

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
CLARKSBURG DIVISION**

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

CELLTRION, INC.,

Defendant.

Civil Action No. 1:23-cv-00089-TSK

STIPULATED PROTECTIVE ORDER

Pursuant to Northern District of West Virginia Local Rule 26.05, and upon agreement of the Parties for an order pursuant to Federal Rule of Civil Procedure 26(c), Plaintiff Regeneron Pharmaceuticals, Inc. (“Regeneron”) and Defendant Celltrion, Inc. (“Celltrion”) (each a “Party” and collectively the “Parties”), hereby stipulate to the entry of this Protective Order concerning the confidentiality of documents and other information that has been or will be exchanged between the Parties during discovery in the above-captioned action (the “Action”). Celltrion’s stipulation to this Protective Order is without prejudice to its standing objections to jurisdiction and venue, as set forth in its January 17, 2024 motion papers:

I. Definitions.

1. As used in this Protective Order, these terms have the following meanings:
 - (a) “Patents-in-Suit” refers to United States Patents that Regeneron has claimed Celltrion infringes as set forth in the operative complaint in this Action;
 - (b) “Action” means the case captioned *Regeneron Pharmaceuticals, Inc. v. Celltrion, Inc.*, Case No. 1:23-cv-00089-TSK, which is currently pending in the Northern District of West Virginia;

- (c) “Affiliate” means any Third Party that, directly or indirectly, through one or more intermediaries controls, or is controlled by, or is under common control with, a Party to this Action;
- (d) “CONFIDENTIAL” information includes information that constitutes, contains, reveals, or reflects trade secrets or other confidential research, development, business, or commercial information within the meaning of Federal Rule of Civil Procedure 26(c)(1)(G), including but not limited to: scientific and technical information; financial (including pricing and sales information), budgeting and/or accounting information; information about existing and potential customers; marketing and other business strategies, decisions or negotiations; employee compensation, evaluation and other employment information; business plans; manufacturing information; licensing agreements; regulatory information (including non-public correspondence with the United States and foreign patent offices and regulatory agencies); and information that concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the production, sales, shipments, purchases, transfers, identification of customers, inventories, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or other organization; and any other information that is protected from disclosure by the laws of the United States or another country; and includes such confidential and proprietary information about a Third Party, including parents, subsidiaries, and/or other Affiliates; “Personal Data” as defined

below, and any other information the disclosure of which would harm the competitive position of the Producing Party if the information becomes known to a person or party other than the Producing Party other than as permitted hereunder;

- (e) “CONTROLLED HIGHLY CONFIDENTIAL INFORMATION” means any Disclosure responsive to a subpoena where such Disclosure contains extremely sensitive and highly confidential and proprietary trade secret information deserving even further limitation on its production than OUTSIDE COUNSEL’S EYES ONLY Disclosures. The designation CONTROLLED HIGHLY CONFIDENTIAL INFORMATION may be abbreviated as “CHCI” or “CHCI Disclosure;”
- (f) “Designated In-house Counsel” means an attorney, or member of an in-house legal division, who is an employee of a Party or a Party’s Affiliate and is designated in accordance with Paragraph 9(h);
- (g) “Designating Party” is a Party or Third Party that designates information or items that it produces in Disclosures as “CONFIDENTIAL,” “OUTSIDE COUNSEL’S EYES ONLY,” or “CONTROLLED HIGHLY CONFIDENTIAL INFORMATION”;
- (h) “Disclosure(s)” means all documents; written discovery requests and responses; deposition transcripts; correspondence between the Parties; pleadings; exhibits; documents and things made available for inspection; expert testimony and reports; biological materials produced by a Party or Third Party in this Action including, but not limited to, any physical samples

of cells, polynucleotides, or proteins; all other discovery taken pursuant to the Federal Rules of Civil Procedure, including Third Party discovery pursuant to Federal Rule of Civil Procedure 45; and tangible items and any other information produced or disclosed between the Parties in connection with this Action, including the pre-suit exchanges made pursuant to 42 U.S.C. § 262(l). For the sake of clarity, the production of biological samples shall be governed by the terms set forth in Paragraph 45;

- (i) “Document(s)” means all materials within the scope of Federal Rule of Civil Procedure 34(a);
- (j) “Expert” is a person with specialized knowledge or experience in a matter pertinent to the Action who (1) has been retained by a Party or its Outside Counsel to serve as an expert witness or as a consultant in this Action, (2) is not a current employee of a Party, and (3) at the time of retention, is not anticipated to become an officer, director, or employee of a Party. Nothing in this Protective Order purports to alter the requirements for offering testimony under Federal Rule of Evidence 703, or to define the term “expert” for purposes other than those addressed in this Protective Order;
- (k) “In-House Counsel” means an in-house attorney, or member of an in-house legal division, who is an employee of a Party to this Action or a Party’s Affiliate;
- (l) “Third Party” is any natural person, partnership, corporation, association, or other legal entity that is not a Party or a Party’s Affiliate;

- (m) “Outside Counsel” means the external lawyers retained by the Parties to litigate this Action and who have appeared in this Action or are acting at the direction of a lawyer who has appeared in this Action, including, but not limited to, outside attorneys admitted *pro hac vice* in this Action and paralegals, assistants, and other employees or contractors of the respective law firms of Outside Counsel;
- (n) “OUTSIDE COUNSEL’S EYES ONLY” information means particularly sensitive information relevant to the Designating Party’s current or prospective products, scientific or technical information, business information of current or prospective significance and for which production on a confidential basis, even to In-house Counsel, would create a substantial risk of serious harm to the Designating Party that could not be avoided by less restrictive means. For clarity, the OUTSIDE COUNSEL’S EYES ONLY designation shall not be applied to materials disclosed in exchanges made pursuant to 42 U.S.C. §262(l) that were not designated OUTSIDE COUNSEL’S EYES ONLY or CONTROLLED HIGHLY CONFIDENTIAL INFORMATION.
- (o) “Party” means any party to this Action, including all of its officers, directors, employees;
- (p) “Personal Data” means any information that a Party believes in good faith to be subject to data protection laws or other privacy obligations. In particular, such data protection laws include the European Union General Data Protection Regulation (“GDPR”), the German

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