

Filed on behalf of Patent Owner Genentech, Inc. by:

David L. Cavanaugh (Reg. No. 36,476)
Lauren V. Blakely (Reg. No. 70,247)
Robert J. Gunther, Jr. (*Pro Hac Vice*)
Lisa J. Pirozzolo (*Pro Hac Vice*)
Kevin S. Prussia (*Pro Hac Vice*)
Andrew J. Danford (*Pro Hac Vice*)
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Ave., NW
Washington, DC 20006

Adam R. Brausa (Reg No. 60,287)
Daralyn J. Durie (*Pro Hac Vice*)
DURIE TANGRI LLP
217 Leidesdorff Street
San Francisco, CA 94111

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 IPR2017-01488¹
U.S. Patent No. 6,407,213

**PATENT OWNER'S REPLY IN SUPPORT OF ITS MOTION TO
EXCLUDE EVIDENCE**

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

I. THE DECLARATION OF MR. BUSS (EX. 1004) SHOULD BE EXCLUDED.

A. Mr. Buss's Copy-and-Paste Methodology is Inherently Unreliable.

Petitioners have not met their burden of establishing that Mr. Buss's copy-and-paste declaration is "the product of reliable principles and methods" or that the his "scientific, technical, or other specialized knowledge" will help the Board "understand the evidence" or "determine a fact in issue." Fed. R. Evid. 702(a), (c); *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592 n.10 (1993); *see also* 37 C.F.R. § 42.62(a). Petitioners do not contest that (1) Mr. Buss did not perform any independent research or analysis regarding the subject matter of the '213 patent; (2) he only included the references identified in his declaration because the declaration he copied included them; and (3) the only substantive difference between Mr. Buss's declaration and the declaration he copied is Mr. Buss's use of a relaxed definition of a skilled artisan. (*See* Paper 63 at 2-3; Paper 70 at 5-8.)

Nevertheless, Petitioners defend Mr. Buss's declaration by emphasizing one of its few original sentences where he states he applied his "independent judgment and expertise, after having independently reviewed and analyzed" to the materials Dr. Ball selected. (Paper 70 at 3 (quoting Ex. 1003, ¶13).) But this single sentence is insufficient to overcome Mr. Buss's admissions that he had no prior knowledge of the subject matter and did no independent research of his own. (Ex. 2040 at

14:22-15:7, 84:6-25; *see also id.* at 49:17-51:18, 96:18-125:7.) It strains credulity to suggest that such testimony could be the product of reliable methods or assist the trier of fact where Mr. Buss—without any medical training—copied the analysis of a clinical oncologist and claims the analysis now reflects a “protein engineering” view. (Ex. 2040 at 47:12-23); *see Dura Auto Sys. Of Indiana, Inc. v. CTS Corp.*, 285 F.3d 609, 614 (7th Cir. 2002); *Bouygues Telecom, S.A. v. Tekelec*, 472 F. Supp. 2d 722, 729 (E.D.N.C. 2007).

That Patent Owner has not moved to exclude Dr. Leonard, Celltrion's ***oncologist*** in the companion IPRs, (Paper 70 at 5) is not a reason to deny Patent Owner's motion, but rather highlights the unhelpfulness of Mr. Buss's testimony. Dr. Leonard—like Dr. Ball—is an experienced oncologist. (*See* Ex. 2058 at 12; Ex. 1004 in IPR2017-01373, ¶2.) And unlike Mr. Buss, Dr. Leonard at least was aware of the subject matter of the patent before reading and copying Mr. Ball's declaration and performed his own independent research based on his prior knowledge. (Ex. 2040 in IPR2017-01373 at 22:13-24:15, 25:14-22.) In contrast, Mr. Buss brings no such relevant expertise to bear.

Likewise, Petitioners' suggestion that Mr. Buss's testimony is admissible because Patent Owner allegedly did not challenge the substance of Mr. Buss's parroted opinions is beside the point. (Paper 70 at 1, 4-5.) The Rules of Evidence exist to keep this testimony away from the factfinder so the opposing side need not

legitimize unreliable testimony by engaging in a debate on the merits. More fundamentally, Petitioners bear the burden of producing evidence to support a conclusion of unpatentability. 35 U.S.C. § 316(e); *see also In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1375-76 (Fed. Cir. 2016). Unreliable or admissible expert testimony cannot be used to meet that burden.

In any event, Patent Owner did not concede there was a motivation to combine the prior art. (Paper 70 at 4-5.) At best, the portions of Dr. Wilson's deposition identified by Petitioners show that Dr. Wilson agreed that that prior to the invention, HER2-positive breast cancer was a serious disease and that Hudziak says that murine 4D5 was shown to have the greatest effect on cell proliferation. (Ex. 1197 at 19:7-25:16.) Dr. Wilson did not "admit" that "based on Hudziak's data, there was a motivation to investigate the 4D5 antibody as a human therapeutic agent against HER2 overexpressing breast cancer." (Paper 70 at 4-5.) Rather, when asked if there were such a motivation, Dr. Wilson merely stated that Hudziak identified 4D5 as one of many antibodies with "potential." (Ex. 1197 at 24:22-25:16.) And even if Dr. Wilson had made such a concession (he did not), that does not give Petitioners a free pass to rely on inadmissible testimony.

B. Petitioners' Attempts to Run From the "Clinical Aspects" of Mr. Buss's Declaration Confirm That His Opinions Are Unreliable.

Mr. Buss is not a medical doctor and Petitioners have not shown that his experience as a "Higher Scientific Officer" is relevant to the opinions he offers. Petitioners now suggest that his opinion is limited to whether a skilled artisan would have been motivated to humanize murine anti-HER2 antibodies. (Paper 70 at 10-11.) However, Mr. Buss plainly offers *his opinion* that a POSA "would have recognized the power and potential of monoclonal antibodies" "as therapies for a number of diseases" and "would have identified 4D5 as a promising candidate for humanization." (Ex. 1004, ¶¶15-16; *see also id.*, ¶¶18, 43, 53-55, 63, 67, 69-70.) These opinions are not limited to "undisputed background state of the art" but, as Petitioners concede, "underl[ie]" the remainder of his opinions. (Paper 70 at 11.). Indeed, if the scope of Mr. Buss's declaration were limited to the "humanization of 4D5," there is no reason why it could not have been addressed by Dr. Foote.

Petitioners also argue that Mr. Buss need not have any medical training to offer his opinions because he could have relied on a hypothetical oncologist to fill in the gaps in his knowledge. (Paper 70 at 9-10 ("the role of the clinician (*e.g.*, oncologist) on a team making up the person of ordinary skill in the art would be to provide input as to what might be 'good targets' to generate antibodies against").) But that is not what Mr. Buss purports to do. Mr. Buss—without any medical

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