

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FRESENIUS KABI USA, LLC, and
FRESENIUS KABI SWISSBIOSIM GMBH
Petitioner,

v.

CHUGAI SEIYAKU KABUSHIKI KAISHA and
HOFFMANN-LA ROCHE INC.,
Patent Owner.

IPR2021-01542
Patent 8,580,264 B2

Before ERICA A. FRANKLIN, JOHN G. NEW, and ZHENYU YANG,
Administrative Patent Judges.

YANG, *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 motion.

¹ Available at <https://www.uspto.gov/TrialPracticeGuideConsolidated>.

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.

Patent Owner has the option to receive preliminary guidance from the Board on its motion to amend. *See* Notice Regarding a New Pilot Program

Concerning Motion to Amend Practice and Procedures in Trial Proceedings under the America Invents Act before the Patent Trial and Appeal Board, 84 Fed. Reg. 9497 (Mar. 15, 2019) (“MTA Pilot Program Notice”); *see also* Consolidated Practice Guide at 67. 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.

Any motion to amend and briefing related to such a motion shall generally follow the practices and procedures described in MTA Pilot Program Notice unless otherwise ordered by the Board in this proceeding. The parties are further directed to the Board’s Guidance on Motions to Amend in view of *Aqua Products, Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017), (<https://go.usa.gov/xU6YV>), *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 15 (PTAB Feb. 25, 2019) (precedential), and *L&P Property Mgmt. v. Remarco Machinery & Tech.*, IPR2019-00255, Paper 15 (PTAB June 18, 2019).

At DUE DATE 3, Patent Owner has the option to file a reply to the opposition to the motion to amend and preliminary guidance, or a revised motion to amend. *See* MTA Pilot Program Notice at 9500–01. 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 provide amendments, arguments, and/or evidence in a manner that is responsive to issues raised in the preliminary guidance and/or Petitioner’s opposition.

If Patent Owner files a revised motion to amend, the Board shall enter a revised scheduling order setting the briefing schedule for that revised motion and adjusting other due dates as needed. *See* MTA Pilot Program Notice at 9501, App. 1B.

As also discussed in the MTA Pilot Program Notice, 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. The reply may only respond to the preliminary guidance. Patent Owner may file a sur-reply in response to Petitioner's reply to the Board's preliminary guidance. The sur-reply may only respond to arguments made in the reply and must be filed no later than three (3) weeks after Petitioner's reply. *See* MTA Pilot Program Notice at 9502. No new evidence may accompany the reply or the sur-reply in this situation.

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.

Unless the Board notifies the parties otherwise, oral argument, if requested, will be held at the USPTO headquarters in Alexandria.

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.

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 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).

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 24, 2022
Patent Owner’s response to the petition	
Patent Owner’s motion to amend the patent	
DUE DATE 2	August 12, 2022
Petitioner’s reply to Patent Owner’s response to petition	
Petitioner’s opposition to motion to amend	
DUE DATE 3	September 23, 2022
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) ³	
DUE DATE 4	October 14, 2022
Request for oral argument (may not be extended by stipulation)	
DUE DATE 5	November 4, 2022
Petitioner’s sur-reply to reply to opposition to motion to amend	
Motion to exclude evidence	
DUE DATE 6	November 14, 2022
Opposition to motion to exclude	
Request for prehearing conference	
DUE DATE 7	November 21, 2022
Reply to opposition to motion to exclude	
DUE DATE 8	December 1, 2022
Oral argument (if requested)	

³ 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.

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