine anti-TAC antibody, and that Queen 1990 "does not specifically state anywhere that the humanized anti-TAC antibody that was tested and reported in Queen 1990 had a better binding affinity than the original murine antibody." This testimony is generally relevant to Petitioners' argument that the "up to 3-fold more" binding affinity limitation of claim 65 would have been obvious. (Paper 56, Petitioner Reply at 21-23.) In particular, this testimony is relevant to Dr. Foote's testimony in paragraphs 176-177 of his Reply Declaration (Ex. 1202) in which he asserts that Queen 1990's "testing showed its humanized antibodies may have 3 to 4 fold ***more*** binding affinity than the parent, within the limits of testing."

5. In Exhibit 2059 at 52:22-53:9 and 55:7-18, Dr. Foote stated that he is not aware of the PDB database containing any information with respect to the binding affinity of any particular antibody. This testimony is generally relevant to Petitioners' argument that the "up to 3-fold more" binding affinity limitation of

claim 65 would have been obvious. (Paper 56, Petitioner Reply at 21-23.) In particular, this testimony is relevant to Dr. Foote's testimony in paragraphs 176-178 of his Reply Declaration (Ex. 1202) in which he states that "a skilled artisan would expect to be able to achieve around the same binding affinity as the parent and would not have been surprised of at least a moderate improvement in affinity."

6. In Exhibit 2059 at 63:16-64:4, 76:21-77:12, and 78:2-16 Dr. Foote admitted that of the four humanized antibody constructs reported in Kurrle (Ex. 1071), Kurrle reported that two constructs (CIV1 and CIV2) did not bind to the target, and that Kurrle did not include any binding data whatsoever on one construct (CIV4). Dr. Foote further admitted that Kurrle reported that the final construct (CIV3) had approximately the same binding affinity as the native murine antibody, but that there was "no clear evidence that it's better" than the native murine antibody. This testimony is generally relevant to Petitioners' argument that the "up to 3-fold more" binding affinity limitation of claim 65 would have been obvious. (Paper 56, Petitioner Reply at 21-23.) In particular, this testimony is relevant to Dr. Foote's testimony in paragraphs 176-178 of his Reply Declaration (Ex. 1202) in which he states that "a skilled artisan would expect to be able to achieve around the same binding affinity as the parent and would not have been surprised of at least a moderate improvement in affinity."

7. In Exhibit 2059 at 80:19-81:13 and 82:8-20, Dr. Foote admitted that

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