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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 No. 6,407,213

PATENT OWNER'S MOTION TO STRIKE PURSUANT TO PAPER NO. 60

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

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Pursuant to Paper No. 60, Patent Owner files this motion to strike new evidence and argument presented in Petitioners' Reply (Paper 57) pertaining to the alleged disclosure of a "consensus" sequence in the prior art. First, Petitioners argue that a new exhibit, Foote 1989 (Ex. 1193), teaches that a "consensus" sequence was used by Petitioners' expert to generate the humanized antibody in Riechmann 1988 (Ex. 1069). Neither Foote 1989 nor Riechmann 1988 were cited or discussed in the Petition. Second, Petitioners present a new argument that Kurrle (Ex. 1071) discloses a humanized antibody with a "consensus" sequence. For the reasons set forth below, the Board should strike:

- Exhibit 1193 submitted with Petitioners' Reply and the associated arguments and testimony that rely on this exhibit, including the first full paragraph of Page 27 of the Reply; Ex. 1202, ¶¶ 12, 41-43, 79, 82, 119, 162, and 187; Ex. 1197, 176:25-178:23; Ex. 2039, 327:12-331:11.
- The last paragraph of page 16 and the graphic on page 17 of the Reply and the testimony relying on Petitioners' new theory including: Ex. 1202, ¶¶7, 12, 82, 104-106, 119, 160-162, 187; Ex. 1197, 2258:3-263:21; 264:9-267:18; 267:24-268:12; Ex. 2039, 313:7-320:11.

I. PETITIONERS' EVOLVING INVALIDITY THEORY

Claims 4, 33, 62, 64, and 69 require the use of "consensus" sequence. The '213 patent provides a specific definition of the claimed human "consensus"

sequence, "which comprises the most frequently occurring amino acid residues at each location in all human immunoglobulins of any particular subclass or subunit structure." (Ex 1001, 11:32-38; *see also* Paper 27 at 8.) The Petition argued that the "consensus" limitation was met by Queen 1990's (Ex. 1050) disclosure of "us[ing] a consensus framework from many human antibodies." (*See, e.g.*, Paper 1 at 36-37, 39, 45-47, 50.) Petitioners did not argue in the Petition that Foote 1989, Riechmann 1988, or Kurrle anticipate, render obvious, or otherwise disclose a "consensus" sequence as claimed in the '213 patent.

Consistent with the arguments in the Petition, Patent Owner's Response focused on showing that Queen 1990 does not teach the "consensus" sequence limitations of claims 4, 33, 62, 64, and 69. (*See, e.g.*, Paper 45 at 48-49.) For the first time in their Reply, Petitioners pivot from relying solely on Queen 1990 with respect to the "consensus" sequence limitations, and now invite the Board to find those limitations in a new reference, Foote 1989, as well as in Kurrle.

II. PETITIONERS' NEW ARGUMENTS ARE FORECLOSED BY FEDERAL CIRCUIT PRECEDENT, STATUTE, AND THE BOARD'S REGULATIONS.

A. Applicable Law

Evidence introduced in a reply "must be responsive and not merely new evidence that could have been presented earlier" to support the petition. *Patent Trial Practice Guide*, 77 Fed. Reg. 48,612, 48,620 (Aug. 14, 2012); *see also* 37

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