

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

REGENERON PHARMACEUTICALS, INC.,
Petitioner,

v.

NOVARTIS PHARMA AG,
NOVARTIS TECHNOLOGY LLC,
NOVARTIS PHARMACEUTICALS CORPORATION,
Patent Owner.

IPR2021-00816
Patent 9,220,631 B2

Before ERICA A. FRANKLIN, ROBERT L. KINDER, and
JAMIE T. WISZ, *Administrative Patent Judges*.

KINDER, *Administrative Patent Judge*.

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

I. ORAL ARGUMENT

A. *Time and Format*¹

Oral arguments will commence at 11:30 AM ET, on Thursday, July 21, 2022, at USPTO Headquarters in Alexandria, Virginia.² The Board will provide a court reporter for the hearing, and the reporter's transcript will constitute the official record of the hearing.³

Petitioner will have a total of forty-five (45) minutes to present argument in this case and Patent Owner will have a total of forty-five (45) minutes to respond. Petitioner will open the hearing by presenting its case regarding the challenged claims for which the Board instituted trial.⁴ Thereafter, Patent Owner will respond to Petitioner's argument. Petitioner may reserve rebuttal time to respond to arguments presented by Patent

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 The U.S. Patent and Trademark Office ("USPTO") is concerned with the health and safety of all of its stakeholders, and will continue to follow all applicable health guidance. Prior to arriving at any USPTO office location, please consult the following to verify entry requirements:

<https://www.uspto.gov/coronavirus>.

³ 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.

⁴ On May 26, 2022, Patent Owner filed a "Notice of Withdrawal of Its Contingent Motion to Amend," which states "[p]ursuant to the Board's Pilot Program Concerning Motion to Amend Practice and Procedures . . . Patent Owner hereby withdraws its Contingent Motion to Amend [Paper 37]." Paper 89, 1. Accordingly, the oral hearing will not address any issues raised only in the withdrawn Contingent Motion to Amend.

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 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 and emailed to the Board at least two business days prior to the day of the hearing (July 19).⁶

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

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

⁶ The parties may stipulate to an alternative schedule for serving and filing demonstratives, and request that the Board modify the schedule for filing and serving demonstratives at least seven (7) business days before the hearing date.

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 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).

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 two days before 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.⁷ 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 ten (10) business days prior to the hearing date.

The parties have requested that the option be made available for representatives (in-house counsel) to attend the hearing virtually, either by video or telephone. This request is granted. Each party should contact the

⁷ If time permits, the Board may schedule a conference call with the parties to discuss any filed objections.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.