

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.

IPR2024-00647 (Patent 11,649,287 B2)
IPR2024-00648 (Patent 11,643,462 B2)
IPR2024-00649 (Patent 11,629,187 B2)
IPR2024-00650 (Patent 11,634,491 B2)¹

Before DEBORAH KATZ, SHERIDAN K. SNEDDEN, and
DEVON ZASTROW NEWMAN, *Administrative Patent Judges*.²

KATZ, *Administrative Patent Judge*.

ORDER
Setting Oral Argument
37 C.F.R. § 42.70

¹ This Order addresses issues common to each of these proceedings and we use this caption for efficiency. The parties may not use this style heading in any subsequent papers without authorization.

² This is not an expanded panel.

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*A. Time and Format*³

The parties both requested in-person oral argument. (See Papers 44, 45.⁴) Oral arguments will commence at **1:00 p.m. (Eastern Time) on June 26, 2025, in Alexandria, VA**. The Board will provide a court reporter for the hearing, and the reporter's transcript will constitute the official record of the hearing.

If there are any concerns about disclosing confidential information, the parties must contact the Board at Trials@uspto.gov at least ten (10) business days before the hearing date if the party wishes to request that any of the hearing be closed to the public.

Petitioner will have 45 minutes to present argument in this case, and Patent Owner will have 45 minutes to respond. Petitioner will open the hearing by presenting its case regarding the challenged claims for which the Board instituted trial. Thereafter, Patent Owner will respond to Petitioner's argument. Petitioner may reserve rebuttal time to respond to arguments presented by Patent Owner. In accordance with the Consolidated Trial Practice Guide⁵ ("CTPG"), issued in November 2019, Patent Owner may request to reserve time for a brief sur-rebuttal. See CTPG 83.

The panel is cognizant that the oral argument will encompass eight different proceedings and can be flexible if it appears that more time is needed to address issues unique to one or more of the proceedings. Many of the issues raised in these

³ If a party is no longer able to appear in-person for the hearing, the party must contact PTABHearings@uspto.gov as soon as possible.

⁴ We refer to IPR2024-00647 when referencing filed papers. Corresponding papers were filed in each proceeding.

⁵ Available at <https://www.uspto.gov/TrialPracticeGuideConsolidated>.

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proceedings are common to all of the proceedings. Therefore, to conserve resources by minimizing unnecessary redundancies, the panel requests that the parties consolidate arguments on similar issues. In addition, because a final decision on IPR2024-00240, which addresses some issues also raised in the current proceedings, will issue before this hearing, the parties may wish to focus on issues unique to the current proceedings in their allotted time for oral argument.

The parties may request a pre-hearing conference in advance of the hearing, if one is necessary. *See id.* at 82. “The purpose of the pre-hearing conference is to afford the parties the opportunity to preview (but not argue) the issues to be discussed at the oral argument, and to seek the Board’s guidance as to particular issues that the panel would like addressed by the parties.” *Id.* If either party desires a pre-hearing conference, the parties should jointly contact the Board at Trials@uspto.gov at least seven (7) business days before the hearing date to request a conference call for that purpose.

B. Demonstratives

As set forth in 37 C.F.R. § 42.70(b), demonstratives shall be served on opposing counsel at least seven (7) business days before the hearing date.⁶ The demonstratives should be filed no later than **June 19, 2025**.

Demonstratives are not a mechanism for making new arguments. Demonstratives also are not evidence and will not be relied upon as evidence. Rather, demonstratives are visual aids to a party’s oral presentation regarding

⁶ The parties may stipulate to an alternative schedule for serving demonstratives, but may not alter the date for filing demonstratives with the Board absent authorization.

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arguments and evidence previously presented and discussed in the papers.

Accordingly, demonstratives shall be clearly marked with the words

“DEMONSTRATIVE EXHIBIT – NOT EVIDENCE” in the footer. *See Dell Inc.*

v. Acceleron, LLC, 884 F.3d 1364, 1369 (Fed. Cir. 2018) (holding that the Board is obligated under its own regulations to dismiss untimely argument “raised for the first time during oral argument”). “[N]o new evidence may be presented at the oral argument.” CTPG 86; *see also 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 such arguments are based on evidence of record).

Furthermore, because of the strict prohibition against the presentation of new evidence or arguments at a hearing, it is strongly recommended that each demonstrative include a citation to a paper in the record, which allows the Board to easily ascertain whether a given demonstrative contains “new” argument or evidence or, instead, contains only that which is developed in the existing record.

Due to the nature of the Board’s consideration of demonstratives and the opportunity afforded for the parties to reach an agreement without involving the Board, the Board does not anticipate that objections to demonstratives are likely to be sustained. Nevertheless, to the extent that a party objects to the propriety of any demonstrative, the parties shall meet and confer in good faith to resolve any objections to demonstratives prior to filing the objections with the Board. If such objections cannot be resolved, the parties may file any objections to demonstratives with the Board no later than the time of the hearing. The objections shall identify with particularity which portions of the demonstratives are

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subject to objection (and should include a copy of the objected-to portions) and include a one (1) sentence statement of the reason for each objection. No argument or further explanation is permitted. The Board will consider any objections, and may reserve ruling on the objections. Any objection to demonstratives that is not timely presented will be considered waived.

The parties are reminded that each presenter should identify clearly and specifically each paper (e.g., by slide or screen number for a demonstrative) referenced during the hearing to ensure the clarity and accuracy of the court reporter's transcript and for the benefit of all participants appearing electronically.

If the parties choose to refer to confidential information related to objective evidence of non-obviousness, or any other issue, during oral argument, the panel will request that these discussions occur at the end of Patent Owner's main argument and at the beginning of Petitioner's rebuttal argument so that the proceeding is closed to the public only once.

C. Presenting Counsel

The Board generally expects lead counsel for each party to be present at the hearing. *See* CTPG 11. Any counsel of record may present the party's argument as long as that counsel is present.

D. Remote Attendance Requests

Members of the public may request to listen to and/or view this hearing. If resources are available, the Board generally expects to grant such requests. If either party objects to the Board granting such requests, for example, because confidential information may be discussed, the party must notify the Board at PTABHearings@uspto.gov at least ten (10) business days prior to the hearing date.

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E. Audio/Visual Equipment Requests

Any special requests for audio-visual equipment should be directed to PTABHearings@uspto.gov. A party may also indicate any special requests related to appearing at a video hearing, such as a request to accommodate deaf or hard-of-hearing individuals and blind or low vision individuals and indicate how the PTAB may accommodate the special request. Any special requests must be presented in a separate communication at least five (5) business days before the hearing date.

F. Legal Experience and Advancement Program

The Board has established the “Legal Experience and Advancement Program,” or “LEAP,” to encourage advocates with less legal experience to argue before the Board to develop their skills. The Board defines a LEAP practitioner as a patent agent or attorney having three (3) or fewer substantive oral arguments in any federal tribunal, including PTAB.⁷

The parties are encouraged to participate in the Board’s LEAP program. Either party may request that a qualifying LEAP practitioner participate in the program and conduct at least a portion of the party’s oral argument. The Board will grant up to fifteen (15) minutes of additional argument time to that party, depending on the length of the proceeding and the PTAB’s hearing schedule. A

⁷ Whether an argument is “substantive” for purposes of determining whether an advocate qualifies as a LEAP practitioner will be made on a case-by-case basis with considerations to include, for example, the amount of time that the practitioner argued, the circumstances of the argument, and whether the argument concerned the merits or ancillary issues.

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party should submit a request, no later than at least five (5) business days before the oral hearing, by email to the Board at PTABHearings@uspto.gov.⁸

The LEAP practitioner may conduct the entire oral argument or may share time with other counsel, provided that the LEAP practitioner is offered a meaningful and substantive opportunity to argue before the Board. The party has the discretion as to the type and quantity of oral argument that will be conducted by the LEAP practitioner.⁹ Moreover, whether the LEAP practitioner conducts the argument in whole or in part, the Board will permit more experienced counsel to provide some assistance to the LEAP practitioner, if necessary, during oral argument, and to clarify any statements on the record before the conclusion of the oral argument. Importantly, the Board does not draw any inference about the importance of a particular issue or issues, or the merits of the party's arguments regarding that issue, from the party's decision to have (or not to have) a LEAP practitioner argue.

In instances where an advocate does not meet the LEAP eligibility requirements due to the number of "substantive" oral hearing arguments, but nonetheless has a basis for considering themselves to be in the category of advocates that this program is intended to assist, the Board encourages argument

⁸ Additionally, a LEAP Verification Form shall be submitted by the LEAP practitioner, confirming eligibility for the program. A combined LEAP Practitioner Request for Oral Hearing Participation and Verification Form is available on the LEAP website, www.uspto.gov/leap.

⁹ Examples of the issues that a LEAP practitioner may argue include claim construction argument(s), motion(s) to exclude evidence, or patentability argument(s) including, e.g., analyses of prior art or objective indicia of non-obviousness.

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by such advocates during oral hearings. Even though additional argument time will not be provided when the advocate does not qualify for LEAP, a party may share argument time among counsel and the Board will permit the more experienced counsel to provide some assistance, if necessary, during oral argument, and to clarify any statements on the record before the conclusion of the oral argument. All practitioners appearing before the Board shall demonstrate the highest professional standards.

All practitioners are expected to have a command of the factual record, the applicable law, and Board procedures, as well as the authority to commit the party they represent.

II. ORDER

Accordingly, it is ORDERED that oral argument for this proceeding shall commence at 1:00 p.m. (Eastern Time) on June 26, 2025, in Alexandria, VA and proceed in the manner set forth herein.

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FOR PETITIONER:

Naveen Modi
Bruce Wexler
Preston Ratliff
Daniel Zeilberger
PAUL HASTINGS LLP
naveenmodi@paulhastings.com
brucewexler@paulhastings.com
prestonratliff@paulhastings.com
danielzeilberger@paulhastings.com

FOR PATENT OWNER:

Nicholas Stephens
Grace Kim
Todd G. Miller
Matthew L. Chun
Kristi Sawert
FISH & RICHARDSON P.C.
nstephens@fr.com
gkim@fr.com
miller@fr.com
mchun@fr.com
sawert@fr.com