

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 B2

**PATENT OWNER'S NOTICE OF OBJECTIONS TO
NEW ARGUMENTS AND EVIDENCE**

As authorized in the Board’s Order (Paper 82), Patent Owner respectfully submits its objections to Petitioner’s arguments and/or evidence that were improperly raised for the first time during the March 31, 2025, oral hearing (“the oral hearing”). *See* PTAB Consolidated Trial Practice Guide, 85 (Nov. 2019) (providing that, during an oral hearing, a party “may only present arguments relied upon in the papers previously submitted”); *Dell Inc. v. Acceleron, LLC*, 818 F.3d 1293, 1301 (Fed. Cir. 2016) (stating that, because a patent owner is entitled to notice and fair opportunity to respond, no new evidence or arguments may be presented at PTAB’s oral hearing); *St. Jude Med., Cardiology Div., Inc. v. The Bd. of Regents of the Univ. of Mich.*, IPR2013-00041, Paper 65, 2–3 (PTAB Jan. 27, 2014) (explaining that demonstratives may not present new arguments even if those arguments are based on evidence of record); *see also* Tr., 112:11-13; 122:17-18; Order, Paper 65 at 2 (Feb. 20, 2025) (stating that “Petitioner may reserve rebuttal time to ***respond to arguments*** presented by Patent Owner.” (emphasis added)).

Citations to the transcript of the oral hearing are provided below. For each, Patent Owner objects to cited portions of the transcript because Petitioner’s arguments/demonstratives were improperly raised for the first time during the oral hearing, and/or because Petitioner’s arguments/demonstratives were outside the scope of proper rebuttal.

<u>Relevant Transcript Citations</u>	<u>Objections</u>
Page 39, lines 20-23	Petitioner's arguments were improperly raised for the first time during the oral hearing because Petitioner never argued that a presumption of nexus applies to product patents but not to method of treatment patents in its Petition or Reply.
Page 102, lines 5-9	Petitioner's arguments were improperly raised for the first time during the oral hearing because Petitioner did not dispute in its Petitioner's Reply Patent Owner's evidence (presented in the POR) that a doctor following the Keytruda label practices the claims of the '393 Patent.
Page 111, lines 6-10	Petitioner's arguments and/or evidence were improper rebuttal because neither Petitioner nor Patent Owner addressed JHU's IND or statements made therein during their direct arguments or in their demonstratives.
Page 112, line 24 to page 113, line 16	Petitioner's arguments and/or evidence were improper rebuttal because neither Petitioner nor Patent Owner addressed JHU's IND or statements made therein during their direct arguments or in their demonstratives.
Page 117, lines 6-16	Petitioner's arguments and/or evidence were improperly raised for the first time during the oral hearing because Petitioner neither cited this testimony from its expert nor raised arguments relating to that testimony in its Petition, Reply, or demonstratives, including improperly creating impromptu demonstratives during the hearing.
Page 117, line 21 to page 118, line 12	Petitioner's arguments and/or evidence were improperly raised for the first time during the oral hearing because Petitioner neither cited this testimony from its expert nor raised arguments

	relating to that testimony in its Petition, Reply, or demonstratives, including improperly creating impromptu demonstratives during the hearing.
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For at least the above reasons, Patent Owner objects to the untimely raised arguments and evidence identified above and submits that they should not be considered. *See Dell*, 884 F.3d at 1369 (holding that the Board is obligated under its own regulations to dismiss untimely argument “raised for the first time during oral argument”); Order, Paper 65 at 3.

Respectfully submitted,

Date: May 6, 2025

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(4) and 42.205(b), the undersigned certifies that on May 6, 2025, a complete and entire copy of this Patent Owners Objections was provided via email to the Petitioner by serving the correspondence address of record as follows:

Naveen Modi (Reg. No. 46,224)
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Preston K. Ratliff II (Reg. No. 43,034)
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