

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., CELLTRION, INC., and APOTEX,
INC.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

IPR2021-00880 (Patent 9,669,069 B2)¹
IPR2021-00881 (Patent 9,254,338 B2)²

Before ERICA A. FRANKLIN, JOHN G. NEW, and
SUSAN L. C. MITCHELL, *Administrative Patent Judges*.

PER CURIAM.

ORDER³
Granting Requests for Oral Hearing
37 C.F.R. § 42.70

¹ IPR2022-00257 and IPR2022-00301 have been joined with this proceeding.

² IPR2022-00258 and IPR2022-00298 have been joined with this proceeding.

³ The combined caption is for administrative convenience only and does not indicate that IPR2021-00880 and IPR2021-00881 have been joined together. The parties are not authorized to use this caption without express permission of the Board.

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We instituted *inter partes* review on November 10, 2021. Paper 21.⁴ Mylan Pharmaceuticals Inc. (“Petitioner”) and Regeneron Pharmaceuticals, Inc. (“Patent Owner”) have separately requested an in-person oral hearing pursuant to 37 C.F.R. § 42.70(a). See Papers 69, 70, respectively. The requests are GRANTED, as specified in this Order.

The hearing will be conducted in-person on August 10, 2022, in Hearing Room B, on the ninth floor of Madison Building East, 600 Dulany Street, Alexandria, Virginia at 2:00 PM 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 will constitute the official record of the hearing. At the parties’ request, video attendance by in-house counsel and other non-arguing attorneys will also be accommodated.

To facilitate planning, each party must contact PTAB Hearings at PTABHearings@uspto.gov no later than three (3) business days prior to the date of the oral hearing to receive any video set-up information. As a reminder, all arrangements and 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. Should a party prefer to participate in the oral hearing telephonically, they should notify

⁴ Papers cited in this Order are those filed in IPR2021-00880. Unless otherwise noted, corresponding papers have also been filed in IPR2021-00881.

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PTAB Hearings at the above email address three (3) business days prior to the hearing to receive dial-in connection information.

At the hearing, the Board will consider arguments concerning the two cases together. Each party will have a total of sixty (60) minutes to present its case. Petitioner bears the ultimate burden of demonstrating that the claims as challenged in the petition and proposed in the revised motion to amend are unpatentable. Thus, Petitioner will open the hearing by presenting its case regarding the unpatentability of both the challenged claims and the proposed substitute claims. Patent Owner will follow with its response to Petitioner's presentation. Petitioner may reserve rebuttal time (of no more than half their total presentation time) to reply to Patent Owner's arguments. Likewise, Patent Owner may reserve sur-rebuttal time (of no more than half its total presentation time) to reply to Petitioner's rebuttal. *See* Office Consolidated Trial Practice Guide, November 2019 Edition, 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.

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 these proceedings (*see* Paper 71) and certain evidence has been filed under seal pursuant thereto. If protected 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 at the oral

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hearing, and (2) contact the Board at least three (3) business days before the hearing to discuss the matter.⁵

At least three (3) 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

⁵ We note that we have granted Petitioner's request that its Lead Counsel be relieved of any requirement to attend Oral Argument. Petitioner represents that it expects that its designated Backup Counsel will attend in person to make arguments for Petitioner.

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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 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 July 27, 2022. To request such a conference, an email should be sent to Trials@uspto.gov, and propose several dates and

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