Trials@uspto.gov
571-272-7822

Paper 10
Date: February 24, 2025

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIOFRONTERA INC., BIOFRONTERA BIOSCIENCE GMBH, BIOFRONTERA PHARMA GMBH, and BIOFRONTERA AG,
Petitioner,

v.

SUN PHARMACEUTICAL INDUSTRIES, INC.,
Patent Owner.

IPR2024-01312
Patent 11,697,028 B2

Before WILLIAM V. SAINDON, ERICA A. FRANKLIN, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

FRANKLIN, *Administrative Patent Judge*.

SCHEDULING ORDER

A. GENERAL INSTRUCTIONS

1. Initial and Additional Conference Calls

The parties are directed to contact the Board within a month of this Order if there is a need to discuss proposed changes to this Scheduling Order or proposed motions that have not been authorized in this Order or other prior Order or Notice. *See* Consolidated Trial Practice Guide ("Consolidated Practice Guide")[1] at 9–10, 65 (guidance in preparing for a conference call); *see also* 84 Fed. Reg. 64,280 (Nov. 21, 2019). A request for an initial conference call shall include a list of proposed motions, if any, to be discussed during the call.

The parties may request additional conference calls as needed. Any email requesting a conference call with the Board should: (a) copy all parties, (b) indicate generally the relief being requested or the subject matter of the conference call, (c) include multiple times when all parties are available, (d) state whether the opposing party opposes any relief requested, and (e) if opposed, either certify that the parties have met and conferred telephonically or in person to attempt to reach agreement, or explain why such meet and confer did not occur. The email may not contain substantive argument and, unless otherwise authorized, may not include attachments. *See* Consolidated Practice Guide at 9–10.

2. Protective Order

No protective order shall apply to this proceeding until the Board enters one. If either party files a motion to seal before entry of a protective order, a jointly proposed protective order shall be filed as an exhibit with the

[1] Available at https://www.uspto.gov/TrialPracticeGuideConsolidated.

motion. It is the responsibility of the party whose confidential information is at issue, not necessarily the proffering party, to file the motion to seal.[2] The Board encourages the parties to adopt the Board's default protective order if they conclude that a protective order is necessary. *See* Consolidated Practice Guide at 107–122 (App. B, Protective Order Guidelines and Default Protective Order). If the parties choose to propose a protective order deviating from the default protective order, they must submit the proposed protective order jointly along with a marked-up comparison of the proposed and default protective orders showing the differences between the two and explain why good cause exists to deviate from the default protective order.

The Board has a strong interest in the public availability of trial proceedings. Redactions to documents filed in this proceeding should be limited to the minimum amount necessary to protect confidential information, and the thrust of the underlying argument or evidence must be clearly discernible from the redacted versions. We also advise the parties that information subject to a protective order may become public if identified in a final written decision in this proceeding, and that a motion to expunge the information will not necessarily prevail over the public interest in maintaining a complete and understandable file history. *See* Consolidated Practice Guide at 21–22.

3. Discovery Disputes

The Board encourages parties to resolve disputes relating to discovery on their own. To the extent that a dispute arises between the parties relating to discovery, the parties must meet and confer to resolve such a dispute

[2] If the entity whose confidential information is at issue is not a party to the proceeding, please contact the Board.

before contacting the Board. If attempts to resolve the dispute fail, a party may request a conference call with the Board.

4. Testimony

The parties are reminded that the Testimony Guidelines appended to the Consolidated Practice Guide at 127–130 (App. D, Testimony Guidelines) apply to this proceeding. The Board may impose an appropriate sanction for failure to adhere to the Testimony Guidelines. 37 C.F.R. § 42.12. For example, reasonable expenses and attorneys' fees incurred by any party may be levied on a person who impedes, delays, or frustrates the fair examination of a witness.

5. Cross-Examination

Except as the parties might otherwise agree, for each due date: Cross-examination ordinarily takes place after any supplemental evidence is due. 37 C.F.R. § 42.53(d)(2).

Cross-examination ordinarily ends no later than a week before the filing date for any paper in which the cross-examination testimony is expected to be used. *Id.*

6. Motion to Amend

Patent Owner may file a motion to amend without prior authorization from the Board. Nevertheless, Patent Owner must confer with the Board before filing such a motion. 37 C.F.R. § 42.121(a). To satisfy this requirement, Patent Owner should request a conference call with the Board no later than two weeks prior to DUE DATE 1. *See* Section B below regarding DUE DATES.

Any motion to amend and briefing related to such a motion shall comply with the rules pertaining to motions to amend (37 C.F.R. § 42.121)

and the practices and procedures described in *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 15 (PTAB Feb. 25, 2019) (precedential).

Patent Owner has the option to receive preliminary guidance from the Board on its motion to amend. *See* 37 C.F.R. § 42.121(e). If Patent Owner elects to request preliminary guidance from the Board on its motion, it must do so in its motion to amend filed on DUE DATE 1. *Id.* at § 42.121(a)(1)(ii).

At DUE DATE 3, Patent Owner may file a reply to the opposition to the motion to amend and/or the preliminary guidance. 37 C.F.R. § 42.121(e)(3). In lieu of a reply, Patent Owner has the option to file a revised motion to amend that addresses the issues raised in the preliminary guidance or in petitioner's opposition to the motion to amend. *Id*. at § 42.121(f)(1)-(2). Patent Owner may elect to file a revised motion to amend even if Patent Owner did not request to receive preliminary guidance on its motion to amend. A revised motion to amend must include one or more new proposed substitute claims in place of the previously presented substitute claims, where each new proposed substitute claim presents a new claim amendment. *Id.*

If Patent Owner files a revised motion to amend, the Board may determine whether to request the Chief Administrative Patent Judge to extend the final written decision deadline more than one year from the date a trial is instituted in accordance with § 42.100(c) and whether to extend any remaining deadlines under § 42.5(c)(2). 37 C.F.R. § 42.121(f)(1). Typically the Board will enter a revised scheduling order setting the briefing schedule for that revised motion and adjusting other due dates as needed.

At DUE DATE 5, Petitioner may file a sur-reply that is limited to responding to the preliminary guidance and/or arguments made in the patent

owner's reply brief. *Id.* at § 42.121(e)(3). The sur-reply may not be accompanied by new evidence, but may comment on any new evidence filed with the reply and/or point to cross-examination testimony of a reply witness, if relevant to the arguments made in the reply brief. *Id.*

If the Board issues preliminary guidance on the motion to amend, and Patent Owner files neither a reply to the opposition to the motion to amend nor a revised motion to amend at DUE DATE 3, Petitioner may file a reply to the Board's preliminary guidance, no later than three (3) weeks after DUE DATE 3 or at any other DUE DATE that the Board specifies in a revised scheduling order. The reply may only respond to the preliminary guidance and may not be accompanied by new evidence. 37 C.F.R. § 42.121(e)(4). Patent Owner may file a sur-reply in response to Petitioner's reply to the Board's preliminary guidance. *Id.* The sur-reply may only respond to petitioner's reply and may not be accompanied by new evidence. *Id.* The sur-reply must be filed no later than three (3) weeks after Petitioner's reply or at any other DUE DATE that the Board specifies in a revised scheduling order.

In the event the Board requests examination assistance pursuant to 37 C.F.R. § 42.121(d)(3)(ii), the parties will be notified of the request and may adjust the scheduling order as needed.

7. Oral Argument

Requests for oral argument must comply with 37 C.F.R. § 42.70(a). To permit the Board sufficient time to schedule the oral argument, the parties may not stipulate to an extension of the request for oral argument beyond the date set forth in the Due Date Appendix.

The parties may request that the oral argument be held at the USPTO headquarters in Alexandria or virtually by videoconference. For the parties' information in making this decision, if oral argument is held at the USPTO headquarters in Alexandria, at least one judge will appear remotely by video. The parties should state in the request for oral argument, DUE DATE 4, whether the parties would prefer either a video hearing or an in-person hearing. To the extent the parties disagree, they should meet and confer; if the dispute cannot be resolved by meeting and conferring, the parties should inform the Board of each party's individual preferences. PTAB will only conduct an in-person hearing when requested by all parties.

Note that the Board may not be able to honor the parties' preferences due to, among other things, the availability of hearing room resources, the needs of the panel, and USPTO policy at the time of the hearing. The Board will consider the parties' request and notify the parties of how and where the hearing will be conducted.

For in-person hearings, seating in the Board's hearing rooms may be limited, and will be available on a first-come, first-served basis. If either party anticipates that more than five (5) individuals will attend the argument on its behalf, the party should notify the Board as soon as possible, and no later than the request for oral argument. Parties should note that the earlier a request for accommodation is made, the more likely the Board will be able to accommodate additional individuals.

The Board has established the "Legal Experience and Advancement Program," or "LEAP," to encourage advocates before the Board to develop their skills and to aid in succession planning for the next generation. 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. Parties are encouraged to participate in the Board's LEAP program.[3] 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.[4]

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. The Board discerns that it is often LEAP practitioners who have the best understanding of the facts of the case and the evidence of record, and the Board encourages their participation.

B. DUE DATES

This Order sets due dates for the parties to take action after institution of the proceeding. The parties may stipulate different dates for DUE DATES 1, 5, and 6, as well as the portion of DUE DATE 2 related to Petitioner's reply (earlier or later, but no later than DUE DATE 3 for Patent Owner's sur-reply) and the portion of DUE DATE 3 related to Patent Owner's sur-reply (earlier or later, but no later than DUE DATE 7). The parties may not stipulate to a different date for the portion of DUE DATE 2 related to

[3] Information about the LEAP program can be found at www.uspto.gov/leap.
[4] 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 at www.uspto.gov/leap.

Petitioner's opposition to a motion to amend, or for the portion of DUE DATE 3 related to Patent Owner's reply to an opposition to a motion to amend (or Patent Owner's revised motion to amend) without prior authorization from the Board. In stipulating to move any due dates in the scheduling order, the parties must be cognizant that the Board requires four weeks after the filing of an opposition to the motion to amend (or the due date for the opposition, if none is filed) for the Board to issue its preliminary guidance, if requested by Patent Owner. A notice of the stipulation, specifically identifying the changed due dates, must be promptly filed. The parties may not stipulate an extension of DUE DATES 4, 7, and 8.

In stipulating different times, the parties should consider the effect of the stipulation on times to object to evidence (37 C.F.R. § 42.64(b)(1)), to supplement evidence (§ 42.64(b)(2)), to conduct cross-examination (§ 42.53(d)(2)), and to draft papers depending on the evidence and cross-examination testimony.

1. DUE DATE 1

Patent Owner may file—

a. A response to the petition (37 C.F.R. § 42.120). If Patent Owner elects not to file a response, Patent Owner must arrange a conference call with the parties and the Board. Patent Owner is cautioned that any arguments not raised in the response may be deemed waived.

b. A motion to amend the patent (37 C.F.R. § 42.121) after conferring with the Board under 37 C.F.R. § 42.121(a).

2. DUE DATE 2

Petitioner may file a reply to the Patent Owner's response.

Petitioner may file an opposition to the motion to amend.

3. DUE DATE 3

Patent Owner may file a sur-reply to Petitioner's reply.

Patent Owner may also file either:

a. a reply to the opposition to the motion to amend and/or preliminary guidance (if provided); or

b. a revised motion to amend.

NOTE: If Patent Owner files neither of the above papers (a reply to the opposition or a revised motion to amend), and the Board has issued preliminary guidance, Petitioner may file a reply to the preliminary guidance, no later than three (3) weeks after DUE DATE 3. Patent Owner may file a sur-reply to Petitioner's reply to the preliminary guidance no later than three (3) weeks after Petitioner's reply.

4. DUE DATE 4

Either party may file a request for oral argument (may not be extended by stipulation).

5. DUE DATE 5

Petitioner may file a sur-reply to Patent Owner's reply to the opposition to the motion to amend.

Either party may file a motion to exclude evidence (37 C.F.R. § 42.64(c)).

6. DUE DATE 6

Either party may file an opposition to a motion to exclude evidence.

Either party may request that the Board hold a pre-hearing conference.

7. DUE DATE 7

Either party may file a reply to an opposition to a motion to exclude evidence.

8. DUE DATE 8

The oral argument (if requested by either party) shall be held on this date. Approximately one month prior to the argument, the Board will issue an order setting the start time of the hearing and the procedures that will govern the parties' arguments.

DUE DATE APPENDIX

DUE DATE 1 ..... May 21, 2025

Patent Owner's response to the petition

Patent Owner's motion to amend the patent

DUE DATE 2 ..... August 13, 2025

Petitioner's reply to Patent Owner's response to petition

Petitioner's opposition to motion to amend

DUE DATE 3 ..... September 24, 2025

Patent Owner's sur-reply to reply

Patent Owner's reply to opposition to motion to amend (or Patent Owner's revised motion to amend)[5]

DUE DATE 4 ..... October 15, 2025

Request for oral argument (may not be extended by stipulation)

DUE DATE 5 ..... November 5, 2025

Petitioner's sur-reply to reply to opposition to motion to amend

Motion to exclude evidence

DUE DATE 6 ..... November 12, 2025

Opposition to motion to exclude

Request for prehearing conference

DUE DATE 7 ..... November 19, 2025

Reply to opposition to motion to exclude

DUE DATE 8 ..... December 3, 2025

Oral argument (if requested)

[5] If Patent Owner files neither a reply to Petitioner's opposition to the MTA nor a revised MTA, the parties are directed to Section B(3) above.

For PETITIONER:

James Murphy
Corey Casey
Megan Hart
POLSINELLI PC
jpmurphy@polsinelli.com
ccasey@polsinelli.com
mkhart@polsinelli.com

For PATENT OWNER:

Gabrielle Higgins
Yung-Hoon Ha
DESMARAIS LLP
ghiggins@desmaraisllp.com
yha@desmaraisllp.com