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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 IPR2017-01489[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 IPR2017-02140 has been joined with this proceeding.

Pursuant to the Joint Notice of Stipulation to Revise Schedule (Paper 51), 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 53). 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. 1569, 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. 1569 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 53, Petitioner Reply at 11-15.) In particular, this testimony is relevant to Dr. Foote's testimony in paragraph 47 of his Reply Declaration (Ex. 1702) in which he asserts that both the '213 patent and the Riechmann paper (Ex. 1569) state that candidates for FR substitution include those that may interact with CDRs.

2. In Exhibit 2059 at 29:5-10, Dr. Foote admitted that the experimental example in Queen 1989 (Ex. 1534) "made no substitutions that are recited in the

'213 patent claims." 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 with a reasonable expectation of success and/or that the prior art teaches humanized antibodies with the recited substitutions that bind antigen. (Paper 53, Petitioner Reply at 11-15, 19-20.) In particular, this testimony is relevant to Dr. Foote's testimony in paragraph 144 of his Reply Declaration (Ex. 1702) in which he asserts that a person of skill in the art "would be led by Queen in combination with the PDB to make humanized antibodies with the recited FR substitutions as a matter of course if the antibody being humanized differed from the chosen framework at one or more of those positions . . . ."

3. In Exhibit 2059 at 30:13-31:2 and 31:15-32:3, Dr. Foote admitted that the experimental example in Queen 1990 (Ex. 1550) "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 with a reasonable expectation of success and/or that the prior art teaches humanized antibodies with the recited substitutions that bind

antigen. (Paper 53, Petitioner Reply at 11-15, 19-20.) In particular, this testimony is relevant to Dr. Foote's testimony in paragraph 144 of his Reply Declaration (Ex. 1702) in which he asserts that a person of skill in the art "would be led by Queen in combination with the PDB to make humanized antibodies with the recited FR substitutions as a matter of course if the antibody being humanized differed from the chosen framework at one or more of those positions . . . ."

4. 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. 1534) or Queen 1990 (Ex. 1550) 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 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 with a reasonable expectation of success and/or that the prior art teaches humanized antibodies with the recited substitutions that bind antigen. (Paper 53, Petitioner Reply at 11-15, 19-20.) In particular, this testimony is relevant to Dr. Foote's testimony in paragraph 144 of his Reply Declaration (Ex. 1702) in which he asserts that a person of skill in the art "would be led by Queen in combination with the PDB to make humanized antibodies with the recited FR

substitutions as a matter of course if the antibody being humanized differed from the chosen framework at one or more of those positions . . . ."

5. In Exhibit 2059 at 37:8-20 and 38:12-20, Dr. Foote admitted that the humanized anti-TAC antibody reported in Queen 1989 (Ex. 1534) had one-third the measured binding affinity of the native murine anti-TAC antibody, and that Queen 1989 "does not disclose a humanized antibody with better binding affinity than the original murine antibody from which it was made." 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 53, Petitioner Reply at 20-22.) In particular, this testimony is relevant to Dr. Foote's testimony in paragraphs 176-178 of his Reply Declaration (Ex. 1702) 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 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

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