

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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TWI PHARMACEUTICALS, INC.,  
Petitioner,

v.

MERCK SERONO SA,  
Patent Owner.

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IPR2023-00049 (Patent 7,713,947 B2)  
IPR2023-00050 (Patent 8,377,903 B2)<sup>1</sup>

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Before ULRIKE W. JENKS, ZHENYU YANG and TINA HULSE,  
*Administrative Patent Judges.*

JENKS, *Administrative Patent Judge.*

SCHEDULING ORDER

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<sup>1</sup> This order addresses issues that are common to both cases. We, therefore, exercise our discretion and issue a single order that has been entered in each case. The parties may use this style caption when filing a single paper in multiple proceedings, provided that such caption includes a footnote attesting that “the identical paper is filed in each proceeding identified in the caption.”

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## 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”)<sup>2</sup> 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.

### 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. It is the responsibility of the party whose confidential information is at issue, not necessarily the proffering party, to file the motion to seal.<sup>3</sup> 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

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<sup>2</sup> Available at <https://www.uspto.gov/TrialPracticeGuideConsolidated>.

<sup>3</sup> If the entity whose confidential information is at issue is not a party to the proceeding, please contact the Board.

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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 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

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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.

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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 *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 15 (PTAB Feb. 25, 2019) (precedential), and Rules of Practice To Allocate the Burden of Persuasion on Motions To Amend in Trial Proceedings Before the Patent Trial and Appeal Board, 85 Fed. Reg. 82923 (Dec. 21, 2020).

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

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