

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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

Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,  
Patent Owner.

Patent No. 11,253,572

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*Inter Partes* Review No. IPR2023-00884<sup>1</sup>

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**MOTION FOR AMENDED PROTECTIVE ORDER**

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<sup>1</sup> 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.

IPR2023-00884

Dated: 5/31/2024

Respectfully submitted,

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