

Filed: May 12, 2025

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

**PETITIONER'S RESPONSE TO
PATENT OWNER'S NOTICE OF OBJECTIONS**

Pursuant to the Board's Orders dated April 2, 2025 (Paper 82) and May 1, 2025 (Paper 83), Petitioner Merck submits this response to Patent Owner JHU's Notice of Objections to Merck's rebuttal in the oral hearing.¹ As reflected below, Merck did not improperly raise new arguments or rely upon new evidence during the oral hearing. *See Chamberlain Grp., Inc. v. One World Techs., Inc.*, 944 F.3d 919, 924-25 (Fed. Cir. 2019) ("We understand the reference to 'arguments' [in the PTO guidelines] to refer to *new issues*. Parties are not barred from *elaborating on their arguments* on issues previously raised.") (emphasis added) (citing *Interactive Gift Express, Inc. v. CompuServe Inc.*, 256 F.3d 1323, 1347 (Fed. Cir. 2001)).

Page 39, lines 20-23: Merck made the indisputable argument that the '393 patent is not a product patent and does not have claims directed to a product, which is supported by its Reply at pages 2 and 5, and argued that JHU's alleged secondary considerations are tied to the Keytruda product and the Keytruda product is claimed by Merck's patents as explained in its Reply at pages 4, 23, 27, and 29 31 and by its declarants Drs. Oberstein and Sheridan at EX1150, ¶187 and EX1151, ¶¶22-24,

¹ The Board should not consider JHU's first two objections because they are waived. JHU cites Merck's *opening*, which was not subject to objection in JHU's response or rebuttal. The Board also did not authorize JHU to file objections to Merck's opening argument. *See* Paper 82 at 2 ("The notice shall identify with particularity which portions of Petitioner's *rebuttal* are objected to...") (emphasis added); *see also* Tr., 122:16-25 (JHU requesting post-hearing briefing to "deal with those new arguments that were raised during Petitioner's rebuttal").

26-35, and, based on these prior arguments Merck noted a presumption of nexus here is not warranted.

Page 102, lines 5-9: Merck argued that JHU's alleged secondary considerations evidence are tied to the Keytruda product and the Keytruda product is claimed by Merck's patents as explained in its Reply at pages 4, 23, 27, and 29-31 and by its declarants Drs. Oberstein and Sheridan at EX1150, ¶187 and EX1151, ¶¶22-24, 26-35, thereby undermining any alleged presumption of nexus based on the Keytruda labeling.

Page 111, lines 6-10: Merck highlighted JHU's pre-patent filing representations to the FDA (Tr., 111:3-113:16) to rebut JHU's arguments made during JHU's response portion of its argument regarding (1) the MSR as an alleged "invitation to investigate" (Tr., 63:18-66:6), (2) the state of the prior art (Tr., 80:22-82:13), and (3) the alleged unexpectedness of the MSI-H Study results (Tr., 88:1-89:22), all of which Merck disputed in its Reply at 7, 17-18, 20-23, 24-25, and Merck and its declarant, Dr. Oberstein, previously discussed JHU's pre-patent filing representations to the FDA in Merck's Reply (Reply at 20-21, 22-23, 24) and Dr. Oberstein's declaration (EX1150, ¶¶35-51, 115-116, 182, 184).

Page 112, line 24 – Page 113, line 16: Merck highlighted JHU's pre-patent filing representations to the FDA (Tr., 111:3-113:16) to rebut JHU's arguments made during JHU's response portion of its argument regarding (1) the MSR as an

alleged “invitation to investigate” (Tr., 63:18-66:6), (2) the state of the prior art (Tr., 80:22-82:13), and (3) the alleged unexpectedness of the MSI-H Study results (Tr., 88:1-89:22), all of which Merck disputed in its Reply at 7, 17-18, 20-23, 24-25, and Merck and its declarant, Dr. Oberstein, previously discussed JHU’s pre-patent filing representations to the FDA in Merck’s Reply (Reply at 20-21, 22-23, 24) and Dr. Oberstein’s declaration (EX1150, ¶¶35-51, 115-116, 182, 184).

Page 117, lines 6-16: Merck did not present new arguments or evidence regarding unpatentability based on the MSI-H Study Record in combination with Pernot, nor did Merck affirmatively rely on this deposition testimony, but rather Merck displayed deposition excerpts to provide necessary context regarding JHU’s impermissible mischaracterization in its responsive argument citing Dr. Neugut’s deposition testimony (EX2163 at 151:17-152:6).

Page 117, line 21 – Page 118, line 12: Merck did not present new arguments or evidence regarding unpatentability based on the MSI-H Study Record in combination with Pernot, nor did Merck affirmatively rely on this deposition testimony, but rather Merck displayed deposition excerpts to provide necessary context regarding JHU’s impermissible mischaracterization in its responsive argument citing Dr. Neugut’s deposition testimony (EX2163 at 137:8-15; *see also id.* 115:20-24).

Dated: May 12, 2025

Respectfully submitted,

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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 Petitioner's Response to Patent Owner's Notice of Objections by electronic means on May 12, 2025:

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