

By: John A. Bauer
Nelson Mullins Riley & Scarborough LLP
280 Park Avenue, 15th Floor West
New York, NY 10017
(646) 428-2615 (telephone)
(646) 428-2610 (facsimile)

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENOME & COMPANY,
Petitioner

v.

THE UNIVERSITY OF CHICAGO,
Patent Owner

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

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

TABLE OF CONTENTS

	<u>Page</u>
TABLE OF AUTHORITIES	iv
TABLE OF EXHIBITS	v
TABLE OF ABBREVIATIONS.....	x
I. SUMMARY OF ARGUMENT	1
II. THE CLAIMS OF THE ‘302 PATENT ARE INVALID.....	3
A. PO’s Failure to Cite to the ‘302 Specification to Rebut Petitioner’s Lack of Enablement Assertions Confirms the ‘302 Specification Does Not Enable the ‘302 Claims.....	3
1. PO Fails to Address the Broad Scope of the Functionally Claimed CPIs, Broad Genus of <i>Bifodobacterium</i> Species, and Inoperable Routes of CPI and <i>Bifodobacterium</i> Administration	3
2. PO Fails to Deny the ‘302 Specification Does Not Provide Meaningful Guidance to Practice the Claimed Invention.....	6
3. The Undisputed Lack Of Guidance Provided By the ‘302 Specification Combined with The Highly Unpredictable Nature of CPIs and <i>Bifodobacterium</i> to Treat Cancer in Humans Confirms That Extensive and Undue Experimentation Is Required To Practice The Claimed Invention.....	6
B. PO’s Reliance Exclusively on Third Party CPI Publications to Rebut Petitioner’s Lack of Enablement Charge Fails to Rescue the Deficient ‘302 Disclosure.....	7
1. PO’s Reliance Exclusively on Third Party Publications To Supply <i>Necessary</i> Information Missing From the ‘302 Specification Is Not Only Legally Impermissible But Also Substantively Deficient.....	7

2.	Cancer Immunotherapy Is Vastly More Complex and Uncertain Than Simply Targeting Immune Checkpoints.....	12
3.	CPIs Show Low Response Rates In A Limited Number Of Cancers And For Only A Subset Of Cancer Patients Having Those Cancers	13
4.	PO Fails to Rebut Petitioner’s Evidence that Extensive and Undue Experimentation Is Required To Practice the Claims of the ‘302 Patent.....	15
III.	The ‘302 Claims are Obvious (3841 Words Up to Here).....	18
A.	(Ground 2) Korman ‘401 in View of Singh and Dong Render Obvious Claims 1-9, 12-17, and 19-25, and 27-28	18
B.	(Ground 5) Korman ‘401 in View of Kohwi Renders Obvious Claims 1-4, 7-9, 12-17, 19-25, and 27-28.....	21
1.	Claims 5, 6, 9, 10, 11, 23, 24 and 26 Are Obvious	24
C.	Ground (9) Korman ‘401 in View of Mohania and Prakash ‘449 Renders Obvious Claims 1-9, 12-17, and 19-25, and 27-28	25
IV.	CONCLUSION	28

TABLE OF AUTHORITIES

Page(s)

Cases

ALZA Corp. v. Andrx Pharm. LLC, 603 F.3d 935 (Fed. Cir. 2010)8

Enzo Life Sciences, Inc. v. Roche Molecular Systems et al,
928 F.3d 1340 (Fed. Cir. 2019)8

Genentech Inc. v. Novo Nordisk A/S, 108 F.3d 1361 (Fed. Cir. 1997)3, 7

TABLE OF EXHIBITS

Previously Filed Exhibits

Exhibit	Description
1001	U.S. Patent No. 9,855,302
1002	First Declaration of Jonathan Braun, M.D., Ph.D.
1003	U.S. Publication No. 2009/027401 to Korman <i>et al.</i>
1004	Jagveer Singh <i>et al.</i> , <i>Bifidobacterium longum</i> , a lactic acid-producing intestinal bacterium inhibits colon cancer and modulated the intermediate biomarkers of colon carcinogenesis, <i>Carcinogenesis</i> (1997)
1005	Ping Dong <i>et al.</i> , <i>The role of intestinal Bifidobacteria on immune system development in young rats</i> , <i>Early Human Development</i> (2010)
1006	Suzanne L. Topalian <i>et al.</i> , <i>Survival, Durable Tumor Remission, and Long-Term Safety in Patients With Advanced Melanoma Receiving Nivolumab</i> , <i>Journal of Clinical Oncology</i> (Apr. 1, 2014)
1007	Yoshinori Kohwi <i>et al.</i> , <i>Antitumor effect of Bifidobacterium Infantis in Mice</i> , <i>Gann</i> (Oct. 1978)
1008	Dheeraj Mohania <i>et al.</i> , <i>Modulation of expression of Programmed Death-1 by administration of probiotic Dahi in DMH-induced colorectal carcinogenesis in rats</i> , <i>Acta Biomed</i> (2013)
1009	U.S. Publication No. 2010/0028449 to Prakash <i>et al.</i>
1010	D. van der waaij <i>et al.</i> , <i>The Influence of antibiotics on gut colonizastion</i> , <i>Journal of Antimicrobial Chemotherapy</i> (1986)
1011	Do Kyung Lee <i>et al.</i> , <i>Anti-proliferative effects of Bifidobacterium adolescentis SPM0212 extract on human colon cancer cell lines</i> , <i>BMC Cancer</i> , (Oct. 2008)
1012	U.S. Provisional Patent Application No. 62/169,112
1013	U.S. Provisional Patent Application No. 62/248,741
1014	File History of U.S. Patent No. 9,855,302
1015	File History of U.S. Patent Application No. 15/718,735
1016	Elad Sharon <i>et al.</i> , <i>Immune checkpoints in cancer clinical trials</i> , <i>Chinese Journal of Cancer</i> (2014)
1017	U.S. Publication No. 2012/0276143 to O'Mahony <i>et al.</i>

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.