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Paper 18
Entered: February 17, 2023

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

IPR2022-00853
Patent 9,464,140 B2

Before ULRIKE W. JENKS, SUSAN L. C. MITCHELL, and ROBERT A. POLLOCK, *Administrative Patent Judges.*

POLLOCK, *Administrative Patent Judge*

DECISION
Denying Petitioner's Request for Rehearing
of Decision Denying Institution of Inter Partes Review
37 C.F.R. § 42.71(d)

I. INTRODUCTION

Miltenyi Biomedicine GmbH and Miltenyi Biotec Inc. (collectively, "Petitioner") requests rehearing of our decision (Paper 11, "Decision" or "Dec.") denying institution of *inter partes* review of claims 1–19 and 21–28 of U.S. Patent No. 9,464,140 B2 ("the '140 Patent," Ex. 1001). Paper 12 ("Request" or "Req."). With our authorization, Patent Owner filed a Response to the Request (Paper 15, "Response" or "Resp."), Petitioner filed a Reply in support of its Request (Paper 16, "Reply"), and Patent Owner filed a Sur-reply (Paper 17, "Sur-reply").

We deny the Request for the reasons explained below.

II. STANDARD OF REVIEW

In response to a request for rehearing, the panel reviews a decision whether to institute trial for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion may be found if there was an erroneous interpretation of law, a factual finding not supported by substantial evidence, or an unreasonable judgment in weighing relevant factors. 37 C.F.R. § 42.71(c); *Star Fruits S.N.C. v. U.S.*, 393 F.3d 1277, 1281 (Fed. Cir. 2005); *The Arnold Partnership v. Dudas*, 362 F.3d 1338, 1340 (Fed. Cir. 2004); *In re Gartside*, 203 F.3d 1305, 1315–16 (Fed. Cir. 2000). "The burden of showing a decision should be modified lies with the party challenging the decision." 37 C.F.R. § 42.71(d). The rehearing request "must specifically identify all matters the [requesting] party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply." *Id.*

III. OVERVIEW OF PETITIONER'S REQUEST

Our Decision addressed the four Grounds challenging claims of the '140 patent. Dec. 4. Petitioner challenges our analysis of Grounds I and II as based on an erroneous "interpretation of the law governing reasonable expectation of success." Req. 1. With respect to Ground III, Petitioner contends that we incorrectly interpreted the prosecution record resulting in an unreasonable weighing of the relevant *Advanced Bionics* factors. *See id.* at 3. Petitioner does not challenge our analysis of Ground IV.

IV. GROUNDS I and II

In denying institution, we determined that Petitioner did not establish sufficiently that a one of ordinary skill in the art would have been motivated to practice the challenged method claims with a reasonable expectation of success, "[c]onsidering the inherent unpredictability of the field and the history of failure of similar technology." Dec. 41. We noted in our Decision that "[t]he claims at issue in *OSI Pharms.*, were structurally similar to those at issue here and directed to a method of treating non-small cell lung cancer ("NSCLC") in a mammal using a therapeutically effective amount of erlotinib, which had previously been shown to inhibit the epidermal growth factor receptor ("EGFR") in vitro." Dec. 40 (citing *OSI Pharms., LLC v. Apotex Inc.*, 939 F.3d 1375, 1378–79 (Fed. Cir. 2019)). We also noted the *OSI* court's reasoning that:

> Cancer treatment is highly unpredictable. Even though the EGFR was identified in some cancers as a drug target, the *in vitro* (i.e., in a test tube) effectiveness of a drug in inhibiting the EGFR turned out to be a poor proxy for how effective that drug actually was in treating cancer *in vivo* (i.e., in the body).

> Numerous EGFR inhibitors that showed promising *in vitro* activity failed for a variety of reasons.

Id. (quoting 939 F.3d at 1377). We further noted the *OSI* court's description of high failure rates for NSCLC treatments, and its finding that

> the asserted references do not disclose *any* data or other information about erlotinib's efficacy in treating NSCLC. The record does not contain any clinical (human) data or preclinical (animal) data. It does not even include *in vitro* (test tube) data regarding erlotinib's effect on NSCLC.

Id. (quoting 939 F.3d at 1384).

Petitioner now argues that we misapprehended the facts underlying the court's decision in *OSI*, and abused our discretion in analogizing the facts of the present case to *OSI* rather than to *Genzyme Therapeutic Prods. v. Biomarin Pharm.*, 825 F.3d 1360 (Fed. Cir. 2016). Req. 4–9. Petitioner asserts that "the *OSI* facts are . . . diametrically opposed to the facts here," and contends that we

> misunderstood the *OSI* decision as finding that "erlotinib [] ***had previously been shown*** to inhibit the epidermal growth factor receptor ('EGFR') ***in vitro***." *Id.* In fact, just the opposite was true: the prior art did "***not*** even include *in vitro* (test tube) data regarding erlotinib's effect on NSCLC."

Req. 8–9 (quoting *OSI*, 939 F.3d at 1383); *see* Reply 2.

We did not misunderstand the facts underlying *OSI*; rather, Petitioner suggests a false equivalency between erlotinib's *in vitro* inhibition of EGFR and *in vitro* data regarding erlotinib's effect on NSCLC that is not reflected in our Decision. Consistent with our description, the *OSI* court explained that "erlotinib inhibits the EGFR and has good anticancer activity in some cancers," but that the art did not encompass "in vitro . . . data regarding

erlotinib's effect on NSCLC," nor teach "efficacy in treating NSCLC." *See OSI* at 1383, 1384; Dec. 40. Although we found that *in vitro* data of record placed Petitioner in a "somewhat better" position than that described in *OSI*, we weighed Petitioner's evidence against Patent Owner's evidence of "the inherent unpredictability of the field and the history of failures of similar technology," and the lack of "clinical (human) data or preclinical (animal) data" highlighted in *OSI*. *Id.* at 40–41 (citations omitted).

In addressing unpredictability of the field and the history of failures, the *OSI* court stated that "[t]he lack of erlotinib-NSCLC efficacy data or other indication of success here is significant because of the highly unpredictable nature of treating NSCLC, which is illustrated by the over 99.5% failure rate of drugs entering Phase II." *OSI* at 1384. Petitioner, however, argues that *OSI* is distinguishable, because "[i]n the field of CD19-directed CAR T-cell therapy before 2010, there were nine other trials aside from the one described by CART-19 ClinicalTrials.gov." Req. 8 (citing Ex. 2037, 1036). According to Petitioner, the record "provided evidence of positive results in three of them." *Id.* at 8–9 (citing Pet., 36; Ex. 1002 ¶¶ 178-84). In describing the latter three trials, Petitioner asserts that "[a] POSA would have also known that several other anti-CD19 CAR T cells in the art had been used successfully in cancer patients, indicating that at a minimum, there would be a decrease in the number of tumor cells." Pet. 36.

But we also considered Patent Owner's evidence that "[t]he literature was so riddled with failed CAR-T cell therapy experiments that "[i]nfluential scientists [at the National Institutes of Health] didn't think engineered T cells could ever work." Prelim. Resp. at 3 (citing Ex. 2001 at

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