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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUYE PHARMA GROUP LTD., LUYE PHARMA(USA) LTD., SHANDONG LUYE PHARMACEUTICAL CO., LTD., and NANJING LUYE PHARMACEUTICAL CO., LTD., Petitioner,

v.

ALKERMES PHARMA IRELAND LTD. and ALKERMES CONTROLLED THERAPEUTICS, INC., Patent Owner.

Case IPR2016-01096 Patent 6,667,061 B2

Before LORA M. GREEN, ROBERT A. POLLOCK, and JACQUELINE T. HARLOW, *Administrative Patent Judges*.

GREEN, Administrative Patent Judge.

SCHEDULING ORDER 37 C.F.R. § 42.5



### A. GENERAL INSTRUCTIONS

### 1. Initial Conference Call

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* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,765–66 (Aug. 14, 2012) ("Practice Guide") (guidance in preparing for the initial conference call). 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. The Board encourages the parties to adopt the Board's default protective order if they conclude that a protective order is necessary. *See* Default Protective Order, Practice Guide, App. B. 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.

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* Practice Guide, at 48,761.

### 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 Trial Practice Guide, Appendix D, 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

evidence is due. 37 C.F.R. § 42.53(d)(2).

Except as the parties might otherwise agree, for each due date: Cross-examination ordinarily takes place after any supplemental

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. Observations on Cross-Examination

Observations on cross-examination provide the parties with a mechanism to draw the Board's attention to relevant cross-examination testimony of a reply witness because no further substantive paper is permitted after the reply. *See* Trial Practice Guide, at 48,768. The observation must be a concise statement of the relevance of precisely identified testimony to a precisely identified argument or portion of an exhibit. Each observation must not exceed a single, short paragraph. The opposing party may respond to the observation. Any response must be equally concise and specific. Observations and responses are each limited to 10 pages or less.

## 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.

Oral argument, if requested, will be held at the USPTO headquarters in Alexandria, Virginia.

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, including counsel, 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 to different dates for DUE DATES 1 through 5 (earlier or later, but no later than DUE DATE 6). A notice of the stipulation, specifically identifying the changed due dates, must be filed promptly. The parties may not stipulate to an extension of DUE DATES 6 and 7, or to the date for requesting oral argument.

When stipulating to 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 (37 C.F.R. § 42.64(b)(2)), to conduct cross-examination (37 C.F.R. § 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 for patentability not raised in the response may be deemed waived.
- b. A motion to amend the patent (37 C.F.R. § 42.121). 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. The parties are directed to the Board's Web site for precedential, informative, and representative decisions relating to



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