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Paper: 52
Date: June 26, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO. LTD, BIOCON BIOLOGICS INC.
Petitioner(s),
v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

IPR2023-00739
Patent 10,888,601 B2[1]

Before JOHN G. NEW, ROBERT A. POLLOCK, and RYAN H. FLAX, *Administrative Patent Judges*.

NEW, *Administrative Patent Judge*.

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

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[1] IPR2024-00201 has been joined with IPR2023-00739.

We instituted *inter partes* review in this case on October 20, 2023. Paper 9. Petitioner Samsung Bioepis Co. Ltd ("Petitioner") and Patent Owner Regeneron Pharmaceuticals, Inc. ("Patent Owner") have jointly requested in-person oral argument pursuant to 37 C.F.R. § 42.70(a). Paper 50. The parties' joint request is GRANTED and, as specified in this Order below, a hearing in the above-referenced proceedings shall be held.

The hearing will be conducted in person on July 24, 2024, in Hearing Room A, on the ninth floor of Madison Building East, 600 Dulany Street, Alexandria, Virginia at 10:00 AM EDT. The hearing will be open to the public for in-person attendance, which will be accommodated on a first-come, first-served basis. The Board will provide a court reporter for the hearing, and the reporter's transcript shall constitute the official record of the hearing.

Counsel and other interested parties planning on attending the hearing in person are reminded that they are required to subscribe to the USPTO's COVID self-certification procedures prior to attending. The COVID self-certification procedure is available at: https://www.uspto.gov/sites/default/files/document/COVID-Self-Certification.pdf. Counsel and other interested parties are also notified that individuals displaying symptoms (e.g., coughing, sneezing) during the hearing will be asked to either don a mask or leave the hearing. Failure to comply with such request may result, at the panel's discretion, in postponement of the hearing.

As requested by both parties, argument for this case will be allotted sixty (60) minutes total time, with each party having a total of thirty (30) minutes to present its arguments.

Petitioner bears the ultimate burden of demonstrating that the claims are unpatentable as challenged in the petition. Therefore, Petitioner will open the hearing by presenting its case regarding the unpatentability of the challenged claims. Patent Owner will follow with its response to Petitioner's presentation. Petitioner may reserve rebuttal time (of no more than one-third of their total presentation time) to reply to Patent Owner's arguments. Similarly, Patent Owner may reserve sur-rebuttal time (of no more than one-third of its total presentation time) to reply to Petitioner's rebuttal. *See* Office Consolidated Trial Practice Guide 83, *available at*: https://www.uspto.gov/TrialPracticeGuideConsolidated; *see also* 84 Fed. Reg. 64,280 (Nov. 21, 2019). A party may only present argument and evidence at the hearing for which a proper foundation exists in the record. New arguments will not be considered.

Unless ordered otherwise, the parties are to refrain from disclosing any confidential information during the hearing or including any confidential information in a demonstrative exhibit. We note that a Protective Order has been entered in this proceeding. Paper 29. If confidential material is intended to be discussed at the oral hearing, the parties are instructed to (1) meet and confer with respect to the use or discussion of such material in advance of the oral hearing, and (2) contact the Board at least three (3) business days before the hearing to discuss the matter.

At least five (5) business days prior to the hearing, each party shall serve on the other party any demonstrative exhibits it intends to use during the hearing. *See* 37 C.F.R. § 42.70(b). Demonstrative exhibits are not evidence and may not introduce new evidence or arguments. Demonstrative exhibits should be clearly marked as such. At least three (3) business days

before the hearing, the parties must submit a copy of any demonstrative exhibits to the Board by filing them as an exhibit. Any demonstrative exhibit not served on a party or filed with the Board may not be used during the hearing.

The parties must meet and confer in good faith to resolve any objections to the propriety of any demonstrative exhibit. Any objection that is not timely presented will be deemed waived. If any objections to demonstrative exhibits cannot be resolved, the objecting party may file a statement of objections with the Board at least two (2) business days before the hearing. The statement of objections should identify with particularity each demonstrative exhibit subject to objection and include a brief statement (no more than a few sentences) of the reason for such objection. No argument or further explanation is permitted. Nor is a party permitted to file a response to the statement of objections.

The Board will consider the statement of objections and schedule a conference call if necessary. Otherwise, the Board will reserve ruling on the objections until the time of the hearing. The parties are advised to limit objections to demonstrative exhibits to egregious violations that are prejudicial to the administration of justice. Generally, if the content of a slide cannot be readily associated with an argument made or evidence referenced in a substantive paper of record, the slide is inappropriate. Conversely, if the content of a slide can be readily associated with an argument made or evidence referenced in a substantive paper, it is typically proper. Ideally, parties should indicate on each slide where support may be found in a substantive paper and/or exhibit of record.

During the hearing, counsel must identify clearly and specifically each demonstrative exhibit (e.g., by slide or screen number) referenced to ensure clarity and accuracy of the transcript. The parties may only rely upon evidence that has been previously submitted in the proceeding and may only present arguments that have been previously made in the submitted papers. No new evidence or arguments may be presented at the hearing. Nor will live testimony be permitted at the hearing.

Either party may request a prehearing conference. *See* Office Consolidated Trial Practice Guide, 82. The request for a prehearing conference must be made by DUE DATE 6, as set forth in the Scheduling Order (Paper 8). To request such a conference, an email should be sent to Trials@uspto.gov, and propose several dates and times of availability for both parties, as appropriate, that are no later than three (3) business days prior to the oral hearing.

The Board generally expects lead counsel for each party to be present in person at the hearing. Any counsel of record, however, may present the party's argument. Should a party decide that its lead counsel will not be attending the hearing, the parties should initiate a joint conference call with the Board no later than three (3) business days prior to the hearing to discuss the matter.

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 oral hearing, such as a request to accommodate visual or hearing impairments, and indicate how the PTAB may accommodate the special request. Any special requests must be

presented in a separate communication not less than three (3) days before the hearing.

The panel will have access to all papers filed with the Board, including any demonstratives. During the oral hearing, the parties are advised to identify clearly and specifically each demonstrative (e.g., by slide or screen number), paper, and exhibit referenced to ensure the clarity and accuracy of the court reporter's transcript.

Members of the public may request to view or listen in on this oral 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 by contacting PTABHearings@uspto.gov at least three (3) business days prior to the oral hearing date.

The Board has established the Legal Experience and Advancement Program ("LEAP") to encourage advocates with less legal experience to argue before the Board to develop their skills. *See* https://www.uspto.gov/patents/ptab/leap. The Board defines a LEAP practitioner as a patent agent or attorney having made three or fewer substantive oral arguments in any federal tribunal, including the PTAB.

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.[2]

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.

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

[2] 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, at www.uspto.gov/patents/ptab/leap.

necessary, during oral argument, and to clarify any statements on the record before the conclusion of the oral argument.

ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, subject to the procedures set forth above, the parties' joint request for an oral hearing is GRANTED; and

FURTHER ORDERED that an oral hearing, conducted in accordance with the procedures set forth above, shall commence at 10:00 AM EDT on July 24, 2024 in Hearing Room A, on the ninth floor of Madison Building East, 600 Dulany Street, Alexandria, Virginia.

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