

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLTRION, INC.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Patent No. 10,464,992

Inter Partes Review No. IPR2023-00462

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

Patent Owner Regeneron Pharmaceuticals, Inc. opposes Petitioner Celltrion, Inc.'s Motion to Seal Portions of Transcript of Dr. Tarantino's Deposition and Video of Deposition ("Motion"), Paper 26. Petitioner fails to show good cause to seal. Petitioner does not attempt to make the required showing that the information it seeks to seal is confidential. Petitioner instead argues that there is good cause to seal because, it alleges, Patent Owner's questions exceeded the scope of Dr. Tarantino's declaration and therefore must have been intended to develop litigation positions. The filings show otherwise: the questions posed in Dr. Tarantino's deposition relate to opinions in his declaration and to Patent Owner's arguments in this IPR. Petitioner's motion should be denied.¹

¹ Petitioner wrongly assumes that Patent Owner opposes the sealing of only those portions of the transcript that Regeneron filed with its Patent Owner Response. Motion at 3 n.2. With its Response, Patent Owner filed excerpts of the Tarantino deposition transcript, Ex.2054, in order to limit the scope of the dispute between the parties about sealing. Petitioner has now filed the complete transcript, Ex.1048; Ex.1049, broadening the scope of the dispute. Patent Owner opposes sealing any portion of Dr. Tarantino's deposition, regardless of whether it was filed with Patent Owner's Response.

I. LEGAL STANDARD

In an IPR, the “default rule” is that all materials remain “open and available.” *Argentum v. Alcon*, IPR2017-01053 Paper 27 at 3 (PTAB Jan. 19, 2018) (informative) (quoting *Garmin Int’l v. Cuozzo Speed Techs., LLC*, IPR2012-00001 Paper 34 at 2 (PTAB Mar. 14, 2013)); 37 C.F.R. § 42.14. This rule reflects a “strong public policy” favoring public access. *Argentum*, IPR2017-01053 Paper 27 at 3.

A party may move to seal information filed in an IPR, 37 C.F.R. § 42.14, but only “confidential information” may be protected from disclosure, *Garmin*, IPR2012-00001 Paper 34 at 2. The movant must show good cause to seal, and the good cause standard requires a showing that “the information sought to be sealed is truly confidential.” *Argentum*, IPR2017-01053 Paper 27 at 3-4.

The following types of information are typically treated as “confidential information” in IPR proceedings: “trade secret or other confidential research, development, or commercial information.” 37 C.F.R. § 42.54; Patent Trial and Appeal Board Consolidated Trial Practice Guide I.E.2. (Nov. 2019); *see also* *Garmin*, IPR2012-00001 Paper 34 at 2.

II. THE TRANSCRIPT AND VIDEO OF DR. TARANTINO’S DEPOSITION CONTAIN NO CONFIDENTIAL INFORMATION

Petitioner’s motion to seal does not mention or attempt to make the required showing that “the information sought to be sealed is truly confidential” as defined

in the Board's rules. *Argentum*, IPR2017-01053 Paper 27 at 3-4. Petitioner does not allege that any of the information it seeks to seal is "trade secret or other confidential research, development, or commercial information." 37 C.F.R.

§ 42.54. Nor can it. Petitioner notes that it recently filed an abbreviated Biologics License Application ("aBLA") for a biosimilar version of EYLEA® and entered litigation against Patent Owner under the Biologics Price Competition and Innovation Act ("BPCIA"). Motion at 1-2. But Patent Owner did not seek, and Dr. Tarantino did not provide, any information about the aBLA or any of Petitioner's confidential information from the BPCIA litigation. Instead, Patent Owner asked about general principles of protein formulation and their application to the prior art in this case. Because the transcript and video do not include any of the enumerated categories of "confidential information," the Board should make a determination that they are not entitled to confidential treatment under the operative protective order, Ex.2046 (Default Protective Order) at 5(A)(i); *see* Paper 29 (entering Default Protective Order), and deny Petitioner's motion.

III. PATENT OWNER'S DEPOSITION QUESTIONS ARE RELEVANT TO DR. TARANTINO'S DECLARATION AND THE PATENT OWNER RESPONSE

Petitioner's theory of good cause for sealing portions of the record fails because Patent Owner's deposition questions were within the proper scope of cross-examination and relevant to Patent Owner's arguments in this IPR.

Petitioner accuses Patent Owner of exceeding the proper scope of discovery in order to develop litigation positions. Under 37 C.F.R. §§ 42.51(b)(1)(ii) and 42.53(d)(5)(ii), parties are entitled to cross examine declarants within “the scope of the direct testimony.” The questions in the portions of Dr. Tarantino’s deposition that Petitioner now seeks to seal are within the scope of his declaration and relevant to this proceeding. Below, Patent Owner summarizes how the testimony from Dr. Tarantino relates to Dr. Tarantino’s declaration and to positions developed by Patent Owner in its Patent Owner’s Response (“POR”). Far from being asked for an “improper purpose,” as Petitioner contends, the summary below confirms that the questions Dr. Tarantino was asked are directly relevant to this proceeding and his opinions. Patent Owner may not like the testimony Dr. Tarantino provided, but that is not a reason to seal any portions of his deposition.

Cleavage—Petitioner moves to seal questions and answers regarding proteolytic cleavage. Ex.1048, 22-24; Ex.1049, 22-24. But these questions were directed to Dr. Tarantino’s discussion of cleavage in his opening declaration, which he identified as an “instabilit[y] that may arise during development of a complex protein like aflibercept.” Ex.1002 ¶ 69. Dr. Tarantino also listed protein fragments (which can result from cleavage) among the degradation products that

can be detected with size exclusion chromatography. Ex.1002 ¶ 79-80; *see* Ex.1047, 21.

During his deposition, Patent Owner asked Dr. Tarantino what a formulator would think of an excipient that could lead to cleavage. Ex.1049 at 22-24. These questions relate to Dr. Tarantino's opinions regarding phosphate and citrate-phosphate buffers because, as Patent Owner explained, phosphate ions catalyze proteolytic cleavage. POR 63; Ex.2047 ¶ 30. Dr. Tarantino opined that a POSA would be motivated to use Fraser's formulation, which contains "buffer composed of 5 mM phosphate, 5 mM citrate," Ex.1002 ¶¶ 147-150; Ex.1009, 1115, and would seek to minimize aggregation by making "incremental adjustments to the concentration[] of ... phosphate buffer," Ex.1002 ¶ 159. Patent Owner responded that Fraser's choice of buffer would lead a POSA to doubt that the prior art formulation had been optimized, POR 46, and further argued that adjusting the buffer concentration to minimize aggregation could "risk catalyzing other forms of degradation," POR 55-56.

Patent Owner's questions about cleavage are also relevant to Dr. Tarantino's opinion that claims 9 and 18, which require a phosphate buffer, are obvious based on Fraser. Ex.1002 ¶ 185. Patent Owner responded that Fraser's formulation contains a citrate-phosphate buffer and that a POSA would not be motivated to

replace it with a phosphate buffer, due in part to concerns about cleavage. POR 62-64.

Antibody structure—Petitioner also moves to seal questions and answers regarding the primary, secondary, and tertiary structure of daclizumab, an antibody Dr. Tarantino is familiar with from his prior work. Ex.1048, 27-30; Ex.1049, 27-30. The structure of antibodies is within the scope of Dr. Tarantino’s declaration, in which he opined that “aflibercept and antibodies have similar structures.” Ex.1002 ¶ 70. Based on that assertion, Dr. Tarantino relied on references related to antibodies for various purposes, including as part of his opinion that a POSA would be motivated to achieve 98 or 99% native conformation of aflibercept and would have a reasonable expectation of success because “the art disclosed numerous embodiments of *antibody* formulations that had 98 or 99% native conformation.” Ex.1002 ¶ 153 (emphasis added); *see also* Ex.1002 ¶¶ 72-75, 77-78, 88-97, 102. Patent Owner responded that aflibercept is a fusion protein, and fusion proteins and antibodies are “structurally distinct in 3-dimensional space, with different primary, secondary, and tertiary structure.” POR 60. Thus, Patent Owner argued, a POSA would not expect based on Petitioner’s antibody referenced that the recited native conformation result could be achieved for aflibercept. *Id.*; *see also* POR 3-4 (“[E]very protein has its own

unique physiochemical properties, which may present unique stability concerns and challenges.”).

Patent Owner asked Dr. Tarantino whether changes to the primary sequence of daclizumab would impact stability. Ex.1049, 30. This question is within the scope of Dr. Tarantino’s opinion that the Dix reference provides stability data for Fraser’s protein formulation. Ex.1002 ¶¶ 96-102. As Patent Owner argued, Fraser does not include enough information to know that the protein used for that study had the same sequence (primary structure) as Dix’s, and sequence can impact stability. POR 33-35.

Osmolarity, Tonicity, and Viscosity—Petitioner also moves to seal questions and answers regarding osmolarity, tonicity, and viscosity, and the relationship between these properties and the concentration of sucrose in a formulation. Ex.1048, 33-38, 61-67, 81-87; Ex.1049 at 33-38, 61-67, 81-87. These questions are within the scope of Dr. Tarantino’s opinions that a POSA would look to the formulations of Fraser and Wulff that contain 20% sucrose. Ex.1002 ¶¶ 146-150. Dr. Tarantino opined that a POSA would assume the 20% sucrose formulation was “relatively advanced” and would use it as a starting point to formulate aflibercept. *Id.* Patent Owner responded that such a high concentration of sucrose would be concerning to a POSA, including because it would create a hypertonic solution “suboptimal for human patient comfort.” POR

45-46. For this reason among others, a POSA “would not have viewed Fraser’s formulation...as a suitable starting point.” POR 46.

Stability and Other Formulation Objectives and Constraints—Petitioner also moves to seal questions and answers regarding the various objectives and constraints a formulator would face. Exs.1048 & 1049, 22:6-20 (cleavage); 33:2-34:7 (viscosity), 65:24-66:23 (tonicity), 81:10-82:19 (tonicity), 86:20-87:24 (tonicity, safety, efficacy), 88:5-22 (chemical and physical stability), 88:23-90:3 (aggregation and denaturation). These are all within the scope of Dr. Tarantino’s opinion that a POSA “would have been motivated to reduce aggregation as much as possible” and would adjust the concentrations of excipients to achieve this goal. Ex.1002 ¶¶ 153-159. Patent Owner responded that a POSA would actually “balance and make tradeoffs between the extent of aggregation on one hand and other formulation objectives, including protein concentration, tonicity, viscosity, and other physical and chemical instabilities, on the other.” POR 55-58.

Based on the foregoing, Petitioner is wrong that Patent Owner’s deposition questions exceeded the scope of Dr. Tarantino’s declaration and were asked for purposes of developing litigation positions. All of the questions Petitioner seeks to seal fall within the scope of Dr. Tarantino’s declaration, his expertise, and the issues in this IPR proceeding. Therefore, even if seeking discovery for improper

purposes were a permissible basis for sealing, there is no evidence of such an improper purpose here. For this independent reason, the Board should make a determination that nothing in the transcript or video is entitled to confidential treatment under the operative protective order, Ex.2046, 5(A)(i); Paper 29, and should deny Petitioner's motion.

Dated: December 15, 2023

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Certificate of Service (37 C.F.R. § 42.6(e)(4))

I hereby certify that the attached PATENT OWNER'S OPPOSITION TO PETITIONER'S MOTION TO SEAL PORTIONS OF TRANSCRIPT OF DR. TARANTINO'S DEPOSITION AND VIDEO OF DEPOSITION was served on the date listed below via email (by agreement) upon the following counsel of record for Petitioner.

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