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

PATENT OWNER'S RESPONSE TO PETITIONER'S REQUEST FOR REHEARING OF INSTITUTION DECISION

(authorized by Order of November 23, 2022, Ex. 3004)

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STATUTES AND REGULATIONS

35 U.S.C. § 325(d) 13, 15

37 C.F.R. § 42.71(c) & (d).....2

37 C.F.R. § 42.71(d) 3, 7

Miltenyi's Request for Rehearing of the Board's decision not to institute trial on U.S. Patent No. 9,464,140 (the "'140 patent") comes nowhere close to establishing that the Board misapprehended or overlooked a dispositive argument for institution. In a thorough opinion, the Board considered Miltenyi's arguments and evidence and concluded that given "the inherent unpredictability of the field" and "the history of failures of similar technology," Miltenyi was not likely to demonstrate a reasonable expectation of success on Grounds 1 and 2. In Ground 3, it then exercised its discretion not to revisit the same reference the Examiner considered in detail. The Board properly denied institution.[1]

Unable to undermine the Board's critical factual predicates, Miltenyi argues as to Grounds 1 and 2 that the Board got the law wrong when it analogized this case to *OSI v. Apotex*, 939 F.3d 1375 (Fed. Cir. 2019). But the Board was correct—and certainly did not misapprehend or overlook anything—when it concluded that the facts of this case mirror *OSI*'s and that there would have been no reasonable expectation of success. Miltenyi's favored case, *Genzyme v. Biomarin*, 825 F.3d 1360 (Fed. Cir. 2016), does not permit the Board to sidestep the reasonable expectation analysis when there is a teaching or motivation or a pending clinical trial; it simply held on the facts of that case—where unlike here

[1] Petitioner does not challenge the Board's decision to not institute on Ground 4.

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