

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NOVARTIS PHARMACEUTICALS CORPORATION,
Petitioner,

v.

REGENTS OF THE UNIVERSITY OF MICHIGAN AND UNIVERSITY
OF SOUTH FLORIDA,
Patent Owner.

IPR2023-01346
Patent 10,633,344 B2

Before JEFFREY N. FREDMAN, MICHAEL J. FITZPATRICK, and
SHERIDAN K. SNEDDEN, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*.

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

I. ORAL ARGUMENT

Petitioner and Patent Owner both request oral argument. Paper 26 (Petitioner's Request), Paper 27 (Patent Owner's Request). The parties' requests for oral argument are granted.

A. Time and Format

Oral arguments will commence at **1:00 PM Eastern Time on January 8, 2025**, at the USPTO Headquarters in Alexandria, VA in Hearing Room B.^{1,2} The Board will provide a court reporter for the hearing, and the reporter's transcript will constitute the official record of the hearing.

Petitioner will have a total of sixty (60) minutes to present argument, and Patent Owner will have a total of sixty (60) 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 Guide³ ("CTPG"), issued in November 2019, Patent Owner may request to reserve time for a brief sur-rebuttal. *See* CTPG 83.

¹ 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

² 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.

³ Available at <https://www.uspto.gov/TrialPracticeGuideConsolidated>.

The parties may request a pre-hearing conference in advance of the hearing. *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 hearing, 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.⁴ In place of the default filing date provided in § 42.70(b), the parties shall file demonstrative exhibits no later than two (2) business days before the hearing to allow the panel sufficient time to review the materials.

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 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. Accelaron, 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

⁴ The parties may stipulate to an alternative schedule for serving demonstratives.

oral argument”). “[N]o new evidence may be presented at the oral argument.” CTPG 85; *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 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.⁵ Any objection to demonstratives that is not timely presented will be considered waived.

Finally, 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.

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 in person.

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 seven (7) business days prior to the hearing date.

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

⁵ If time permits, the Board may schedule a conference call with the parties to discuss any filed objections.

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.⁶

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 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.⁷

The LEAP practitioner may conduct the entire oral argument or may share time with other counsel, provided that the LEAP practitioner is offered

⁶ 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.

⁷ 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.

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.⁸ 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 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

⁸ 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.

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 PM Eastern Time on January 8, 2025** at the USPTO Headquarters in Alexandria, VA in Hearing Room B, and proceed in the manner set forth herein.

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Patent 10,633,344 B2

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