Trials@uspto.gov Paper: 25 Tel: 571-272-7822 Date: September 25, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTAS PHARMACEUTICALS LTD., Petitioner,

v.

ATOSSA THERAPEUTICS, INC., Patent Owner.

PGR2023-00043 Patent 11,572,334 B2

K SNEDDEN TINA E HIJI SE and

Before SHERIDAN K. SNEDDEN, TINA E. HULSE, and JAMIE T. WISZ, *Administrative Patent Judges*.

HULSE, Administrative Patent Judge.

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

#### I. ORAL ARGUMENT

#### A. Time and Format

The parties have both requested oral argument in this proceeding. Paper 23 (Patent Owner's request); Paper 24 (Petitioner's request). Accordingly, oral argument will commence at **1:00 pm Eastern Time** on **October 30, 2024,** by **video**. <sup>1,2</sup> Paper 12, 11. 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 minutes to present its argument in this proceeding and Patent Owner will have a total of sixty minutes to respond. Petitioner will open the hearing by presenting its argument regarding the challenged claims for which the Board instituted trial. Patent Owner will then respond to Petitioner's argument. Petitioner may reserve rebuttal time to respond to arguments presented by Patent Owner and Patent Owner may reserve time for a sur-rebuttal. *See* Consolidated Trial Practice Guide<sup>3</sup> ("CTPG") 83. Neither the rebuttal nor sur-rebuttal may exceed 30 minutes.

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,

<sup>&</sup>lt;sup>1</sup> Although Patent Owner requests that the oral argument be held in person (Paper 23, 2), Petitioner requests that the oral argument be held virtually via videoconference. Paper 24, 1. As explained in the Scheduling Order, we will only conduct an in-person hearing when requested by all parties. Paper 12, 7.

<sup>&</sup>lt;sup>2</sup> If there are any concerns about disclosing confidential information, the parties must contact the Board at Trials@uspto.gov at least ten business days before the hearing date.

<sup>&</sup>lt;sup>3</sup> Available at <a href="https://www.uspto.gov/TrialPracticeGuideConsolidated">https://www.uspto.gov/TrialPracticeGuideConsolidated</a>.

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 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 business days before the hearing date and filed as an exhibit no later than the time of the hearing. The parties shall also provide a courtesy copy of any demonstrative exhibits to the Board **no later than three business days before the hearing** by emailing them to Trials@uspto.gov.<sup>4</sup>

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. 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 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 "new" evidence includes evidence already of record but not previously discussed in any paper of record).

<sup>&</sup>lt;sup>4</sup> The parties may also satisfy this courtesy-copy requirement by filing their demonstratives no later than three business days before the hearing.

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 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.<sup>5</sup> Any objection to demonstratives that is not timely presented will be considered waived.

# 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.

<sup>&</sup>lt;sup>5</sup> If time permits, the Board may schedule a conference call with the parties to discuss any filed objections.

### D. Video or Telephonic Hearing Details

To facilitate planning, each party must contact the Board at PTABHearings@uspto.gov at least five business days prior to the hearing date to receive video set-up information. As a reminder, all arrangements and the expenses involved with appearing by video, such as the selection of the facility from which a party will attend by video, must be borne by that party. If a video connection cannot be established, the parties will be provided with dial-in connection information, and the hearing will be conducted telephonically.

If one or both parties would prefer to participate in the hearing telephonically, they must contact the Board at PTABHearings@uspto.gov at least five business days prior to the hearing date to receive dial-in connection information.

Counsel should unmute only when speaking. The panel will have access to all papers filed with the Board, including demonstratives. During the hearing, the parties are reminded to identify specifically each paper referenced (e.g., by slide number for a demonstrative) to ensure the clarity and accuracy of the court reporter's transcript and for the benefit of all participants appearing electronically. In addition, the parties are advised to identify themselves each time they speak. Furthermore, the remote nature of the hearing may also result in an audio lag, and thus the parties are advised to observe a pause prior to speaking, so as to avoid speaking over others.

If at any time during the hearing, counsel encounters technical or other difficulties that fundamentally undermine counsel's ability to adequately represent its client, please let the panel know immediately, and adjustments will be made.<sup>6</sup>

<sup>&</sup>lt;sup>6</sup> For example, if a party is experiencing poor video quality, the Board may provide

## E. 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 business days prior to the hearing date.

# F. 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 business days before the hearing date.

## G. 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 or fewer substantive oral arguments in any federal tribunal, including PTAB.<sup>7</sup>

alternate dial-in information.

<sup>&</sup>lt;sup>7</sup> 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

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 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 business days before the oral hearing, by email to the Board at PTABHearings@uspto.gov.<sup>8</sup>

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. 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.

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concerned the merits or ancillary issues.

<sup>&</sup>lt;sup>8</sup> 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.

<sup>&</sup>lt;sup>9</sup> Examples of the issues that a LEAP practitioner may argue include claim construction arguments, motions to exclude evidence, or patentability arguments including, e.g., analyses of prior art or objective indicia of non-obviousness.

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 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 **October 30, 2024**, by **video**, and proceed in the manner set forth herein.

PGR2023-00043 Patent 11,572,334 B2

# PETITIONER:

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## PATENT OWNER:

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