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Paper 10
Entered: October 11, 2022

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

IPR2022-00855
Patent 9,540,445 B2

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

JENKS, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

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I. INTRODUCTION

A. Background

Miltenyi Biomedicine GmbH and Miltenyi Biotec Inc. (collectively, "Petitioner") filed a Petition for an *inter partes* review of claims 1–19 and 21–30 of U.S. Patent No. 9,540,445 B2 ("the '445 Patent," Ex. 1001). Paper 1 ("Pet."). Trustees of the University of Pennsylvania ("Patent Owner") timely filed a Preliminary Response. Paper 7. ("Prelim. Resp."). Petitioner further filed an authorized Reply to the Preliminary Response (Paper 8, "Reply"); Patent Owner filed a responsive Sur-Reply (Paper 9, "Sur-Reply").

We have authority, acting on the designation of the Director, to determine whether to institute an *inter partes* review under 35 U.S.C. § 314 and 37 C.F.R. § 42.4(a)(2020). *Inter partes* review may not be instituted unless "the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). The Supreme Court held that a decision to institute under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018).

For the reasons set forth below, upon considering the Petition, Preliminary Response, and supporting evidence of record, we determine that Petitioner has sufficiently shown for the purpose of institution that the information presented in the Petition establishes a reasonable likelihood that Petitioner will prevail with respect to at least one of the challenged claims.

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Accordingly, we institute *inter partes* review on all of the challenged claims based on all of the grounds identified in the Petition.

Our findings of fact, conclusions of law, and reasoning discussed below are based on the evidentiary record developed thus far, and made for the sole purpose of determining whether the Petition meets the threshold for initiating review. This decision to institute trial is not a final decision as to the patentability of any challenged claim or the construction of any claim limitation. Any final decision will be based on the full record developed during trial.

B. Real Parties-in-Interest

Petitioner identifies itself, Miltenyi Biomedicine GmbH and Miltenyi Biotec Inc. as the real parties-in-interest. Pet. 11. Patent Owner, identifies itself, The Trustees of the University of Pennsylvania and its licensee, Novartis Pharma AG, as real parties-in-interest. Paper 5, 2.

C. Related Matters and Chain of Priority

The '445 patent issued from application No. 14/997,136 ("the '136 application") which is a continuation of application No. 13/992,622 ("the '622 application"), filed as application No. PCT/US2011/064191 ("the PCT application") on December 9, 2011. The '445 patent further claims benefit of priority to provisional application No. 61/421,470. filed on December 9, 2010, and provisional application No. 61/502,649. filed on June 29, 2011.

Petitioner reasonably contends that the challenged claims of the '445 patent are not entitled to benefit of the provisional applications. Pet. 13, 71 (citing, e.g., Ex. 1021, 402). Patent Owner does not presently contest this assertion. *See* Prelim. Resp. 41. On the present record, we consider

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December 9, 2011, filing date of the PCT application, to be the earliest possible priority date for the challenged claims.

Petitioner concurrently challenges claims of related U.S. Patent Nos. 9,518,123 B2 ("the '123 patent) and 9,464,140 B2 ("the '140 patent") in IPR2022-00852 and IPR2022-00853, respectively. The '123 and '140 patents similarly issued from continuation applications of the '622 parent application and, thus, share the substantially the same specification. The '622 parent application issued as U.S. Patent No. 9,499,629 B2 ("the '629 patent.). The '123, '140, '445, and '629 patents were Examined by the same Examiner.

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D. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability (Pet. 5):

Ground	Claims Challenged	35 U.S.C §[1]	Reference(s)/Basis
1	1–4, 6, 8, 9, 11, 16, 21, 22, 27–30	§ 103	Campana,[2] Nicholson,[3] Honsik,[4] CART-19 ClinicalTrials.gov[5]
2	1–6, 8, 9, 11, 13, 16, 21, 22, 27–30	§ 103	Campana, Jensen,[6] Honsik, CART-19 ClinicalTrials.gov
3	1–30	§ 103	Campana, Milone,[7] CART-19 ClinicalTrials.gov, Nicholson, Jensen, Littman,[8] Sadelain,[9] Honsik, Riddell[10]
4	1–30	§ 103	Campana, Porter,[11] Nicholson, Jensen, Littman, Sadelain, Honsik, Riddell

[1] The Leahy-Smith America Invents Act ("AIA") included revisions to 35 U.S.C. § 103 that became effective on March 16, 2013. Because the '140 patent issued from an application that is a continuation of an application filed before March 16, 2013, we apply the pre-AIA version of the statutory basis for unpatentability.
[2] US 2005/0113564, publ. May 26, 2005. Ex. 1003 ("Campana").
[3] Nicholson et al., "*Construction and Characterisation of a Functional CD19 Specific Single Chain Fv Fragment for Immunotherapy of B Lineage Leukaemia and Lymphoma*," 34 MOL. IMMUNOL. 1157 (1997). Ex. 1004 ("Nicholson").
[4] US 4,844,893, issued July 4, 1989. Ex. 1005 ("Honisk").
[5] "*Pilot Study for Patients with Chemotherapy Resistant or Refractory CD19 Leukemia and Lymphoma (CART-19)*," https:/clinicaltrials.gov/ct2/show/NCT00891215. Ex. 1006 (includes Declaration of Duncan Hall).
[6] US 2004/0126363, published July 1, 2004. *Ex.* 1007 ("Jensen") .
[7] Milone et al., "*Chimeric Receptor Containing CD137 Signal Transduction Domains Mediate Enhanced Survival of T Cells and Increased Antileukemic Efficacy In Vivo*," 17 MOL. THERAPY 1453 (2009). Ex. 1008 ("Milone").

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