

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Merck Sharp & Dohme LLC,
Petitioner

v.

The Johns Hopkins University,
Patent Owner

Case IPR2024-00240
Patent 11,591,393

AUTHORIZED RESPONSE TO DIRECTOR REVIEW REQUEST

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I. INTRODUCTION

After litigating on the merits and losing, JHU tries to erase the prior work of the Board by asking the Director to order that this proceeding, and multiple related proceedings, should have never been instituted. But JHU does not challenge the correctness of the Board's thorough merits analysis. Instead, JHU presents a misleading and unsupported narrative about Merck to distract from its loss. JHU's Request is highly improper and should be denied.

These IPR proceedings are the direct result of JHU's gamesmanship. JHU signed a contract with Merck to collaborate on a study regarding the treatment of cancer patients with Merck's drug pembrolizumab. At the time, Merck's drug was far along in development, covered by Merck's patents, and was showing efficacy in treating cancer patients. Merck provided JHU Merck's drug, free of cost, and otherwise supported the joint study. The treatment method was published in the MSI-H Study Record ("MSR"). Over two years after publication of the MSR, and without informing Merck, JHU filed for patent claims covering the MSR treatment method—which the Board ultimately found anticipated and obvious by the MSR. JHU used this same previously published treatment method to create a series of repetitive patents (the subject of the remaining eight IPRs). And then JHU demanded that Merck pay JHU hundreds of millions of dollars, tied to Merck's sales of Merck's own product.

To address the situation, Merck sued JHU for *breach of contract* and related relief of non-infringement. For example, Merck cannot be liable for infringement of any JHU patent because its contract with JHU provides that Merck has the right to use all data generated by the Parties' joint study for any legitimate business purpose, which includes using the data in combination with additional Merck studies to seek certain FDA-approved cancer indications. JHU's Request fails to disclose these facts to the Director. When JHU counterclaimed alleging infringement of its patents, Merck promptly filed IPRs, as permitted by statute.

JHU had more than a full and fair opportunity to present its case. JHU received a *25% increased word limit* for its POR (Paper 36), relied on *six* different declarations and *more than 400 pages* of testimony, and argued for more than *105 minutes* at the oral hearing. JHU's Request also relies on misrepresentations about the process it has been afforded by the USPTO. JHU tells the Director that it requested cancellation of the hearings in related proceedings because the Board did not provide it with sufficient argument time. (Paper 91, 4.) That is knowingly false. As JHU told the Board in asking for cancellation, "Patent Owner raised with Petitioner requesting cancellation of the upcoming oral hearings,"¹ and did so "[i]n light of the Board's Final Written Decision in IPR2024-00240 and in an effort to

¹ JHU was allotted 90 minutes of argument time, with the Board specifically noting it could be flexible if more time would be needed. (*E.g.*, IPR2024-00622, Paper 56, 2; IPR2024-00648, Paper 46, 2.)

conserve both the Board and the Parties’ resources.” (IPR2024-00622, EX3009.)

JHU itself has acknowledged its patents have “similar (if not identical)” issues of validity. *Merck Sharp & Dohme LLC v. The Johns Hopkins Univ.*, No. 1-22-cv-03059-JRR, D.I. 51, at 4 (D. Md. Aug. 24, 2023) (JHU statement).

Neither efficiency nor principles of avoiding undue prejudice are served by granting JHU’s Request to vacate the Final Written Decision (“FWD”) and overturn the institution decisions in this and the eight additional proceedings that are fully briefed and awaiting FWD.

II. ARGUMENT

A. JHU Improperly Attempts to Challenge the Institution Decisions

A request for Director Review of a FWD should not be directed to issues related to institution. (Director Review Process, § 2.B., *available at* <https://www.uspto.gov/patents/ptab/decisions/director-review-process> (“a request for Director Review of a final decision is not an opportunity to raise issues related to the Board’s decision on institution, for example, . . . how the Board exercised the Director’s institution discretion”).) Further, the Director has explained that she “will not consider new evidence or new arguments not part of the official record.” (*Id.*, § 3.E.) JHU’s Request runs afoul of the Director’s guidance.

JHU’s reliance on the updated discretionary denial of institution process and related USPTO guidance is misplaced. (Paper 91, 8-11). By its own terms, the

updated guidance does not apply to this or the related IPR proceedings filed by Merck. (Interim Processes for PTAB Workload Management (Mar. 26, 2025) (“Interim Processes”), 3.) JHU’s Request also improperly makes an unauthorized request for review in the other proceedings between Merck and JHU not part of the record of the instant proceeding. (Paper 91, 5, 15 (requesting the Director to “terminate all nine proceedings” between Merck and JHU).)

B. JHU’s Request Seeks to Promote Inefficiency, Waste the PTAB’s Resources, and is Based on Mischaracterizations

JHU’s Request to unwind this and the related IPR proceedings and force the district court, and possibly a jury, to consider validity issues for the first time anew does not align with the Director’s “aim[s] to improve PTAB efficiency.” (Interim Processes, 3.) No efficiencies are gained in this matter by de-instituting the statutorily permitted proceeding after the trial has concluded and the FWD has issued. *See Innoscience (Zhuhai) Tech. Co., Ltd. et al. v. Efficient Power Conversion Corp.*, IPR2023-01381, Paper 55, at 2 (June 10, 2025) (“[h]aving already conducted a trial and issued a Final Written Decision, the Office will not gain any efficiencies by terminating this proceeding”).) Indeed, the Board is best suited to review a proceeding like this one involving nine overlapping patents asserted against Merck in response to a breach of contract claim. *Tesla, Inc. v. The United States of America*, IPR2025-00341, Paper 12, at 2-3 (June 13, 2025).

JHU asks the Director to override the plain language of 35 U.S.C. § 315(a) to

find Merck’s IPR challenge impermissible based on a purported “DJ loophole” and unfounded allegations of “gamesmanship.” (Paper 91, 8-15.) Even if there may be a case where a “DJ loophole” could counsel against institution, this is not it. The institution decision was more than a year ago, with a prior JHU request for Director Review of the institution decision on a different issue (which was denied), full briefing on the merits, oral argument, and a final decision rendering all 42 claims unpatentable as both anticipated and obvious. And JHU’s eight remaining patents, which JHU itself has recognized present “similar (if not identical)” issues (*supra*, 2-3) and provide “no reason to believe that the Board will decide differently” regarding validity (Paper 91, 4), will soon receive final decisions.

JHU’s Request also relies on numerous mischaracterizations and accusations: (1) JHU’s allegations about the Parties’ “licensing negotiations” and study funding are misleading, (2) JHU, not Merck, sought to litigate in two forums by opposing Merck’s stay request after the Board instituted trial, (3) JHU was not deprived of discovery (JHU sought specific documents that did not exist (*e.g.* sales by FDA-approved indication (Paper 30, 1-5)) and Merck suggested IQVIA data as a cooperative resolution), and (4) Merck was consistent in claim construction positions as the Board’s detailed analysis in the FWD reflects (Paper 90, 14-15).

III. CONCLUSION

Merck respectfully requests that the Director deny Director Review.

Respectfully submitted,

Dated: July 7, 2025

By: /Preston K. Ratliff II/
Preston K. Ratliff II (Reg. No. 43,034)
Naveen Modi (Reg. No. 46,224)
Bruce M. Wexler (Reg. No. 35,409)
Daniel Zeilberger (Reg. No. 65,349)
Dana R. Weir (Reg. No. 55,865)
Jessica Stauring (*pro hac vice*)

Counsel for Petitioner

CERTIFICATE OF SERVICE

I hereby certify that I caused to be served on the counsel identified below a true and correct copy of the foregoing Authorized Response to Director Review Request by electronic means on July 7, 2025:

Nicholas Stephens
Grace J. Kim
Todd G. Miller
Frank E. Scherkenbach
Corrin N. Drakulich
Christina D. Brown-Marshall
Casey M. Kraning
Madelyn S. McCormick
Sarah E. Jack
Kristi L.R. Sawert
Caroline Koonce
Fish & Richardson P.C.
IPR52261-0005IP1@fr.com

Respectfully submitted,

Dated: July 7, 2025

By: /Preston K. Ratliff II/
Preston K. Ratliff II (Reg. No. 43,034)
Counsel for Petitioner