

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STEADYMED LTD.,
Petitioner,

v.

UNITED THERAPEUTICS CORPORATION,
Patent Owner.

Case IPR2016-00006
Patent 8,497,393 B2

Before LORA M. GREEN, JONI Y. CHANG, and
JACQUELINE T. HARLOW, *Administrative Patent Judges*.

HARLOW, *Administrative Patent Judge*.

ORDER
Oral Hearing
37 C.F.R. § 42.70

On April 8, 2016, we instituted the instant *inter partes* review (Paper 12), and issued a Scheduling Order (Paper 13), which set the date for oral hearing to November 29, 2016, if oral hearing is requested by either party and granted by the Board. Both parties request an oral hearing pursuant to 37 C.F.R. § 42.70. Papers 61 and 64. We grant those requests.

The parties request a total of 90 minutes of oral argument time. *Id.* Upon review of the record, we agree that the parties' requests are appropriate, and grant a total of 90 minutes of oral argument time, with a total of 45 minutes allocated to each side.

Some information in the record of this trial has been sealed pending the outcome of the ruling on the parties' Motions to Seal. Patent Owner requests that the hearing be closed to the public, and further, that any attendees from Petitioner's side sign the Protective Order prior to the hearing. Paper 64, 3. We deny Patent Owner's requests.

There is a strong public policy interest in making all information presented in these proceedings public, as the review determines the patentability of claims in an issued patent and thus affects the rights of the public. Put differently, there is a strong public policy for making all information filed in an *inter partes* review in support of a substantive argument open to the public, so that a complete and understandable file history is maintained. The default rule is that all papers filed in an *inter partes* review will be open and available for access by the public; only "confidential information" may be protected from disclosure upon a showing of good case. *See* 35 U.S.C. §§ 316(a)(1), 316(a)(7); 37 C.F.R. §§ 42.14,

42.54(a). This policy is reflected in part in 35 U.S.C. § 316(a)(1), which provides that the file of any *inter partes* review shall be made available to the public, except that any petition or document filed with the intent that it be sealed, if accompanied by a motion to seal, shall be “provisionally sealed on receipt of the motion and remain so pending the outcome of the decision on motion.” Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,760 (Aug. 14, 2012).

We have considered the strong public interest in making all aspects of the trial available to the public, while also considering the Patent Owner’s interest in protecting truly confidential information. *See* 37 C.F.R. §§ 42.14, 42.54; Office Patent Trial Practice Guide, 77 Fed. Reg. at 48,760. In this proceeding, for example, the public has a strong interest in knowing what evidence Patent Owner is relying on to establish that the process steps recited in the challenged claims impart structural or functional differences to the claimed product. We further note that should a final written decision rely upon any information in a sealed exhibit, such a sealed exhibit, in its entirety, will be unsealed and open to the public. In addition, any argument or information that the parties consider to be persuasive at the oral hearing also should be open to the public. At oral argument, each party should be mindful not to make public information that the other party has asserted in a motion to be confidential and has requested to be sealed. Rather, the parties may present their arguments without disclosing specifically any allegedly confidential information during oral argument. Accordingly, we make the

oral hearing publically available via in-person attendance, and the transcript of the oral hearing will be open to the public.

The hearing will commence at 1:00 PM Eastern Time, on November 29, 2016, and will be conducted at the USPTO central headquarters located in Alexandria, Virginia. Each party will have 45 minutes of total time to present its arguments. At the oral hearing, Petitioner will proceed first to present its case as to the challenged claims and instituted grounds of unpatentability. Thereafter, Patent Owner will respond to Petitioner's case. After that, Petitioner will make use of the rest of its time responding to Patent Owner's presentation on all matters.

The hearing will be open to the public for in-person attendance at the USPTO central headquarters, the ninth floor of Madison Building East, 600 Dulany Street, Alexandria, Virginia, 22314. In-person attendance will be accommodated on a first-come first-served basis. The Board will provide a court reporter for the hearing, and the reporter's transcript will constitute the official record of the hearing.

Under 37 C.F.R. § 42.70(b), demonstrative exhibits must be served no later than five business days before the hearing date. They shall be filed with the Board no later than three business days prior to the hearing date. Because the hearing will be open to the public, any demonstrative exhibits shall not contain any information alleged to be confidential by either party. The parties must initiate a conference call with the Board at least two business days prior to the hearing to resolve any dispute over the propriety of each party's demonstrative exhibits. The parties are directed to *St. Jude*

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Medical, Cardiology Division, Inc. v. The Board of Regents of the University of Michigan, Case IPR2013-00041 (PTAB Jan. 27, 2014) (Paper 65), for guidance regarding the appropriate content of demonstrative exhibits. *See also CBS Interactive Inc. v. Helferich Patent Licensing, LLC*, Case IPR2013-00033 (PTAB Oct. 23, 2013) (Paper 118) (The Board has the discretion to limit the parties' demonstratives to pages in the record should there be no easy resolution to objections over demonstratives.).

The Board expects lead counsel for each party to be present at oral hearing, although any backup counsel may make the actual presentation, in whole or in part. If lead counsel for either party is unable to attend the oral argument, the Board should be notified via a joint telephone conference call no later than two business days prior to the oral hearing to discuss the matter.

Any requests regarding special equipment or needs, such as for audio visual equipment, should be directed to Trials@uspto.gov. Requests for audio-visual equipment are to be made at least five business days in advance of the hearing date. Judge Harlow (Denver) shall participate in the hearing remotely. If a demonstrative is not made available to the Board in the manner indicated above, that demonstrative may not be available to each of the judges during the hearing and may not be considered. Further, images projected, using audio visual equipment in Alexandria, will not be visible to Judge Harlow in Denver. Because of limitations on the audio transmission systems in our hearing rooms, the presenter may speak only when standing at the hearing room podium. The parties are reminded that the presenter

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