

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD., CELLTRION INC.,
and BIOCON BIOLOGICS INC.

Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Patent No. 11,253,572

Inter Partes Review No. IPR2023-00884¹

MOTION FOR AMENDED PROTECTIVE ORDER

¹ IPR2024-00260 and IPR2024-00298 are joined with this proceeding.

Patent Owner Regeneron Pharmaceuticals, Inc. moves for entry of the Amended Protective Order, filed concurrently as Ex. 2245. The amended protective order includes an “Outside Counsel Only” tier for highly confidential information. Good cause exists to so amend the protective order because Regeneron will be producing highly confidential documents related to its recent strategic decision-making and its proprietary manufacturing process.

I. PROCEDURAL BACKGROUND

Regeneron is litigating the ’572 and other patents in the Northern District of West Virginia in several actions, including in *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, No. 1:22-cv-00061-TSK (N.D. W.Va.) (“Mylan Litigation”). A trial was held in that case in June 2023.

In the present IPR, Petitioner Samsung Bioepis Co., Ltd requested additional discovery of deposition and trial exhibits from the Mylan Litigation. Ex.1070, 11-12. Many of the requested materials were produced in the Mylan Litigation subject to the protective order in that litigation. Some were designated “Outside Counsel’s Eyes Only.” When Regeneron noted this fact, Samsung “agree[d] that documents produced on an Outside Counsel’s Only basis in the Mylan Litigation can be designated as Outside Counsel’s Eye[]s Only in this IPR.” Ex.1070, 8.

The Board granted Samsung’s motion for additional discovery on May 23, 2024. Paper 58. The Board ordered Regeneron to produce the requested documents

by May 31, 2024 and invited the parties to request a modified protective order if necessary. Paper 58 at 10-11.

II. GOOD CAUSE EXISTS TO AMEND THE PROTECTIVE ORDER

The Board may issue a protective order “for good cause” in order “to protect a party from disclosing confidential information.” 37 C.F.R. § 42.54. The protective order may require “that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a specified way.” 37 C.F.R. § 42.54(a)(7).

Good cause exists to amend the protective order. The additional discovery Regeneron will serve encompasses highly confidential information. Regeneron does not believe that the Board’s default protective order, which currently governs this IPR, offers an adequate level of protection for these materials. For example, Regeneron will produce the following:

- A 2018 internal PowerPoint presentation describing the potential commercial effects of biosimilar competition and Regeneron’s strategic responses to such competition, as well as deposition testimony about the same.
- Interrogatory responses describing Regeneron’s manufacturing processes. Regeneron developed new manufacturing processes within the last ten years, aspects of which are Regeneron’s trade secrets.

Some of the requested documents were produced subject to “Outside Counsel’s Eyes Only” protective order provisions in the Mylan Litigation. Regeneron would be harmed if its competitors obtained this information and intentionally or inadvertently misused or disclosed it. The default protective order does not restrict the party itself from accessing confidential information, which creates a risk of widespread distribution within the company, and in turn a risk of disclosure or misuse of Regeneron’s confidential information.

The Regeneron and Samsung have agreed to a protective order that addresses Regeneron’s concern. Ex.2045; Appendix A (redline comparison to default protective order). The proposed protective order includes heightened “Outside Counsel Only” protections for highly confidential information.

III. CERTIFICATION

Pursuant to 37 CFR § 42.54, Patent Owner certifies that it has conferred with Petitioners regarding this motion for a protective order. Samsung does not object to the motion. Petitioners Celltrion Inc. and Biocon Biologics Inc. have not responded with their position.

Dated: 5/31/2024

Respectfully submitted,

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

I hereby certify that the attached MOTION FOR AMENDED PROTECTIVE ORDER was served as of the below date via email on the Petitioner (by agreement) at the following correspondence address:

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Matthew A. Traupman (Reg. No. 50,832)
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Dated: 5/31/2024

/Adam R. Brausa/
Adam R. Brausa, Reg. No. 60,287

Appendix A

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD., CELLTRION INC.,
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AMENDED PROTECTIVE ORDE

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~~DEFAULT~~ AMENDED PROTECTIVE ORDER

This protective order governs the treatment and filing of confidential information, including documents and testimony.

1. Confidential information shall be clearly marked “PROTECTIVE ORDER MATERIAL.” or “PROTECTIVE ORDER MATERIAL – OUTSIDE COUNSEL ONLY.”

2. Access to confidential information marked “PROTECTIVE ORDER MATERIAL” is limited to the following individuals who have executed the acknowledgment appended to this order:

(A) Parties. Persons who are owners of a patent involved in the proceeding and other persons who are named parties to the proceeding.

(B) Party Representatives. Representatives of record for a party in the proceeding.

(C) Experts. Retained experts of a party in the proceeding who further certify in the Acknowledgement that they are not a competitor to any party, or a consultant for, or employed by, such a competitor with respect to the subject matter of the proceeding.

(D) In-house counsel. In-house counsel of a party.

(E) Support Personnel. Administrative assistants, clerical staff, court reporters and other support personnel of the foregoing persons who are reasonably necessary to assist those persons in the proceeding shall not be required to sign an Acknowledgement, but shall be informed of the terms and requirements of the Protective Order by the person they are supporting who receives confidential information.

(F) The Office. Employees and representatives of the United States Patent and Trademark Office who have a need for access to the confidential information shall have such access without the requirement to sign an Acknowledgement. Such employees and representatives shall include the Director, members of the Board and their clerical staff, other support personnel, court reporters, and other persons acting on behalf of the Office.

3. Access to confidential information marked “PROTECTIVE ORDER MATERIAL – OUTSIDE COUNSEL ONLY” is limited to the following individuals who have executed the acknowledgment appended to this order:

(A) Party Representatives. Representatives of record for a party, who have appeared in the proceeding (IPR2023-00884) as of May 31, 2024, who are not also in-house counsel for a party.

(B) Experts. Retained experts of a party in the proceeding who (1) are not current employees of a party, (2) at the time of retention, are not anticipated to become officers, directors, or employees of a Party, and (3) are not a competitor to any party, or a consultant for, or employed by, such a competitor with respect to the subject matter of the proceeding.

(C) Support Personnel. Administrative assistants, clerical staff, court reporters and other support personnel of the foregoing persons who are reasonably necessary to assist those persons in the proceeding shall not be required to sign an Acknowledgement, but shall be informed of the terms and requirements of the Protective Order by the person they are supporting who receives confidential information.

(D) The Office. Employees and representatives of the United States Patent and Trademark Office who have a need for access to the confidential information shall have such access without the requirement to sign an Acknowledgement. Such employees and representatives shall include the Director, members of the Board and their clerical staff, other support personnel, court reporters, and other persons acting on behalf of the Office.

For clarity, the omission of in-house counsel from this list of individuals is intended to preclude in-house counsel for the non-disclosing party from accessing the disclosing party's confidential information; it is not intended to preclude in-

house counsel for a disclosing party from accessing the disclosing party's own confidential information. The "PROTECTIVE ORDER MATERIAL – OUTSIDE COUNSEL ONLY" designation shall be applied only to confidential information that has not been made publicly available and that is competitively sensitive—i.e., if disclosed, could reasonably be used to inform or guide business decisions that would compete with or otherwise harm the designating party.

4. Employees (e.g., corporate officers), consultants, or other persons performing work for a party, other than those persons identified above in ~~(d)(Paragraphs 2)(A)–(E) and 3(A)–(C)~~, shall be extended access to confidential information only upon agreement of the parties or by order of the Board upon a motion brought by the party seeking to disclose confidential information to that person and after signing the Acknowledgment. The party opposing disclosure to that person shall have the burden of proving that such person should be restricted from access to confidential information.

45. Persons receiving confidential information shall use reasonable efforts to maintain the confidentiality of the information, including:

(A) Maintaining such information in a secure location to which persons not authorized to receive the information shall not have access;

(B) Otherwise using reasonable efforts to maintain the confidentiality of the information, which efforts shall be no less rigorous than those the recipient uses to maintain the confidentiality of information not received from the disclosing party;

(C) Ensuring that support personnel of the recipient who have access to the confidential information understand and abide by the obligation to maintain the confidentiality of information received that is designated as confidential; and

(D) Limiting the copying of confidential information to a reasonable number of copies needed for conduct of the proceeding and maintaining a record of the locations of such copies.

56. Persons receiving confidential information shall use the following procedures to maintain the confidentiality of the information:

(A) Documents and information Filed With the Board.

(i) A party may file documents or information with the Board along with a Motion to Seal. The Motion to Seal should provide a non-confidential description of the nature of the confidential information that is under seal, and set forth the reasons why the information is confidential and should not be made available to the public. A party may challenge the confidentiality of

the information by opposing the Motion to Seal. The documents or information shall remain under seal unless the Board determines that some or all of it does not qualify for confidential treatment.

(ii) Where confidentiality is alleged as to some but not all of the information submitted to the Board, the submitting party shall file confidential and non-confidential versions of its submission, together with a Motion to Seal the confidential version setting forth the reasons why the information redacted from the non-confidential version is confidential and should not be made available to the public. A party may challenge the confidentiality of the information by opposing the Motion to Seal. The non-confidential version of the submission shall clearly indicate the locations of information that has been redacted. The confidential version of the submission shall be filed under seal. The redacted information shall remain under seal unless the Board determines that some or all of the redacted information does not qualify for confidential treatment.

(B) Documents and Information Exchanged Among the Parties. Documents (including deposition transcripts) and other information designated as confidential that are disclosed to another party during discovery or other proceedings before the Board shall be clearly marked as “PROTECTIVE ORDER MATERIAL” or “PROTECTIVE ORDER MATERIAL –

OUTSIDE COUNSEL ONLY” and shall be produced in a manner that maintains its confidentiality.

~~67.~~ Within 60 days after the final disposition of this action, including the exhaustion of all appeals and motions, each party receiving confidential information must return, or certify the destruction of, all copies of the confidential information to the producing party.

~~(k) Standard Acknowledgement of Protective Order. The following form may be used to acknowledge a protective order and gain access to information covered by the protective order:~~

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~~Standard~~ Acknowledgement for Access to Protective Order Material

I _____, affirm that I have read the Protective Order; that I will abide by its terms; that I will use the confidential information only in connection with this proceeding and for no other purpose; that I will only allow access to support staff who are reasonably necessary to assist me in this proceeding; that prior to any disclosure to such support staff I informed or will inform them of the requirements of the Protective Order; that I am personally responsible for the requirements of the terms of the Protective Order and I agree to submit to the jurisdiction of the Office and the United States District Court for the Eastern District of Virginia for purposes of enforcing the terms of the Protective Order and providing remedies for its breach.

[signature]

² IPR2024-00260 and IPR2024-00298 are joined with this proceeding.