Trials@uspto.gov
571.272.7822

Paper No. 8
Entered: April 15, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENOME & COMPANY,
Petitioner,

v.

THE UNIVERSITY OF CHIGAGO,
Patent Owner.

Case No. PGR2019-00002
Patent 9,855,302 B2

Before SUSAN L. C. MITCHELL, JACQUELINE T. HARLOW, and JOHN E. SCHNEIDER, *Administrative Patent Judges*.

SCHNEIDER, *Administrative Patent Judge*.

DECISION
Institution of Post-Grant Review
35 U.S.C. § 324(a)

I. INTRODUCTION

A. Background

Genome & Company ("Petitioner") filed a Petition requesting post-grant review of claims 1–29 of U.S. Patent No. 9,855,302 B2 (Ex. 1001 "the '302 patent"). Paper 1, ("Pet."). The University of Chicago ("Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp.").

We have authority to determine whether to institute post grant review under 35 U.S.C. § 324, which provides that a post grant review may not be instituted unless the information presented in the Petition, if unrebutted, "would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable." 35 U.S.C. § 324(a). On April 24, 2018, the Supreme Court held that a decision to institute may not institute review on fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1355–56 (2018). Also, in accordance with USPTO Guidance, "if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition." *See Guidance on the Impact of SAS on AIA Trial Proceedings* (April 26, 2018) (available at https://www.uspto.gov/patents-application-process/patent-trial-and-appealboard/trials/guidance-impact-sas-aia-trial).

Having considered the arguments and the evidence presented, for the reasons described below, we determine that Petitioner has demonstrated that it is more likely than not that at least one of the claims challenged in the Petition is unpatentable. Accordingly, we institute a post-grant review of all claims and all grounds asserted in the Petition.

B. Additional Proceedings

Petitioner represents that there are no related matters. Pet. 3.

C. Eligibility for Post Grant Review

Post-grant review is available only for patents "described in section 3(n)(1)" of the Leahy-Smith America Invents Act ("AIA"), Pub L. No. 112-29, 125 Stat. 284 (2011). AIA § 6(f)(2)(A). Those are patents that issue from applications "that contain[] or contained at any time . . . a claim to a claimed invention that has an effective filing date in section 100(i) of title 35, United States Code, that is on or after" "the expiration of the 18-month period beginning on the date of the enactment of" the AIA. *See* AIA § 3(n)(1).

Because the AIA was enacted on September 16, 2011, post-grant review is available only for patents that, at one point, contained at least one claim with an effective filing date, as defined by 35 U.S.C. § 100(i), on or after March 16, 2013. The earliest filing date for the '302 patent is June 1, 2015, which is after the March 16, 2013 date. *See* Ex. 1001 [60].

The AIA also requires that the petition be filed within nine months of the issue date of the patent being challenged. 35 U.S.C. § 321(c). The '302 patent issued on January 2, 2018. Ex. 1001 [45]. The Petition has been accorded a filing date of October 2, 2018, within the nine-month window.

Based on the foregoing, we conclude that the '302 patent is eligible for post-grant review and that Petitioner has timely filed its petition.

D. The '302 Patent (Ex. 1001)

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 '752 patent claims priority to U.S. Provisional Application No. 60/169,112 filed on June 1, 2015, and U.S. Provisional Application No. 60/248,741 filed on October 30, 2015. *Id.* at [60].

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

The ’302 patent discloses that the co-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*. Ex. 1001, col. 3, ll. 10–29.

E. Illustrative Claims

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. The Asserted Grounds of Unpatentability

[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, Abstract. Drugs that inhibit these pathways are called checkpoint inhibitors and their use is seen as a potential new strategy for treating cancer. *Id.*

Petitioner contends that the challenged claims are unpatentable on the following grounds. Pet. 7.

Ground	References	Basis	Claims Challenged
1		§ 112(a) Lack of Enablement	1–29
2	Korman[2], Singh,[3] and Dong[4]	§ 103(a)	1–9, 12–17, 19–25, 27, and 28
3	Korman, Singh, Dong, and van der Waaij[5]	§ 103(a)	10, 11, and 26
4	Korman, Singh, Dong, and Topalian[6]	§ 103(a)	18 and 29
5	Korman and Kohwi[7]	§ 103(a)	1–4, 7–9, 12–17, 19–25, 27, and 28
6	Korman, Kohwi, and Singh	§ 103(a)	5, 6, 23, and 24
7	Korman, Kohwi, and van der Waaij	§ 103(a)	10, 11, and 26
8	Korman, Kohwi, and Topalian	§ 103(a)	18 and 29

[2] Korman et al., US 2009/0217401 A1, published Aug. 27, 2009 ("Korman") Ex. 1003.
[3] 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.
[4] Dong et al., *The role of intestinal bifidobacteria on immune system development in young rats*, 86 EARLY HUMAN DEVEL. 51 (2010) ("Dong") Ex. 1005.
[5] van der Waaij et al., *The influence of antibiotics on gut colonization*, 18 J. ANTIMICROBIAL CHEMOTHERAPY 155 (1986) ("van der Waaij") Ex. 1010.
[6] 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.
[7] Kohwi et al., *Antitumor Effects of Bifidobacterium infantis in Mice*, 69 GANN. 613 (1978) ("Kohwi") Ex. 1007.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.