#### UNITED STATES PATENT AND TRADEMARK OFFICE

#### BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER, INC., and SAMSUNG BIOEPIS CO., LTD.,<sup>1</sup> Petitioners,

v.

GENENTECH, INC., Patent Owner.

Case IPR2017-01488 Patent 6,407,213

#### PETITIONERS' OPPOSITION TO PATENT OWNER'S MOTION TO STRIKE PURSUANT TO PAPER NO. 60<sup>2</sup>

<sup>1</sup> Samsung Bioepis Co. Ltd.'s IPR2017-02139 has been joined with this

proceeding. (IPR2017-02139, Paper 42.)

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<sup>&</sup>lt;sup>2</sup> All emphases within are added.

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#### I. INTRODUCTION

PO asserts that Petitioners have changed the bases for their position that the prior art disclosed use of a "consensus" sequence. That is incorrect. Petitioners did not "pivot" to relying "for the first time in their Reply" on Foote 1989, Reichmann 1988, and Kurrle for this limitation. Much of the evidence PO seeks to excludeincluding evidence that Riechmann's CAMPATH antibody was made using the "consensus" approach, and that Kurrle teaches use of a "consensus" sequence in its humanization method-was squarely raised in the Petition and supporting declaration of Dr. Foote. In fact, PO deposed Dr. Foote about it before filing its POR. The evidence and argument PO seeks to exclude also is legitimate reply, as it responds directly to the inaccurate description of the state of the art, and flawed secondary considerations arguments, PO and its expert presented in the Response. PO also waived its objection to the Foote and Wilson deposition testimony, and the Foote 1989 reference discussed therein. PO's counsel did not raise timely objections during the depositions as 37 C.F.R. § 42.64(a) requires.

#### II. FACTUAL BACKGROUND

Challenged claims 4, 33, 62, 64 and 69 of the '213 patent recite a "consensus" sequence element. Pet. at 9-10. The Petition cited Queen 1990 as disclosing or rendering obvious the "consensus" sequence element in the recited invalidity grounds. Pet. at 34-51, 56-61. The Petition and supporting expert declaration *also* 

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showed use of "consensus" sequences in humanizing antibodies was otherwise known. For example, the Petition cited Dr. Foote's testimony that the prior art CAMPATH antibody Riechmann 1988 described was made using "*a 'consensus' sequence*." Ex. 1003, ¶ 103 (cited Pet. at 11) (describing use of a consensus sequence "in which relatively uncommon residues in certain positions were substituted with more commonly found ones," where "[j]udgment of whether a residue type was common or uncommon at a particular position was based on the Kabat database, 1983 edition"). The Petition also cited Dr. Foote's testimony that, when humanizing an antibody with a given human framework in Kurrle's method, one should "consider changing the chosen human framework residue *with the consensus human residue at that position*." *Id.*, ¶ 123 (cited Pet. at 20).

During Dr. Foote's deposition *before PO submitted its Response*, PO's counsel questioned him extensively about both of these issues. Ex. 2039 at 77:18–88:23; 293:16–304:25. Dr. Foote explained without objection that Riechmann's CAMPATH "consensus" sequence was derived from his own "anti-lysozyme" construct described in Foote 1989. *Id.* at 79:12–80:7, 83:17–16. That reference was subsequently submitted as an exhibit and discussed on redirect, again without objection. *Id.* at 327-332. Indeed, PO's counsel questioned Dr. Foote on Foote 1989 during re-cross. *Id.* at 349:22–350:20. PO's counsel also questioned Dr. Foote regarding Kurrle's choice of a framework, and Dr. Foote testified (again without

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