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

IPR Trial No. IPR2022-00853
U.S. Patent No. 9,464,140
Issue Date: October 11, 2016

Title: Compositions and Methods for Treatment of Cancer

PETITIONER'S REQUEST FOR REHEARING OF INSTITUTION DECISION

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Other Authorities

Petitioner respectfully requests rehearing pursuant to 37 C.F.R. § 42.71(d) of the Board's Decision Denying Institution, Paper 11 ("'140 Decision") for Grounds 1-3, with respect to U.S. Patent No. 9,464,140 ("'140 patent"). A request for rehearing of a non-institution decision should be granted "if a decision is based on an erroneous interpretation of law, if a factual finding is not supported by substantial evidence, or if an unreasonable judgment is made in weighing relevant factors." *Sand Revolution II, LLC v. Continental Intermodal Grp. - Trucking LLC*, IPR2019-01393, Paper 24, at 4 (PTAB June 16, 2020). That is what happened here.

In Grounds 1-2, the '140 Decision erred in its interpretation of the law governing reasonable expectation of success for a method of treatment. The '140 Decision relied on *OSI Pharms., LLC v. Apotex Inc.*, 939 F.3d 1375 (Fed. Cir. 2019)—a case mischaracterized by Patent Owner as being "directly on-point"—in concluding that there was no reasonable expectation of success for practicing the method of claim 1 using a prior-art composition with successful in vitro data and a compelling recommendation for clinical use.

The '140 Decision incorrectly described *OSI* as a case where there was successful in-vitro data in the prior art for the composition employed in the method of treatment claim. There was no such data in *OSI*. The *OSI* decision stands only for the uncontroversial proposition that ***lack of in-vitro data*** can defeat a reasonable expectation of success. Based on this misreading of *OSI*, the Board applied an

unduly heightened standard for reasonable expectation of success that is contrary to the Federal Circuit precedent of *Genzyme Therapeutic Prods. v. Biomarin Pharm.*, 825 F.3d 1360 (Fed. Cir. 2016). In *Genzyme*, like here, the prior art disclosed the claimed composition, provided successful in vitro data, and suggested initiating clinical trials. *Id.* at 1364. The Federal Circuit reasoned that a method of treatment claim was obvious when "there was little left to do but to confirm that the strategy suggested by the various prior art references would work." *Id.* at 1373. So too here.

Due to the erroneous interpretation of *OSI*, the '140 Decision also is at odds with this Board's Decision Granting Institution in related IPR2022-00855 ("'445 Decision") for U.S. Patent No. 9,540,445 ("'445 patent"). The independent claim of this sibling is nearly identical: the '445 patent is directed to a "pharmaceutical composition," whereas the '140 patent is directed to a "method of treating cancer in a human patient" using the same pharmaceutical composition of the '445 patent. In the '445 Decision, the Board found that a nearly identical claim directed to a "pharmaceutical composition comprising an anti-tumor effective amount"—the very same claim language present in the '140 patent—was reasonably likely to be found obvious. Under Federal Circuit precedent, including the law of inherency, a method that treats patients with the very same pharmaceutical composition, in the very same "anti-tumor effective amount," would also be just as obvious.

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.