

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLTRION, INC.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Case No. IPR2023-00462
Patent No. 10,464,992

**PETITIONER'S MOTION TO SEAL PORTIONS OF TRANSCRIPT OF
DR. TARANTINO'S DEPOSITION AND VIDEO OF DEPOSITION**

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I. INTRODUCTION

Petitioner Celltrion, Inc. (“Celltrion”) requests permission to seal portions of the Deposition of Dr. Ralph Tarantino, EX2054,¹ as well as the video of that deposition, under 37 C.F.R. § 42.14. Accompanying this motion is a redacted copy of the transcript from Dr. Tarantino’s deposition (EX1048), as is a complete copy of the unredacted transcript (EX1049), filed for the Board and parties only. The parties have agreed to entry of the default protective order in this proceeding (EX2046). Regeneron opposes this motion.

II. BACKGROUND

Celltrion filed this IPR on January 17, 2023. On April 25, 2023, Patent Owner Regeneron Pharmaceuticals, Inc. filed its Patent Owner’s Preliminary Response. On July 20, 2023, the Board granted institution. Patent Owner filed a notice of deposition for Celltrion’s expert, Dr. Ralph Tarantino on September 05, 2023, and Dr. Tarantino’s deposition was conducted on October 13, 2023.

During the pendency of this IPR, Celltrion filed its aBLA with the FDA in order to bring a biosimilar version of Regeneron’s EYLEA® (aflibercept) product

¹ Celltrion notes that EX2054 submitted by Regeneron is not a complete version of the transcript of Dr. Tarantino’s deposition. The redactions submitted by Celltrion (EX1048) are in the full version of the transcript.

to market. The '992 patent, at issue in this IPR, is listed in the FDA's Purple Book as covering EYLEA®. As a result of filing its aBLA, Regeneron filed a Complaint in the Northern District of West Virginia under the BPCIA in an attempt to prevent Celltrion's biosimilar from coming to market. Moreover, Regeneron and Mylan had recently completed closing arguments in a litigation regarding Mylan's proposed biosimilar to EYLEA®. *See Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, No. 1:2022cv00061 (N.D.W.Va.). The district court has not yet entered a decision in the Mylan case.

III. ARGUMENT

A. Legal Standard

A party to an IPR proceeding may, concurrently with any filing, also file a motion to seal documents. 37 C.F.R. § 42.14. The Board will grant a motion to seal for "good cause." 37 C.F.R. § 42.54; *Garmin Int'l, Inc. v. Cuozzo Speed Technologies, LLC*, IPR2012-00001, Paper 34, p. 3 (March 14, 2013) (precedential). The PTAB has explained that "the rules aim to strike a balance between the public's interest in maintaining a complete and understandable file history and the parties' interest in protecting truly sensitive information." *Id.*, 2. The Board's policy against misuse of IPR proceedings to determine litigation positions is demonstrated by the Board's policies in the context of additional

discovery, wherein asking for litigation positions, as well as the under-lying bases for those positions, is not in the interest of justice. *Garmin* at 6.

B. Good Cause Exists to Seal Portions of Dr. Tarantino’s Deposition

Good cause exists to seal portions of Dr. Tarantino’s deposition to avoid misuse of those portions of the deposition to improperly create litigation positions.

The law is clear that “[f]or cross-examination testimony, the scope of the examination is limited to the scope of the direct testimony.” 37 C.F.R.

§ 42.53(d)(5)(D)(ii). That is, a deposition question “is properly within the scope of cross-examination if it has sufficient underlying basis in a statement made in [the expert’s] declaration.” *One World Tech. Inc. v. Chervon (HK) Ltd.*, IPR2020-00884, -00886, 00887, 00888, Paper 35, 13.

During Dr. Tarantino’s deposition, Regeneron’s counsel asked Dr. Tarantino questions regarding aspects of formulation that had no relevance to the issues in this IPR. Counsel for Celltrion timely objected to these lines of questioning as beyond the scope and irrelevant. *See, e.g.*, EX1049 (Tarantino Dep. Tr.), pp. 33-37 (discussing viscosity); pp. 60-63 (discussing osmolarity); pp. 63-67 and 81-84 (discussing tonicity).² Dr. Tarantino’s declaration did not substantively discuss

² In this context, not all of the pages containing redactions in the transcript proposed by Celltrion were included in the version of the transcript submitted by

these issues. While Patent Owner may argue that issues such as tonicity are “inherently” part of formulation work, and thus relevant, it is undisputed that the claims of the ’992 patent have no tonicity limitations, and Dr. Tarantino provided no substantive opinions regarding tonicity. Tonicity and osmolarity are issues for claims that were asserted in the previous *Mylan* litigation, and thus may also be relevant in the upcoming BPCIA litigation against Celltrion, making it clear why Patent Owner’s counsel asked these questions. *See, e.g.*, U.S. Pat. No 11,084,865 at claims 13, 21 (a Purple Book listed patent for EYLEA® containing claims directed to tonicity agents).

During the questioning regarding tonicity, counsel for Celltrion asked the witness to leave the room, but counsel for Regeneron insisted that the witness stay in the room (counsel later agreed that Dr. Tarantino should leave). EX1049, 67:22-80:14. There was then a discussion on the record where counsel for Celltrion explained that questioning on topics such as tonicity was not proper in view of the fact that it is a topic Dr. Tarantino did not discuss or consider for purposes of his declaration in this IPR, but which may be relevant to later positions concerning

Regeneron. Celltrion assumes, therefore, that Regeneron does not oppose those redactions.

other Purple Book patents involved in a potential BPCIA litigation filed as a result of Celltrion's aBLA filing. *Id.*

The Board has explained that PTAB proceedings such as IPRs should not be used for improper purposes, including building up litigation positions. *See One World Tech. Inc.*, Paper 35, 13 & n.7 (finding that an IPR deposition testimony should be “narrowly focused on a specific issue unique to these proceedings before the Board” rather than used to improperly benefit litigation positions). In this case, the questioning regarding substantive issues outside the scope of Dr. Tarantino's deposition is clearly intended to buttress later litigation positions, and not to shed light on the issues relevant to the '992 patent, the subject of this IPR.

Good cause thus exists, and the Board should thus seal the redacted portions of Dr. Tarantino's deposition, limiting its use to this proceeding and to prevent its misuse by Patent Owner in related litigation. The redactions were limited to strike a balance between the public's interest in maintaining a complete and understandable file history and the parties' interest in protecting truly sensitive information. And as the issues Petitioner seeks to redact are quite limited and not substantively addressed in the claims of the '992 patent, limiting the use of questioning directed to these topics would not affect the public's interest in a complete and understandable file history.

C. Good Cause Exists to Seal the Video of Dr. Tarantino's Deposition

Good cause also exists to seal Dr. Tarantino's video deposition in order to avoid its misuse to improperly create litigation positions. Normally, only a transcript of a deposition is submitted as evidence in a proceeding. 37 C.F.R. § 42.53(a). Although the parties may agree to video-record a deposition, the video-recorded testimony may not be submitted to the Board without prior authorization. *Id.* Here, Celltrion made it clear during the deposition that while it was not objecting to the deposition being video-taped, it was not agreeing to having the video-recorded testimony submitted to the Board. EX1049, 6:10-23. Indeed, Regeneron did not seek authorization to submit any recording as evidence accompanying its POR. Good cause thus exists to seal the video-recorded testimony to prevent Regeneron from using it in its upcoming litigation against Celltrion.

IV. CONCLUSION

For the foregoing reasons, Celltrion respectfully requests that the Board seal certain portions of Dr. Tarantino's deposition (EX1049), as well as the video-recording of this deposition, to limit their use to this proceeding.

Respectfully submitted,

Date: November 17, 2023

/ Lora M. Green /
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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing Petitioner's Motion to Seal was served on November 17, 2023, on the Patent Owner at the following electronic correspondence addresses:

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