

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

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

Case No. 1:22-cv-00061-TSK

JURY TRIAL DEMANDED

PLAINTIFF’S MOTION TO MODIFY PRODUCTION DEADLINE

Plaintiff Regeneron Pharmaceuticals, Inc. (“Regeneron”) respectfully requests a modest modification to the production deadline and procedure set forth in the Court’s April 6, 2023 order, Dkt. 405 (the “Order”). The Order requires Regeneron to produce documents responsive to Mylan’s Request for Production Nos. 144-151 within five days, *i.e.*, by April 11. In light of the holiday weekend and the large volume of materials to be produced, however, Regeneron requests that the Court extend that deadline to April 14. Regeneron will commence a rolling production in advance of April 14.

In addition, a small fraction of the documents at issue in the Order are confidential and restricted by court order in *United States v. Regeneron Pharmaceuticals, Inc.*, No. 1:20-cv-11217-FDS (D. Mass.) (“DOJ Litigation”). These restricted documents fall into two categories.

First, some responsive documents are confidential under the Stipulated Confidentiality Agreement and Protective Order in the DOJ Litigation [Dkt. 54 in the DOJ Litigation; attached hereto as Exhibit A]. The Stipulated Confidentiality Agreement and Protective Order in the DOJ Litigation requires Regeneron to notify each producing party whose documents have been compelled for production “so that the producing party has the opportunity to contest the [Order]

to protect its Confidential information through appropriate legal means.” Ex. A ¶ 7. In addition, “[s]uch notification must include a copy of the . . . court order.” *Id.* This Court’s Order was filed under seal. To address this category of documents, Regeneron requests that the Court enter the accompanying publicly filed order, allow Regeneron one business day from the entry of that order to notify affected third parties, and allow any challenging party to object within ten days, after which time Regeneron shall produce any information that is not the subject of a protective order challenge. A proposed order to that effect is attached hereto as Exhibit B.

Second, a small number of the documents at issue in the Order are under seal or otherwise restricted pursuant to court orders in the DOJ Litigation separate and apart from the Stipulated Confidentiality Agreement and Protective Order in that case. These sealing orders must be modified before the sealed documents at issue in the Order can be produced. Accordingly, Regeneron requests that the Court enter the accompanying publicly filed order and allow Regeneron one business day from the entry of that order to begin the process of notifying affected parties, and then promptly meeting and conferring with them and filing a motion or motion(s) in the DOJ Litigation to modify the operative sealing orders to allow for production in this case if agreement cannot be secured. This process is also reflected in the proposed order attached hereto as Exhibit B.

Regeneron has commenced conferring with Defendant Mylan Pharmaceuticals Inc., which has not yet taken a position. In light of the production timing directed by the Court, Regeneron wished to commence with the Court its request for the limited foregoing modification of the Court’s Order.

Date: April 7, 2023

Respectfully submitted,

Of Counsel:

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Counsel for Plaintiff Regeneron Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on April 7, 2023, I electronically filed the foregoing with the Clerk of the Court by using the Court's CM/ECF system. Counsel of record for all parties will be served by the Court's CM/ECF system.

/s/ David R. Pogue

David R. Pogue (WVSB No. 10806)

EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 1:20-cv-11217-FDS
)	
REGENERON PHARMACEUTICALS, INC.,)	
)	
Defendant.)	
)	

STIPULATED
CONFIDENTIALITY AGREEMENT AND PROTECTIVE ORDER

The Parties, by their undersigned Counsel, hereby stipulate pursuant to Federal Rules of Civil Procedure 26 and 34, subject to approval and entry by the Court, as follows:

1. This Order shall govern all information produced in response to a discovery request, whether formal or informal, in or related to the above-captioned litigation.
2. **Definition of Confidential Information.** The designation “Confidential” shall be limited to information that any producing party, including any third party, in good faith, believes to contain:
 - a. Pricing data governed by the confidentiality provisions of the Social Security Act, 42 U.S.C. § 1396r-8(b)(3)(D), or any applicable state law;
 - b. “Confidential Health Information.” For the purposes of this protective order, “Confidential Health Information” shall mean any document or information supplied in any form, or any portion thereof, that identifies an individual in any manner and related to the past, present, or future care, services, or supplies relating to the physical or mental health or condition of such individual, the provision of health care to such individual, or the past, present, or future payment for the provision of health care to such individual.

ocument property name.

“Confidential Health Information” specifically includes “protected health information” and “individually identifiable health information” as such terms are defined by the Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. Part 160, promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996. “Confidential Health Information” includes, but is not limited to, medical bills, claims forms, charge sheets, medical records, medical charts, test results, notes, dictation, invoices, itemized billing statements, remittance advice forms, explanations of benefits, checks, notices, and requests. “Confidential Health Information” also includes all notes, summaries, compilations, extracts, abstracts, or oral communications that contain, are based on, or are derived from “Confidential Health Information.”

“Confidential Health Information” also includes material subject to the provisions of the Privacy Act, 5 U.S.C. § 552a, or to the provisions of 45 C.F.R. Part 164. “Confidential Health Information” also includes any materials covered by the privacy laws of any individual states as applicable. In order to facilitate the production of “Confidential Health Information”, the parties may produce “Confidential Health Information” to any party in this litigation in unredacted form without such production constituting a waiver of confidentiality;

- c. Trade secret or other confidential research or development information, or commercial information that bears upon a Party’s or third-party’s competitive position;
- d. Personnel files of employees of any of the Parties or third parties;
- e. “Personal Information,” as that term is defined in the Massachusetts Data Security Regulation, 201 C.M.R. 17.02, except that this definition will apply to residents of any jurisdiction (not only Massachusetts), and shall include natural persons’ cell phone numbers; and

f. To the extent not included in the categories above, financial account numbers.

3. **Designation of Confidential Information.** The designation of information as Confidential shall be performed in the following manner:

- a. A Party or Third Party may designate information provided as Confidential by placing on or affixing to a document containing protected information the phrase “CONFIDENTIAL” on each page of the document entitled to such designation (in such manner as will not interfere with the legibility thereof). Information dated January 1, 2015 or later produced and designated by a party as Confidential prior to the filing of the United States’ Complaint shall be treated as presumptively Confidential information under this Protective Order unless and until the designating party re-reviews and agrees to de-designate the document. Information dated December 31, 2014 or earlier produced and designated as Confidential prior to the filing of the United States’ Complaint shall not be treated as Confidential under the terms of this Protective Order after May 30, 2021 unless and until the designating party specifically re-designates the information as Confidential after the party signs this Order. This subsection does not limit Regeneron’s ability to invoke Section 3(e) of this Order in the event Regeneron inadvertently does not re-designate a document containing Confidential information by May 30, 2021.
- b. If information cannot practically be designated Confidential for whatever reason including, but not limited to, the format of the electronically stored information, the producing party shall provide written notice of the designation of the information to the receiving party.
- c. Interrogatory answers or other responses to written discovery and information contained therein shall be designated as Confidential by means of a statement at the conclusion of

each answer specifying the information that is Confidential contained therein, or by another method that clearly indicates which portion of the answer or information is considered Confidential, and by placing the legend referenced in subpart (a) above on the front of any set of interrogatory answers containing such information.

- d. A designation that information is Confidential shall constitute a representation to the Court, made in good faith, that counsel believes that the information so designated constitutes Confidential information as defined in this Order. Upon notification that a document appears to be incorrectly designated, the producing party shall review the designation and change the designation if it was made in error.
- e. If a producing party inadvertently or unintentionally produces to a receiving party any Confidential information without designating it as protected pursuant to paragraph 3(a), 3(b) or 3(c), the producing party shall promptly give notice to the receiving party in writing and thereafter the receiving party shall treat the information as Confidential information. Such inadvertent or unintentional disclosure shall not be deemed a waiver in whole or in part of the producing party's claim of restriction either as to specific documents and information disclosed or on the same or related subject matter.

4. **Right to Challenge Designation.** Nothing in this Order shall be construed in any way as a finding that information designated Confidential actually is Confidential information. If a party to this Order disagrees, in full or in part, with a producing party's designation of Confidential information, such party may notify the producing party in writing stating the basis for its disagreement, and the parties shall confer in good faith as to the designation of the Confidential information. If the parties are unable to reach agreement on the proper designation of the Confidential information, either party may move to re-classify Confidential information pursuant to the terms of this Order.

5. **Access to Confidential Information.** Information designated Confidential may be disclosed only to the following persons:

- a. The Court;
- b. The parties' outside counsel and in-house counsel;
- c. Non-attorney employees at Regeneron responsible for making decisions regarding the course of the litigation;
- d. Experts or consultants retained by the parties; provided, however, that prior to the disclosure of Confidential materials to any such expert or consultant, counsel for the party making the disclosure shall deliver a copy of this Order to such person, shall explain its terms to such person, and shall secure the signature of such person on a statement in the form attached hereto as Exhibit A;
- e. Stenographic and video reporters engaged in proceedings incident to this matter;
- f. Discovery consultants, processors and vendors, outside document copying services, document coding or computerization services, demonstrative exhibit vendors and jury consultants; provided, however, that prior to the disclosure of Confidential materials to any such persons, counsel for the party making the disclosure shall deliver a copy of this Order to such person, shall explain its terms to such person, and shall secure the signature of such person on a statement in the form attached hereto as Exhibit A;
- g. Associated personnel of any person within categories (a) through (e) for whom access to Confidential information is necessary to assist such persons in the action, including any Court personnel assisting the Court, litigation assistants, paralegals, secretarial or other clerical personnel, stenographers or other persons involved in taking or transcribing

testimony in this action, and principals and employees of the firm with which consultants or experts are associated;

- h. Any person known to have created or received Confidential information outside of discovery;
- i. During depositions and preparation for depositions, any deponent and the deponent's counsel, if any; provided, however, that prior to the disclosure of Confidential materials to any such persons, counsel for the party making the disclosure shall deliver a copy of this Order to such person, shall explain its terms to such person, and shall secure the signature of such person on a statement in the form attached hereto as Exhibit A;
- j. Law enforcement personnel, including United States Department of Justice Attorneys, United States Attorneys, their authorized subordinates, and contractors engaged in the purposes of assisting the same with this matter;
- k. Any private mediators utilized in this matter; and
- l. Such other persons as the parties mutually agree upon in writing and in advance of access by such persons; provided, however, that prior to the disclosure of Confidential materials to any such persons, counsel for the party making the disclosure shall deliver a copy of this Order to such person, shall explain its terms to such person, and shall secure the signature of such person on a statement in the form attached hereto as Exhibit A.

6. **Use of Confidential Information.** Information designated Confidential may be used solely for purposes of pretrial preparation and proceedings in this action, trial of this action, and any appellate proceedings in this action. Such Confidential information shall be used for no other purpose unless and until agreed to in writing by all parties to this action or authorized by order of

the Court. No person who receives any Confidential information shall disclose it to any person for any purpose other than for pretrial preparation and proceedings in this action.

7. **Limitations.** Nothing contained in this Order shall abrogate any legal obligation of any party to disclose upon appropriate request to any state, any agency or department of the United States, or any division of any such agency or department, Confidential information relating to any potential violation of law or regulation, or relating to any matter within that agency's jurisdiction, nor shall anything contained in this Order abrogate any legal right to use any such Confidential information by a federal agency in any proceeding relating to any potential violation of law or regulation, or relating to any matter within that agency's jurisdiction. Nor shall anything contained in this Order abrogate any legal obligation of any party to disclose any document or information as required by law, or to Congress pursuant to a Congressional request. If another court or an administrative agency requests, subpoenas, or orders production of Confidential information from a party that has obtained those materials under the terms of this Order, the party shall promptly notify the producing party of such subpoena or other process so that the producing party has the opportunity to contest the request to protect its Confidential information through appropriate legal means. Such notification must include a copy of the request, subpoena, or court order.

8. **Transcripts.** During any deposition in which Confidential information is discussed, counsel for any party or third party may: (a) designate, on the record, the portions of the transcript that will contain Confidential information, in which case the portions of the deposition so designated on the record shall be treated as Confidential information, respectively, and placed in a separately bound volume; or (b) designate in writing to counsel for all parties, within fourteen (14) days of the transcript's delivery, the transcript portions which are to be treated as Confidential information. All deposition transcripts will be considered as Confidential information until the notice set forth above or until the expiration of fourteen (14) days from the transcript's delivery.

9. **Filing Under Seal.** A party seeking to file another party's Confidential discovery material shall provide the producing party notice of the Confidential discovery material it intends to use at least three (3) days prior to filing. The producing party shall then have three (3) days in which either to consent to the request to file said information in the public record or to file a motion pursuant to Local Rule 7.2 to keep such papers under seal. If the producing party moves to keep papers under seal, the papers with the designated Confidential information under seal, or with any references to the Confidential information, will be filed under seal or redacted, as appropriate, until the Court rules on the motion to seal. Notwithstanding the above, natural persons' cell phone numbers may be redacted in public filings as an alternative to filing under seal.

10. **Use of Confidential Information at Trial.** Within 10 days of the parties' exchange of exhibit lists, the producing party shall review the designation and determine whether it wishes to de-designate the material.

11. **Modification Permitted.** Nothing in this Order shall prevent any party from seeking modification of this Order or from objecting to discovery that it believes to be otherwise improper.

12. **Inadvertent or Mistaken Productions Shall Not Waive Privilege Or Protection.** If information subject to a claim of attorney-client privilege or work product protection or any other privilege or protection is inadvertently or mistakenly produced, such production shall in no way prejudice or otherwise constitute a waiver of, or estoppel as to, any claim of privilege or protection for such information as provided under applicable law, including Federal Rule of Evidence 502. If a producing party has inadvertently or mistakenly produced information subject to a claim of protection or privilege, and if the producing party makes a written request for the return of such information, the information for which a claim of inadvertent production is made (including any analyses, memoranda or notes which were internally generated based upon such inadvertently-produced information), as well as all copies, shall be either destroyed or returned

immediately to the producing party, even if the receiving party disputes the claim of privilege. If the receiving party disputes the producing party's assertion of privilege, the producing party must submit the potentially privileged information to the Court for review *in camera*.

13. **Non-Party Information.** Discovery in this proceeding may involve disclosure by a non-party of Confidential information. At the option of a non-party, such information may be produced subject to the provisions of this Protective Order and, in that event, shall provide the non-party with all of the rights and obligations of a party as created by this Protective Order with respect to Confidential information produced by such non-party in connection with the discovery and pre-trial phase of this action.

14. **Termination.** Except for any documents that Regeneron produced to the United States prior to January 1, 2021, within 60 days of the termination of this action, including any appeals, each party shall either destroy or return to the opposing party all documents designated by the opposing party as "Confidential," and all copies of such documents, and shall destroy all extracts and/or data taken from such documents with the exception of any archived materials and attorney work product with embedded Confidential material. Attorneys may retain a set of pleadings and documents filed with the Court, written discovery or other pleadings served by either party on the other party, all transcripts, all correspondence, all consultant or expert reports, and all work product generated in connection with the action. Counsel will make reasonable efforts to identify and destroy emails and other correspondence that transmitted Confidential material but will not be required to restore and search archived material. All Confidential information retained for any reason will continue to be subject to this Order. Each party shall provide a certification as to such return or destruction within the 60-day period.

15. **Term.** This Order survives termination of this litigation and remains in full force and effect unless modified by further order or by written stipulation of the parties filed by the Court.

16. **Miscellaneous.**

- a. Nothing in this Order shall prevent a party from any use of its own Confidential information.
- b. The parties may agree to waive any provision of this Order, provided such waiver is made in writing.
- c. Proper notice under this Order, when required, shall be effected or email.

17. **Counterparts.** This Order may be signed in counterpart, and each such counterpart shall be deemed an original.

18. **Entire Agreement.** This Order constitutes the entire agreement of the parties and supersedes all prior communications, understandings and agreements relating to the subject matter hereof, whether oral or written.

STIPULATED BY:

For Plaintiff United States:

/s/ David Lazarus (with permission)

U.S. Attorney's Office
One Courthouse Way, Suite 9200
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For Defendant Regeneron Pharmaceuticals, Inc.:

/s/ Richard Scheff

Armstrong Teasdale LLP
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APPROVED AND SO ORDERED this

15th day of March, 2021.

BY THE COURT:

/s/ F. Dennis Saylor IV

Hon. F. Dennis Saylor
United States District Judge

EXHIBIT A

CERTIFICATION REGARDING CONFIDENTIAL INFORMATION

I hereby acknowledge that I, _____[NAME],
_____[POSITION AND EMPLOYER], am
about to receive Confidential information supplied in connection with the Proceeding, No. 1:20-cv-11217-FDS. I certify that I understand that the Confidential information is provided to me subject to the terms and restrictions of the Protective Order filed in this Proceeding. I have been given a copy of the Protective Order; I have read it, and I agree to be bound by its terms.

I understand that the information designated as “Confidential” in this Proceeding, including any notes or other records that may be made regarding any such information, shall not be disclosed to anyone except as expressly permitted by the Protective Order. I will not copy or use, except solely for the purposes of this Proceeding, any Confidential information obtained pursuant to this Protective Order, except as provided therein or otherwise ordered by the Court in the Proceeding.

I further understand that I am to retain all copies of all Confidential information provided to me in the Proceeding in a secure manner, and that all copies of such materials are to remain in my personal custody until termination of my participation in this Proceeding, whereupon the copies of such materials will be returned to counsel who provided me with such materials.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this ____ day of ____, 20__, at _____.

Dated: _____

By: _____
Signature

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

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

Case No. 1:22-cv-00061-TSK

ORDER

WHEREAS, on April 6, 2023, the Court entered a Sealed Order granting Defendant's Motion to Compel Production of Documents [ECF No. 405] ("Sealed Order");

WHEREAS, the Sealed Order compels Regeneron Pharmaceuticals, Inc. ("Regeneron") to produce documents responsive to Defendant's RPD Nos. 144-151 within five days of the Order;

WHEREAS, Mylan's RPD Nos. 144-151 call for the following, with "CDF Litigation" including *United States v. Regeneron Pharmaceuticals, Inc.*, No. 1:20-cv-11217-FDS (D. Mass.) (the "DOJ Litigation"):

144. All documents referred to in any Federal Rule of Civil Procedure 26(a)(1) disclosure served by Regeneron in any CDF Litigation.

145. All documents, communications, and things reviewed, relied upon, or considered by any expert for Regeneron in any CDF Litigation.

146. All documents referred to or relied upon by Regeneron in responding to any interrogatory or requests for admission served on Regeneron in any CDF Litigation.

147. All documents, communications, and things produced by Regeneron in any CDF Litigation.
148. All documents received from or produced by a Third Party, including pursuant to a subpoena, in any CDF Litigation.
149. All pleadings and discovery submitted, filed, or otherwise prepared by, or on behalf of, Regeneron in any CDF Litigation, including all briefs, affidavits, declarations, pretrial orders, exhibits, answers to interrogatories, answers to requests for admission, and expert reports (and related exhibits).
150. All pleadings and discovery submitted, filed, or otherwise prepared by, or on behalf of, any plaintiff in any CDF Litigation, including all briefs, affidavits, declarations, pretrial orders, exhibits, answers to interrogatories, answers to requests for admission, and expert reports (and related exhibits).
151. All documents, communications, and things concerning any communications between Regeneron and the CDF.

WHEREAS, Regeneron has represented to the Court that some documents responsive to Defendant's RPD Nos. 144-151 have been designated confidential by producing parties under the Stipulated Confidentiality Agreement and Protective Order in place in the DOJ Litigation, or otherwise placed under seal by court order in the DOJ Litigation;

WHEREAS, Regeneron has filed a Motion to Modify Production Deadline seeking a modification of the production schedule in the Sealed Order in order to comply with the confidentiality obligations arising from the DOJ Litigation;

NOW, THEREFORE, for good cause shown, the Court **GRANTS** Plaintiff Regeneron's Motion to Modify Production Deadline.

A. The Court **ORDERS** that, except for documents addressed in Paragraphs C and D, Regeneron shall produce documents responsive to Mylan's RPD Nos. 144-151 by April 14, 2023.

B. The Court **ORDERS** that Regeneron shall notify all producing parties whose confidential documents are responsive to Mylan's RPD Nos. 144-151 of this Order and provide a copy of the same within one (1) business day of its entry;

C. The Court **ORDERS** that Regeneron shall produce documents responsive to Mylan's RPD Nos. 144-151 that have been designated Confidential under the Stipulated Confidentiality Agreement and Protective Order, Dkt. 54, in *United States v. Regeneron Pharmaceuticals, Inc.*, No. 1:20-cv-11217-FDS (D. Mass.), within ten (10) days of the date of notification required by Paragraph C, absent a filing by a producing party contesting production. In the event a producing party contests production, Regeneron shall only produce upon court order resolving the producing party's objection.

D. With respect to responsive documents from the DOJ Litigation that are sealed or otherwise restricted by court orders in the DOJ Litigation other than the Stipulated Confidentiality Agreement and Protective Order, the Court **ORDERS** that within one (1) business day of this Order, Regeneron shall begin the process of meeting and conferring with parties whose confidential information is reflected in those sealed documents, and in the event agreement to production cannot promptly be obtained, Regeneron shall file a motion or motion(s) in the DOJ Litigation to modify the operative sealing orders to allow for production in this case.

It is so **ORDERED**.

Dated: _____, 2023

JAMES P. MAZZONE
UNITED STATES MAGISTRATE JUDGE