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UNITED STATES PATENT AND TRADEMARK OFFICE

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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PFIZER, INC. AND  
SAMSUNG BIOEPIS CO., LTD.;  
Petitioners,

v.

GENENTECH, INC.,  
Patent Owner.

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Case IPR2017-01489<sup>1</sup>  
U.S. Patent No. 6,407,213

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**PATENT OWNER'S MOTION TO EXCLUDE EVIDENCE  
PURSUANT TO 37 C.F.R. § 42.64**

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<sup>1</sup> Case IPR2017-02140 has been joined with this proceeding.

Pursuant to 37 C.F.R. § 42.64 Patent Owner moves to exclude the Buss Declaration (Ex. 1504); Exhibit 1693 and the argument and testimony pertaining to it; and the evidence and testimony regarding Petitioners' new obviousness theory regarding Kurrle.

**I. THE DECLARATION OF MR. BUSS (EX. 1504) SHOULD BE EXCLUDED.**

The opinions provided by Mr. Timothy Buss at Ex. 1504, ¶¶ 15-16, 18, 30-33, 43-45, 53-55, 63, 67, 69-70 ("Buss Opinions") are inadmissible in this proceeding at least because Petitioners have not shown that Mr. Buss, a lab technician, meets the level of ordinary skill in the art or that his opinions are the product of reliable principles and methods.<sup>2</sup> Because Petitioners cannot meet their burden of demonstrating the admissibility of the Buss Opinions, the Board should exclude them. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592 n.10

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<sup>2</sup> Patent Owner objected to Ex. 1504 as lacking a disclosed basis of sufficient facts or data (FRE 705; 37 C.F.R. § 42.65), not being based on sufficient facts or data, the product of reliable principles and methods, and/or a reliable application of the principles and methods to the facts (FRE 702, 703), and being misleading and/or confusing (FRE 403). (Paper 31 at 1-2; *see also* Paper 42 at 63-64.)

(1993) (“The proponent of expert testimony must demonstrate admissibility by a preponderance of the evidence.”).

**A. Mr. Buss’s Opinions Should be Excluded Because They Are Not the Product of Reliable Principles and Methods, and They Do Not Assist the Trier of Fact to Understand Any Facts at Issue.**

It is undisputed that the Buss Declaration’s analysis of the grounds of unpatentability are nearly identical to the analysis presented by Dr. Edward Ball submitted in *Mylan Pharms. v. Genentech, Inc.*, IPR2016-01694. (*See, e.g.*, Ex. 2058 (Redline of Ball/Buss Declarations); Ex. 2040 at 12:10-14:9.) Despite lacking the credentials of Dr. Ball, a medical doctor with “more than 35 years of practical and research experience specializing in oncology and hematology with an emphasis on treating patients with antibody therapeutics” (Ex. 2056 at ¶23), Mr. Buss copied nearly verbatim the substantive analysis provided by Dr. Ball and he did so while performing no independent research or analysis regarding the subject matter of the ’213 patent. (*See, e.g.*, Ex. 2040 at 14:22-15:7.) He testified that he only gave the ’213 patent “a quick read” and he “read through it briefly,” but he could not recall whether he read the patent before or after he read the Ball declaration. (*Id.* at 84:6-25.)

Mr. Buss also conceded during his deposition that he copied the substance of Dr. Ball’s opinion without knowing who Dr. Ball was; without performing any diligence to determine Dr. Ball’s reputation in the field; and without doing any

research of his own regarding the literature involved in this matter. (Ex. 2040 at 14:10-15:7.) Further, he testified that for nearly every reference cited in his declaration—including Hudziak, which forms the basis of grounds 8-10—he included it in his declaration only because Dr. Ball had cited them. (Ex. 2040 at 95:1-8, 125:8-126:21, 127:21-128:3; *see generally id.* at 96:18-125:7 (discussing over 25 references).) And as of 1991, Mr. Buss had not even heard of HER2-positive breast cancer. (Ex. 2040 at 51:7-11.)

The only expertise contributed by Mr. Buss is the ability to “read[] papers on molecular biology antibodies.” (*See, e.g.*, Ex. 2040 at 145:22-146:13.) But simply copying the work of another expert and reading the documents cited therein is not a reliable method under Federal Rule of Evidence 702. *Bouygues Telecom, S.A. v. Tekelec*, 472 F. Supp. 2d 722, 729 (E.D.N.C. 2007) (“[T]he wholesale adoption of the opinion of another expert verbatim cannot be within the intent of Fed. R. Evid. 702.”). The inherent problems with a “read and copy” methodology are exacerbated here, where the only major substantive difference between the declarations of Mr. Buss and Dr. Ball is Mr. Buss’s use of a more relaxed definition of a person having ordinary skill in the art—a definition that Mr. Buss did not himself write or independently assess. (*See, e.g.*, Ex. 1504 at 22:23-27:13.) As a result, the entirety of the Buss Opinions should be excluded under Federal Rules of Evidence 702, 703.

**B. Mr. Buss's Testimony Regarding the Use of Humanized Antibodies as Therapeutic Agents Should be Excluded.**

Petitioners rely on Mr. Buss to provide opinions related to the use of humanized antibodies as therapeutic agents. For example, Mr. Buss opines that the murine 4D5 antibody would have been “a prime candidate for further development as a therapy for breast cancer.” (Ex. 1504 ¶18; *see also id.* at ¶63 (opining that “the mouse monoclonal the mouse monoclonal antibody 4D5 was identified as a promising new antibody therapeutic for breast cancer treatment”), ¶67 (opining that a reference “called for [4D5] humanization for further development as a therapeutic”), ¶¶69-70 (section titled “Humanization of 4D5 to Enable Therapeutic Use”). Mr. Buss, however, is not an oncologist; his background is as laboratory technician. (Ex. 2040 at 34:15-18, 42:12-13.)

In its Institution Decision, the Board found that a person having ordinary skill in the art would have had either (1) “a Ph.D. or equivalent in chemistry, biochemistry, structural biology, or a closely related field, and experience with antibody structural characterization, engineering, and/or biological testing;” or (2) “an M.D. with practical academic or industrial experience in antibody development.” (Paper 27 at 8.) Mr. Buss does not hold a Ph.D.; his purported expertise derives entirely from the on-the-job experience as a lab technician. (*See, e.g.*, Ex. 2040 at 35:1-10, 40:3-12, 45:14-48:18.) But even if that were

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