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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

IPR2022-00852 (Patent 9,518,123 B2)
IPR2022-00855 (Patent 9,540,445 B2)

Before ULRIKE W. JENKS, SUSAN L. C. MITCHELL, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*

ORDER

Granting Petitioner's Motion for Additional Discovery
37 C.F.R. § 42.51(b)(2)

I. INTRODUCTION AND BACKGROUND

Pursuant to our authorization (Exhibit 3001),[1] Petitioner Miltenyi Biomedicine GmbH and Miltenyi Biotec Inc. (collectively, "Petitioner") filed a motion for additional discovery (Paper 20, "Mot."). Patent Owner, The Trustees of the University of Pennsylvania filed an opposition. (Paper 21, "Opp.").

As Ground 4, Petitioner challenges all claims as obvious in view of a number of references, including Porter,[2] a New England Journal of Medicine Brief Report published within one year of the critical date, and reporting on a patient treated in a clinical trial of CART-cells. *See e.g.*, Paper 1 (Petition), 4; Paper 9 (Institution Decision), 24–25. Among the authors of Porter, only Dr. Adam Bagg is not listed as an inventor of the challenged patents. Relying on the Dr. Bagg's Declaration (Exhibit 2044), Patent Owner argues that Porter is not prior art under 35 U.S.C § 103(a), because Dr. Bagg did not make a requisite inventive contribution in Porter and merely "perform[ed] 'assay[s] and testing' at the inventors' instruction." *See* Opp. 8; Paper 18 (Patent Owner's Response), 29 (second alteration in original). As such, the scope of Dr. Bagg's contribution to Porter is determinative of whether Porter qualifies as prior art.

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[1] Similar Exhibits and Papers are of record in both cases. We cite to those of IPR2022-00852 for convenience.

[2] Exhibit 1012, Porter et al., *Chimeric Antigen Receptor–Modified T Cells in Chronic Lymphoid Leukemia*, 365 N. ENGL J. MED. 725 (2011) and supplementary materials, Exhibit 1013 (collectively, "Porter").

Patent Owner has agreed to make Dr. Bagg available for deposition. Opp. 13.[3] Petitioner further seeks, as additional discovery, documents from Dr. Bagg falling under three Requests for Production ("Requests") which, it contends, "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." Mot. 1. In particular, Petitioner seeks:

> **REQUEST FOR PRODUCTION NO. 1:**
>
> All documents showing your involvement in determinations of remission for patients in the Porter study.
>
> **REQUEST FOR PRODUCTION NO. 2:**
>
> All documents showing your involvement in determinations that patients in the Porter study experienced a reduction in the frequency or severity of at least one clinically relevant sign or symptom of the disease.
>
> **REQUEST FOR PRODUCTION NO. 3:**
>
> All documents showing your contributions to Porter or explaining or documenting the reasons that you were included as a co-author of Porter.

Id. at Appendix A, 13–14.

II. ANALYSIS

Discovery in an *inter partes* review proceeding is more limited than in district court patent litigation, as Congress intended our proceedings to provide a more efficient and cost-effective alternative to such litigation. H. Rep. No. 112-98 at 45–48 (2011). Thus, we take a conservative approach to granting additional discovery. 154 Cong. Rec. S9988-89 (daily ed. Sept.

[3] Patent Owner does not dispute that "Dr. Bagg was employed by Patent Owner at the relevant time and is still employed there today." Mot. 3; *see* Ex. 2044 ¶¶ 4–5.

27, 2008) (statement of Sen. Kyl). Accordingly, a party seeking discovery beyond what is expressly permitted by our rules must establish that such additional discovery is "necessary in the interest of justice." 35 U.S.C. § 316(a)(5); *see also* 37 C.F.R. § 42.51(b)(2) ("The moving party must show that such additional discovery is in the interest of justice.").

The Board has identified five factors (the "*Garmin* Factors") to be considered in determining whether additional discovery is in the interest of justice. *See Garmin Int'l, Inc. v. Cuozzo Speed Techs. LLC*, Case IPR2012-00001, slip op. at 6–7 (PTAB Mar. 5, 2013) (Paper 26) (precedential) ("*Garmin*"). In assessing Petitioner's motion, we address those factors below.

Factor 1 – There must be more than a possibility and mere allegation that something useful will be discovered.

Pursuant to factor 1, we consider whether Petitioner is already in possession of a threshold amount of evidence or reasoning tending to show beyond speculation that something useful will be uncovered via the requested discovery. *Garmin*, IPR2012-00001, Paper 26, at 7. "Useful" in this context does not mean merely "relevant" and/or "admissible." *Id.* Rather, it means favorable in substantive value to a contention of the party moving for discovery. *Id.*

Petitioner argues that the requested discovery is necessary in the interest of justice if, as Patent Owner contends, the claims require a showing of effectiveness of CAR-T therapy as disclosed in Porter. Mot. 2–3. In this respect, Petitioner asserts that, "[b]ased on publicly available information, it appears that Dr. Bagg was responsible in Porter for at least determining minimal residual disease ('MRD') after treatment." *Id.* at 3 (citing Ex. 2013,

36–37; Ex. 1013, Section 3.3). Petitioner further argues that the "requested discovery is necessary to determine the credibility of Patent Owner's contention that Dr. Bagg essentially acted as mere lab technician" and to determine whether he applied his extensive expertise in the relevant field "to make independent judgments about the CAR-T effectiveness disclosed in Porter." *Id.* at 4–5.

In response, Patent Owner points out that merely performing tests that demonstrate efficacy does not necessarily equate to an inventive contribution. Opp. 10–11 (citing e.g., *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 828 F.Supp. 1208, 1210–12 (E.D.N.C. 1993), *aff'd*, 40 F.3d 1223 (Fed. Cir. 1994).). Moreover, referencing Dr. Bagg's extensive credentials and experience, Patent Owner argues that "scientists aiding with assessment of efficacy can act as more than the canonical 'pair of hands' *without* being co-inventors." Opp. 11–12 (citing *Burroughs*, 40 F.3d at 1230).

Patent Owner's points are well taken. We, nevertheless, find that additional discovery is appropriate to determine whether Dr. Bagg's contributions to Porter fall entirely within the confines of *Burroughs*. Moreover, in assessing Dr. Bagg's credibility regarding the scope and content of his contributions, we agree with Petitioner that "[d]eposing Dr. Bagg about his memories from twelve years ago is unlikely to be as reliable as documents from that time period," which may also "refresh Dr. Bagg's recollection from that time." Mot. 6 (citation omitted). Accordingly, Factor 1 favors Petitioner.

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