UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MILTENYI BIOMEDICINE GmbH and MILTENYI BIOTEC INC.
Petitioner

v.

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA
Patent Owner

IPR Trial No. IPR2022-00855
U.S. Patent No. 9,540,445
Issue Date: January 10, 2017

Title: Compositions and Methods for Treatment of Cancer

PETITIONER'S REPLY TO PATENT OWNER'S PRELIMINARY RESPONSE

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As authorized by the Board, Petitioner submits this Reply to address three issues raised in Patent Owner's ("PO") Preliminary Response: (1) Porter as prior art; (2) claim construction; and (3) Section 325(d).

I. Porter is Prior Art

Porter discloses results for a clinical study that treated cancer patients with the prior art Campana CAR. Pet., 26-27; Junghans (Ex. 1002), ¶¶104-112. Other than attacking Porter's status as prior art, PO has provided no argument against Ground 4. POPR, 39-40. Because there is sufficient evidence that the relevant Porter disclosures are "by another," Ground 4 should be instituted.

Non-inventor Dr. Adam Bagg is an author of Porter. Ex. 1012, 725. Relying upon a declaration from Dr. Bagg, PO argues that Dr. Bagg did not contribute to ***any*** disclosure in Porter that is relevant to obviousness. POPR, 40. Dr. Bagg, who is employed by PO, states in his declaration that "all of the portions of Porter cited by the Petitioners reflect the work of my co-authors and not me." Ex. 2044, ¶7. PO's argument and Dr. Bagg's declaration are inconsistent with Porter itself, which states that Dr. Bagg determined the anti-tumor effect reported in the paper.

In its Protocol section, Porter describes Dr. Bagg as evaluating effectiveness by performing "MRD assessments" after CAR T-cell therapy. Ex. 1013, 36. MRD (or minimal residual disease) assessments refer to the measurement of residual tumor cells remaining in the body after treatment, which is relevant to anti-tumor

effectiveness. Porter states: "Subjects will undergo … MRD assessments by Dr. Bagg" on "[d]ay 28" following CAR T-cell therapy. *Id.*, 37. Dr. Bagg's declaration also acknowledges that he "determined the laboratory result indicating remission …." Ex. 2044, ¶8. Petitioner cited the antitumor effect disclosed in Porter as supporting obviousness. Pet., 75-76.

At the very least, Dr. Bagg's declaration raises factual questions about whether a portion of Porter, *e.g.*, determination of antitumor effect, was "by another." The Board has consistently instituted proceedings when patent owners submit testimony attempting to disqualify prior art in preliminary responses.

In *Nelson*, the Board "decline[d] to disqualify" prior art when presented with a declaration from a prior-art author, Mr. Poon, to argue that relied-upon portions of the reference were not "by another." *Nelson Products v. Bal Seal Engineering*, IPR2014-00573, Paper 9 at 9-12 (P.T.A.B. Sept. 29, 2014). The Board instituted, holding that "[o]n this record, we have no reason to doubt Mr. Poon's credibility, however, we hesitate to rely solely on Mr. Poon's testimony at this stage of the proceeding where it would result in a final, non-appealable denial of institution on a ground of unpatentability." *Id.,* 11. The Board has come to similar conclusions in other decisions. *See, e.g.*, *Watson Labs., Inc. v. United Therapeutics Corp.*, IPR2017-01621, Paper 10, 11-14 (P.T.A.B. Jan. 11, 2018) (finding that "for the purposes of institution … Petitioner has provided a sufficient basis on which to

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