UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MILTENYI BIOMEDICINE GmbH and MILTENYI BIOTEC INC.,
Petitioners,

v.

TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA,
Patent Owner.

Case IPR 2022-00853
Patent 9,464,140

SURREPLY OF PATENT OWNER TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA AND REAL PARTY IN INTEREST NOVARTIS PHARMA AG

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Miltenyi's Reply misconstrues the relevant legal standards and ignores key arguments Patent Owner made in its POPR. Institution should be denied.

I. Porter Is Not The Work Of "Another"

Miltenyi does not dispute that the Porter clinical trial is the same one reported in the patent: the seminal study demonstrating, after years of failure, that CAR-T therapy would work as a cancer treatment. Instead, Miltenyi suggests that institution should be granted despite proof that Porter is not "by another" because declarations "attempting to disqualify prior art in [POPRs]" should not defeat institution. Reply 2. But the Board has denied institution on the basis of declarations, like the one here, showing that alleged prior art is not the "work of another," *In re Katz*, 687 F.2d 450, 454 (C.C.P.A. 1982). *E.g.*, *R.J. Reynolds v. Altria*, IPR2021-00793, Paper 7, at 5–7 (PTAB Oct. 27, 2021) (denying institution based on author declaration and evidence of "a common inventive entity"); *cf. Fresenius v. Chugai*, IPR2021-01288, Paper 30 at 41–42 (PTAB Feb. 23, 2022) (considering antedation declaration at institution); *Pfizer v. Genentech*, IPR2018-00373, Paper 12, at 15 (Aug. 2, 2018) (denying institution where Examiner had considered attribution declaration).

Miltenyi's alleged "factual questions" are illusory. Reply 2. As in *R.J. Reynolds*, the documentary evidence here indicates common inventorship even before considering Dr. Bagg's declaration. The named inventors are all co-authors of Porter. And on their face, the patent and Porter plainly disclose the *very same*

clinical trial results. *Compare, e.g.*, Ex. 1001 fig.12 D *with* Ex. 1012 at 5 (depicting identical patient CT scans).

Miltenyi disputes none of this, and is constrained to flyspeck Dr. Bagg's role. Contrary to Miltenyi's assertions, both Porter and Dr. Bagg's declaration consistently indicate that Dr. Bagg analyzed samples, determined laboratory results indicating remission, and passed that information on to the inventors. Ex. 2044 at 3; Ex. 1013 at 36, 37; Reply 1–2. In fact, the assays that Miltenyi touts were described in both Porter *and the patent*. *Compare* Ex. 1013, 36 (describing MRD assessments, cited at Reply 1), *with* Ex. 1001, 57:18–26. Dr. Bagg's contribution—performing "assays and testing" at the inventors' instruction, Ex. 2044 at 2–3—may warrant discretionary co-authorship of academic papers, but does not constitute legal inventorship; he is not part of the "common inventive entity" that conceived the work reported in both Porter and the patent. *Katz* at 455; *Riverwood Int'l v. R.A. Jones*, 324 F.3d 1346, 1356 (Fed. Cir. 2003). There also is no factual dispute because Dr. Bagg did not contribute "the portions of the reference *relied on as prior art*." *Riverwood*, 324 F.3d at 1356. Dr. Bagg's assays were only one factor in *Dr. Porter's* "clinical determination of remission." Ex. 2044 at 3. Miltenyi equates that determination, not the assays, to the "antitumor effect," and does not reference the assay results in its Petition. POPR 42; *compare* Pet. 65–69 *with* Ex. 2044 ¶¶ 7–13.

Miltenyi's cases involve much closer questions. In *Watson*, the Board found

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