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Paper 40
Date: April 14, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENOME & COMPANY,
Petitioner,

v.

THE UNIVERSITY OF CHICAGO,
Patent Owner.

PGR2019-00002
Patent 9,855,302 B2

Before SHERIDAN K. SNEDDEN, SUSAN L.C. MITCHELL, and JOHN E. SCHNEIDER, *Administrative Patent Judges.*

SCHNEIDER, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 328(a)

I. INTRODUCTION

This is a Final Written Decision in a post-grant review challenging the patentability of claims 1–29 ("the challenged claims") of U.S. Patent 9,855,302 B2 ("the '302 patent," Ex. 1001). We have jurisdiction under 35 U.S.C. § 6, and enter this Decision pursuant to 35 U.S.C. § 328(a) and 37 C.F.R. § 42.3. For the reasons set forth below, we determine that Genome & Company ("Petitioner") has shown, by a preponderance of the evidence, that the challenged claims are unpatentable. *See* 35 U.S.C. § 326(e) (2012).

A. Background

Petitioner filed a Petition requesting post-grant review of claims 1–29 of the '302 patent. Paper 1 ("Pet."). The University of Chicago ("Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp.").

On April 15, 2019, pursuant to 35 U.S.C. §324(a), we instituted trial to determine whether any of the challenged claims is unpatentable on the grounds raised in the petition. Paper 8 ("Inst. Dec.").

Patent Owner filed a Request for Rehearing of our Decision to Institute. Paper 11. On January 9, 2020, we denied Patent Owner's request. Paper 34.

Patent Owner filed a Patent Owner's Response on August 1, 2019. Paper 17 ("PO Resp."). Petitioner filed a Reply on November 11, 2019.

Paper 23 ("Pet. Reply"). Patent Owner filed a Sur-Reply on December 17, 2019. Paper 29 ("PO Sur-Reply").

On oral hearing was held on January 15, 2020. A copy of the transcript has been made part of the record. Paper 37, 38 (Corrected) ("Tr.").

B. Real Parties in Interest

Petitioner identifies itself, Genome & Company, as the real party in interest. Pet. 3. Patent Owner identifies itself, the University of Chicago, as the real part in interest and Evelo Biosciences, Inc. as an additional real party in interest. Paper 4, 5

C. Related Matters

The parties assert that there are no related matters involving the '302 patent. Pet. 3; Paper 4, 5

D. The '302 Patent

The '302 patent, titled "Treatment of Cancer by Manipulation of Commensal Microflora" issued on January 2, 2018, from U.S. Patent Application No. 15/170,284 filed on June 1, 2016. Ex. 1001, [54], [45], [21], [22]. The '302 patent claims priority to U.S. Provisional Application No. 62/169,112 filed on June 1, 2015, and U.S. Provisional Application No. 62/248,741 filed on October 30, 2015. *Id.* at [60].

The '302 patent teaches the treatment or prevention of cancer through the manipulation of commensal microflora either alone or in combination with one or more co-treatments. Ex. 1001, Abstr.

The '302 patent discloses that aco-treatment can be the administration of an immune checkpoint inhibitor ("CPI").[1] Ex. 1001, col. 5, ll. 7–8. The CPI used in the practice of the invention disclosed in the '302 patent can be a protein of a peptide, an antibody or fragment thereof, or an interfering nucleic acid molecule. *Id*. at col. 5, ll. 7–20.

The '302 patent discloses that one of the microflora that can be used in practice of the disclosed invention is bacteria of the genus *Bifidobacterium*. *Id.* at col. 3, ll. 10–29.

E. Illustrative Claim

Of the challenged claims, claims 1 is the sole independent claim and reads as follows:

> 1. A method of treating cancer in a human subject comprising co-administering to the subject an immune checkpoint inhibitor and a bacterial formulation comprising bacteria of the genus *Bifidobacterium.*

Ex. 1001, col. 41, ll. 61–64.

F. Evidence

Petitioner relies on the following references:

Korman et al., US 2009/0217401 A1, published Aug. 27, 2009 ("Korman") (Ex. 1003).

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[1]Immune checkpoint inhibitors are described as follows: "We have learned over the last decade that powerful immunologic effector cells may be blocked by inhibitory regulatory pathways controlled by specific molecules often called 'immune checkpoints.' These checkpoints serve to control or turn off the immune response when it is no longer needed to prevent tissue injury and autoimmunity." Ex. 1016, Abstr. Drugs that inhibit these pathways are called checkpoint inhibitors and their use is seen as a potential new strategy for treating cancer. *Id.*

Singh et al., *Bifidobacterium longum, a lactic acid-producing intestinal bacterium inhibits colon cancer and modulates intermediate biomarkers of cancer carcinogenesis,* 18 Carcinogenesis 833 (1997) ("Singh") (Ex. 1004).

Dong et al., *The role of intestinal bifidobacteria on immune system development in young rats,* 86 Early Human Devel. 51 (2010) ("Dong") (Ex. 1005).

van der Waaij et al., *The influence of antibiotics on gut colonization,* 18 J. Antimicrobial Chemotherapy 155 (1986) ("van der Waaij") (Ex. 1010).

Topalian et al., *Survival, Durable Tumor Remission, and Long-Term Safety in Patients with Advanced Melanoma Receiving Nivolumab,* 32 J. Clinical Oncol. 1020 (2014) ("Topalian") (Ex. 1006).

Kohwi et al., *Anti-tumor Effects of Bifidobacterium infantis in Mice,* 69 Gann. 613 (1978) ("Kohwi") (Ex. 1007).

Mohania et al., *Modulation of expression of Programmed Death-1 by administration of probiotic Dahi in DMH-induced colorectal carcinogenesis in rats,* 84 Acta Biomed. 102 (2013) ("Mohania") (Ex. 1008).

Prakash et al., US 2010/028449 A1, published Feb. 4, 2010 ("Prakash") (Ex. 1009).

Petitioner also relies on the Declarations of Jonathan Braun, M.D., Ph.D. (Exs. 1002, 1043). Patent Owner relies on the Declaration of Sridhar Mani, M.D. (Ex. 2007).

G. Prior Art and Asserted Grounds

Petitioner asserts that claims 1–29 would have been unpatentable on the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–29	112	Enablement

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