UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MILTENYI BIOMEDICINE GmbH and MILTENYI BIOTEC INC.,

Petitioners,

v.

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA,

Patent Owner.

Case No.: IPR2022-00852
U.S. Patent No. 9,518,123

Case No.: IPR2022-00855
U.S. Patent No. 9,540,445

PETITIONER'S MOTION FOR ADDITIONAL DISCOVERY

Pursuant to the Board's authorization email to counsel dated March 7, 2023, Petitioner moves for discovery seeking documents relating to Dr. Adam Bagg's declaration (Ex. 2044) and his contributions as a co-author and co-investigator of Exhibit 1012, Porter et al., *Chimeric Antigen Receptor–Modified T Cells in Chronic Lymphoid Leukemia*, 365 N. ENGL J. MED. 725 (2011) and its supplementary materials, Exhibit 1013 (collectively, "Porter").

Petitioner's three Requests for Document Production are attached as an appendix. They are narrowly tailored to Dr. Bagg's involvement in determining anti-tumor efficacy and the reasons he is a co-author and co-investigator of Porter.

Porter is a publication predating the priority date. Dr. Bagg is a co-author of Porter but is not named as inventor of the challenged patents. The requested discovery is highly relevant to whether Porter is prior art, *i.e.*, whether the relevant content of Porter includes the work of Dr. Bagg or is entirely attributable to the named inventors of the challenged patents. *Google LLC v. IPA Techs. Inc.*, IPR2019-00731, 2020 WL 5582275, at *5 (PTAB Sept. 16, 2020) ("In determining whether a reference is the work of the challenged patent's named inventor(s), the inquiry focuses on whether the relevant content of the reference—'which includes the design, trial, and analysis of results'—was solely the work of the inventor(s).").

Porter is the main reference in Ground 4. Given the importance of Porter, narrow document discovery should be allowed to mount a full and fair determination

of the unpatentability. Petitioner's motion should be granted under the *Garmin* factors, which are addressed below.

I. NECESSARY IN THE INTERESTS OF JUSTICE.

The Board may grant additional discovery where necessary "in the interests of justice," 37 C.F.R. § 42.51(b)(2)(i), as it is here. In assessing whether to grant additional discovery, the Board applies a five factor "necessary in the interest of justice" standard. *See Garmin Int'l v. Cuozzo Speed Techs,* IPR2012-00001, Paper 26 at 6-7 (PTAB Mar. 5, 2013). All *Garmin* factors support granting this motion.

A. *Garmin* Factor 1: More Than a Possibility or Mere Allegation That the Requested Discovery Will Yield Useful Information.

Patent Owner's Responses argue that (1) the claims require a showing of effectiveness of CAR-T therapy and (2) the prior art fails to show that. *See e.g.*, IPR2022-00855, POR, Paper 20 at 18 (arguing the claims require a showing of "therapeutic or prophylactic benefit"); IPR2022-0852, POR, Paper 18 at 34 ("In addition, the POSA would have expected that CAR-T cells would not replicate well in humans and would thus have limited, transient effects, if any."). Petitioner disagrees that the claims require a showing of effectiveness.

But if the claims do require a showing of effectiveness, then Petitioner's requested discovery is necessary in the interest of justice. Porter teaches that CAR-T therapy was effective in several respects, including: reduction of tumor cells,

reduction of tumor size, and reduction of clinical symptoms. *See e.g.*, Ex. 1012 at 727 ("no evidence of CLL in the bone marrow"), *id.* ("flow-cytometric analysis showed no residual CLL"), *id.* at 728 ("contrast-enhanced CT" of tumors), *id.* at 725 ("Remission was ongoing 10 months after treatment."). Additional discovery is needed to show that Dr. Bagg, a physician and the sole hematopathologist listed as a co-author and co-investigator on Porter, substantively contributed to the determination of effectiveness disclosed in Porter.

Only Patent Owner possesses documentation of Dr. Bagg's full contributions to Porter. Dr. Bagg was employed by Patent Owner at the relevant time and is still employed there today. Based on limited publicly available information, it appears that Dr. Bagg was responsible in Porter for at least determining minimal residual disease ("MRD") after treatment. *See e.g.*, Ex. 2013 at 36 ("MRD assessments by Dr. Bagg"); *id*. at 37 ("MRD assessments by Dr. Bagg"). MRD assessment is, according to the Porter protocol, one endpoint for determining "anti-tumor responses to CART-19 cell infusions." Ex. 1013, Section 3.3.

Patent Owner submitted a declaration from Dr. Bagg (Ex. 2044) with its PORs to try to remove Porter as prior art. The declaration states that Dr. Bagg "determined the laboratory result indicating remission." Ex. 2044 at ¶8. The PORs argue that Dr. Bagg was merely "performing 'assay[s] and testing' at the inventors' instruction." *E.g.*, IPR2022-0852, Paper 18 at 29.

Petitioner's requested discovery is necessary to determine the credibility of Patent Owner's contention that Dr. Bagg essentially acted as a mere lab technician. Patent Owner contends that Dr. Bagg's role was limited to "performing 'assay[s] and testing at the inventors' instruction," but that is routine work which would not warrant inclusion as a co-investigator and co-author. The criteria for authorship provided by the International Committee of Medical Journal Editors states, in relevant part, that an author must have made "***substantial contributions*** to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work." *Defining the Role of Authors and Contributors*, ICMJE, available at: https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html. Petitioner's discovery request is necessary to show that Dr. Bagg was not simply a technician implementing the inventors' instructions, as Patent Owners contend, but that he made "substantial contributions" to portions of Porter relevant to the challenged claims.

The requested discovery is also necessary to show that Dr. Bagg applied his expertise to make independent judgments about the CAR-T effectiveness disclosed in Porter. Dr. Bagg is an academic researcher and hematopathologist, which requires many years of specialized training after medical school. He had extensive T-cell expertise at the time of Porter, for example, authoring commentary on antigen B-cell and T-cell receptor gene rearrangements, particularly in T-cell lymphoma. Bagg,

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