

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 REPLY IN SUPPORT OF ITS MOTION TO
SEAL PORTIONS OF TRANSCRIPT OF DR. TARANTINO'S
DEPOSITION AND VIDEO OF DEPOSITION**

Patent Owner argues that it should be allowed to improperly buttress its litigation positions using testimony from Dr. Tarantino's deposition. The Board has explained that this is not a proper use of the IPR proceeding. Patent Owner's appeal to the "strong public policy favoring access," Opp., 2, is belied by the fact that the only information Petitioner seeks to seal is material that has no relevance to the '992 Patent. Patent Owner knows this and attempts to point to out-of-context paragraphs in Dr. Tarantino's declaration to try to lend an aura of relevance to its questioning. This attempt fails, and the Board should accordingly seal the relevant parts of Dr. Tarantino's deposition (and Patent Owner's Response that relies on the same). Moreover, Patent Owner does not even attempt to articulate why Dr. Tarantino's video deposition should be made public, as it contains no information that is not in the transcript, and it is not relied upon in the POR. The only possible use would be in the upcoming BPCIA litigation between Regeneron and Celltrion. The Board should seal the entirety of Dr. Tarantino's video deposition in order to prevent its misuse in litigation.

I. ARGUMENT

a. Good Cause Exists to Seal the Deposition

As explained in Petitioner's Motion, PTAB proceedings such as IPRs should not be used for improper purposes, including to develop litigation positions. Mot.,

5. Patent Owner’s questioning, which indisputably was not relevant to the claims of the ’992 patent, is instead being used to develop litigation positions.¹

The case cited by Patent Owner is not to the contrary. In *Argentum v. Alcon*, IPR2017-01053, Paper 27, the Board declined to seal certain irrelevant documents that were not material to any issue in the case where their disclosure would not harm the movant. Here, the material Celltrion seeks to seal has no relevance to *this* proceeding, but may be relevant to the BPCIA litigation. And its disclosure would harm Celltrion, as Patent Owner’s litigation counsel could improperly use the testimony obtained for narrow purposes of this IPR in the litigation for which its use is not authorized. The Board has made clear that IPR proceedings are meant to be focused on the specific issue unique to the IPR proceeding itself, as opposed to being used as a tool to benefit other litigation positions. Mot., 5.

b. The Material Petitioner Seeks to Seal is not Relevant to this IPR

Patent Owner attempts to tie its improper questioning to Dr. Tarantino’s declaration. But cherry-picking words and phrases in Dr. Tarantino’s declaration

¹ Indeed, BPCIA litigation counsel for Regeneron intends to appear at the upcoming deposition of Dr. Klivanov “in a purely observational capacity,” underscoring the importance of this proceeding to Regeneron’s BPCIA litigation outside counsel. *See* EX1050 (January 10, 2024 Email from Brausa to Green).

is not sufficient to show that the broad questioning on these topics, which are not relevant to the challenged claims of the '992 patent, should be fair game for Regeneron to use in an upcoming litigation. In fact, Dr. Tarantino did not substantively discuss these issues in his declaration, and Patent Owner's questioning on them was outside the scope of his report.

Proteolytic Cleavage

Patent Owner asserts that Dr. Tarantino discussed "proteolytic cleavage" in his declaration at ¶69, and again at ¶¶79-80. Opp., 4-5. Patent Owner seems to be referring to a table reproduced in Dr. Tarantino's declaration, which lists "cleavages" as a general stability problem encountered in protein pharmaceutical development, and gives potential causes and solutions. However, the concept of proteolytic cleavage is not relevant to the claims of the '992 patent – none of the claims discuss cleavage or its byproducts. Nor did Dr. Tarantino discuss cleavage substantively in his declaration, other than the mention of the term in this reproduced table. Paragraphs 79-80 discuss aggregation and size exclusion chromatography, and make no mention of "proteolytic cleavage."

Structure of Daclizumab

The '992 patent concerns aflibercept, not daclizumab. Dr. Tarantino's declaration made no mention of daclizumab, and Patent Owner does not claim that it did. Instead, Patent Owner avers that Dr. Tarantino stated that "aflibercept and

antibodies have similar structures,” and that Dr. Tarantino relied on antibody data to make conclusions about aflibercept. Opp. 6-7. According to Patent Owner, this opinion allows for questioning about the structure of a completely unrelated antibody. This unsubstantiated leap is unfounded – Dr. Tarantino’s opinion, which is that the “98% native conformation” was a routine goal that was achieved in the prior art, does not open the door to questioning about daclizumab, a molecule that has no relation to the ’992 patent or Dr. Tarantino’s opinions.

Osmolarity, Tonicity, and Viscosity

Once again, the claims of the ’992 patent do not relate to osmolarity, tonicity, and viscosity. But the claims of other patents at issue in the concurrent BPCIA litigation do. Mot., 3-4. Patent Owner’s argument that the Fraser formulation, which contained 20% sucrose, would result in a “hypertonic solution suboptimal for patient comfort,” Opp., 7, is irrelevant to the claims of the ’992 patent, which nowhere discuss tonicity, or patient comfort. The claims of the ’992 patent cover formulations that are optimal for patient comfort and that are not optimal for patient comfort. There is no indication that patient comfort is an issue at all in the ’992 patent. Accordingly, Patent Owner’s questioning on these topics is again outside the scope of Dr. Tarantino’s declaration.

Other Questions

Patent Owner lumps a number of topics, including some previously discussed, under an umbrella argument regarding Dr. Tarantino's opinion that a POSA would want to minimize aggregation. Opp., 8. Needless to say, Dr. Tarantino's opinion regarding aggregation does not open the door to questioning about every conceivable topic regarding the formulation of proteins that Patent Owner can come up with, especially where there is concern, as here, that such questioning would be improperly used to bolster litigation positions, rather than to support its arguments concerning the claims of the '992 patent, which do not mention topics such as viscosity, tonicity, or safety.

c. The Video Deposition Should be Sealed

Patent Owner does not make any specific argument regarding the video deposition. As explained in Petitioner's motion, video depositions are disfavored at the PTAB, and Patent Owner's POR made no reference to it. Mot., 6. Accordingly, there is no reason, other than its improper use in another proceeding, for the video of Dr. Tarantino's deposition to be made public. Any information that the public would glean from Dr. Tarantino's video deposition can be gleaned from the transcript, the vast majority of which will remain unsealed.

II. CONCLUSION

Therefore, Celltrion respectfully requests that the Board seal certain portions of Dr. Tarantino's deposition (EX1049) and corresponding video recording.

Respectfully submitted,

Dated: January 16, 2024

/ Lora M. Green /

Lora M. Green, Lead Counsel

Reg. No. 43,541

CERTIFICATE OF SERVICE

The undersigned certifies that the forgoing Petitioner's Reply in Support of its Motion to Seal and EX1050 were served on this 16th day of January, 2024, on the Patent Owner at the following electronic correspondence addresses:

Adam R. Brausa	ABrausa@mofo.com
Rebecca Weires	RWeires@mofo.com
Kira A. Davis	KiraDavis@mofo.com
Daralyn J. Durie	DDurie@mofo.com
Regeneron-MoFo-IPR@mofo.com	

Respectfully submitted,

Dated: January 16, 2024

/ Lora M. Green /

Lora M. Green, Lead Counsel

Reg. No. 43,541