UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MILTENYI BIOMEDICINE GmbH and MILTENYI BIOTEC INC.,

Petitioners,

v.

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA,

Patent Owner.

Case No.: IPR2022-00853
U.S. Patent No. 9,464,140

PETITIONERS' REPLY TO REQUEST FOR REHEARING

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The Board's Decision is an outlier: declining to institute on a method of treatment claim when the prior art disclosed a clinical trial using the claimed composition according to the claimed method. This was a situation where "there was little left to do but to confirm that the strategy suggested by the various prior art references would work." *Genzyme Therapeutic Prod. v. Biomarin Pharm.*, 825 F.3d 1360, 1374 (Fed. Cir. 2016). Patent Owner has failed to point to any Federal Circuit case with similar facts and a finding of non-obviousness.

Patent Owner attempts to characterize the challenged claim as a "new method of treatment." Resp. at 11. It is not. The reference CART-19 Clinicaltrials.gov taught using the claimed composition (Campana) in a cancer patient population with a dose that practices the challenged claims. Claim 1 requires nothing else, so there is no "new method of treatment" here. Patent Owner did nothing more than report the results of a prior-art clinical trial that practiced the claimed method.

OSI Pharms. v. Apotex, 939 F.3d 1375 (Fed. Cir. 2019) does not support a finding of non-obviousness. In *OSI*, there was no disclosure of details for a clinical trial practicing the claimed method. Nor was there in-vitro data suggesting the method claimed: treating non-small cell lung cancer (NSCLC). That is the opposite of the facts here, where the challenged claims broadly cover ***all*** cancers, and the prior art disclosed successful in-vitro data for leukemia cancer cells.

The Board's Decision is also an outlier in its discretionary denial of Ground 3: denying institution when the reference (Milone) was overcome only because of a claim limitation not found in the challenged claim 1 here. Petitioner's Request for Rehearing identified two decisions holding that Section 325(d) denial was inappropriate in this scenario. Patent Owner has pointed to no contrary case law.

I. Erroneous Interpretation of Law Concerning Reasonable Expectation of Success For Methods of Pharmaceutical Treatment

It is undisputed that in *OSI*, there was lack of in-vitro data showing success in ***treating the disease that was claimed***. Not so here.

In *OSI*, there was in-vitro efficacy data for erlotnib against certain cancers other than NSCLC. *OSI*, 939 F.3d at 1380. But there was no in-vitro data against NSCLC cancer cells. *Id.* at 1385. The Federal Circuit held, on that basis, there was no reasonable expectation of success for the challenged, narrow claims directed to NSCLC treatment: "[H]ope that a potentially promising drug will treat a ***particular*** cancer is not enough to create a reasonable expectation of success in a highly unpredictable art such as this." *Id.*; *id.* at 1384 (noting that "the lack of erlotnib-***NSCLC efficacy data*** or other indication of success [was] significant"). Here, claim 1 broadly claims "anti-tumor effect[]" and is not limited to any particular cancer. And the successful prior-art in-vitro data was for leukemia, Decision at 21, indisputably falling within the scope of claim 1.

The *Genzyme* case, in contrast, is factually on point and controlling for reasons discussed in the Request at pages 5-7 (and previously in the Petition at page 37). In Response, Patent Owner mischaracterizes the "record" in *Genzyme* as showing "no failure—clinical or otherwise." Resp. at 5. That is not correct. In *Genzyme*, there were decades of failed efforts to treat Pompe disease with enzyme replacement therapy. *Genzyme*, 825 F.3d at 1365 (acknowledging that "research efforts were focused on treating the disease through enzyme replacement therapy" but those "early efforts failed"); *Genzyme*, IPR 2013-00534, Paper 81 at 20 ("The evidence and arguments cited by Patent Owner highlight the difficulties faced in the development of an enzyme replacement therapy for Pompe disease over a period of decades.").

Despite the failures, the Federal Circuit held that because there was successful in-vitro data and a proposed clinical trial, no patent could be issued for merely reporting the trial results: "there was little left to do but to confirm that the strategy suggested by the various prior art references would work." *Genzyme*, 825 F.3d at 1374. That is the exact situation here.

II. Irreconcilable Inconsistency With Institution in Related IPR2022-00855

Patent Owner argues that there is no inconsistency with the institution decision in IPR2022-00855 because the Board only found it obvious to "make the compound and put it on a shelf." Resp. at 12. That is not what the Board found.

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