

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

PATENT OWNER SUR-REPLY

TABLE OF CONTENTS

I. INTRODUCTION: BURDEN OF PROOF	1
II. THE PERSON OF ORDINARY SKILL IS NOT AN AUTOMATON.....	1
III. ENABLEMENT – Ground 1	3
A. Cancer types	3
B. Checkpoint inhibitors	5
C. <i>Bifidobacterium</i> species and strains	8
1. O’Mahony	9
2. Lopez.....	10
D. Routes of administration	11
E. Routine testing.....	12
F. Conclusion.....	13
IV. OBVIOUSNESS.....	13
A. Korman/Singh/Dong – Grounds 2–4.....	13
B. Korman/Kohwi – Grounds 5–8	17
C. Korman/Mohania/Prakash – Grounds 9–11	20
V. CONCLUSION.....	23

I. INTRODUCTION: BURDEN OF PROOF

Patent Owner has shown that Petitioner’s evidence is insufficient to prove the factual predicates required to reach the conclusions that the claims are unpatentable for lack of enablement or for obviousness. Petitioner largely sidesteps Patent Owner’s Response by inaccurately portraying it as a “proof of enablement” (Reply 8) or “obviousness rebuttal” (*id.* at 2). It is not Patent Owner’s burden to prove enablement or nonobviousness. Rather, Patent Owner has presented evidence of gaps, unwarranted assumptions, and flat-out inaccuracies in Petitioner’s case, defects that compel the conclusion, as a matter of law, that Petitioner has not and cannot satisfy its burden to prove unpatentability by a preponderance of the evidence under 35 U.S.C. § 326(e).

II. THE PERSON OF ORDINARY SKILL IS NOT AN AUTOMATON

Petitioner argues that the person of ordinary skill in this case would have “an advanced degree or its substantial equivalent” and “research experience” in the biological sciences. Ex. 1002 ¶ 40. Petitioner also argues that the level of skill is high, requiring specialized knowledge of several fields. Pet. 37 (citing Ex. 1002 ¶ 132). Inherent in the concept of a person of ordinary skill in the art holding an advanced degree, specialized knowledge, and research experience, is the ability to review the scientific literature critically and to evaluate it.

Yet at numerous points in its challenges, Petitioner argues that its highly sophisticated POSA would have blindly accepted the conclusions of research papers, despite demonstrated limitations in experimental design and discrepancies in statistical analysis, because these papers were peer-reviewed and cited by others. Reply 2, 3, 10, 18–20, 22, 23.

Mere publication of results does not make those results true, nor does it constitute credible evidence of what one of ordinary skill would rely on *per se*. Petitioner’s POSA would be a critical reviewer of the literature and not credit conclusions backed by irreproducible data or speculation. *E.g.*, Ex. 2007 ¶ 136 (Dr. Mani testifying that a POSA would have dismissed Kohwi’s results due to their irreproducibility).

Petitioner has not contested Dr. Mani’s critiques of the statistical shortcomings in several papers on which Petitioner’s case critically relies, including Dong (PO Resp. 57; Ex. 2007 ¶¶ 118–121), Kohwi (PO Resp. 63–65; Ex. 2007 ¶¶ 136–140), O’Mahony (PO Resp. 20–23; Ex. 2007 ¶¶ 57–66), and Lopez (PO Resp. 24–36; Ex. 2007 ¶¶ 70–88). Nor has Petitioner responded to the substance of Patent Owner’s argument that a POSA would have questioned these papers given their dubious statistics. Petitioner instead stands on its insistence that its highly trained, skilled, and experienced POSA

would simply accept statements from these papers as true without critical analysis. But just as a POSA would bring to bear a complete knowledge of the relevant prior art and an ordinary creativity in synthesizing that art, *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420–21 (2007), so too would the POSA recognize the limitations of the prior art and refuse to credit its conclusions on insufficient evidence. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1550 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984) (each prior art reference must be considered in its entirety).

III. ENABLEMENT – Ground 1

Enablement is a question of law based upon underlying factual findings. *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991). Petitioner's allegations therefore must be supported by sufficient and credible evidence to justify their finding. Patent Owner has shown, however, that Petitioner's evidence does not support the factual allegations critical to Petitioner's enablement challenge. Patent Owner also has shown through evidence presented in its Response that Petitioner's assertions of uncertainty and unpredictability are premised on unwarranted assumptions. For these reasons, Petitioner's enablement challenge should be rejected.

A. Cancer types

Although Petitioner argues that cancer is a large class of widely varying

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.