

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

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

Civil Action No. 1:22-cv-00061-TSK

**MYLAN’S RESPONSE TO PLAINTIFF’S MOTION  
TO MODIFY PRODUCTION DEADLINE**

Regeneron moved (ECF No. 412) to modify this Court’s April 11, 2023 production deadline (ECF No. 405) granting Mylan’s Motion to Compel Production of Documents Regarding Regeneron’s Anti-Kickback Litigation (“the Court’s Order). As explained below, Mylan opposes any modification of the Court’s Order. Regeneron’s request to delay production fails to consider or address the prejudice to Mylan, in particular given relevant expert depositions are scheduled for April 18 and 19.<sup>1</sup>

Mylan first requested production of the anti-kickback litigation documents on December 13, 2022 — almost four months ago. (ECF No. 360, Ex. 1). Regeneron refused to produce a single document responsive to Mylan’s requests, thereby requiring Mylan to move the Court to compel on March 16, 2023 — over three weeks ago. (ECF No. 360).

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<sup>1</sup> In the event that the Court believes an extension is appropriate, Mylan submits a proposed order attached hereto as Exhibit A which seeks to minimize prejudice to Mylan.

On Thursday afternoon, April 6, 2023, Regeneron contacted Mylan's counsel via email to raise *for the first time* "a couple of logistical issues" relating to the production, without further elaboration. (*See e.g.*, ECF No. 360, Ex. 10; ECF No. 389, Ex. N; ECF. No. 402, Exs. 15-16).

Mylan promptly replied to Regeneron's counsel and the parties met and conferred the following Good Friday holiday morning (April 7, 2023) at 9:30 am ET. Mylan attempted to obtain clarity, inquiring:

- (1) Why Regeneron needed the additional time, especially because the documents had been previously produced in electronic form, and Regeneron had ample notice of Mylan's interest in the documents; and
- (2) How to reduce prejudice to Mylan from the further delay. Depositions of the experts pertinent to the commercial success issue to which the documents pertain are set for April 18 and April 19, 2023. Mylan and its experts must review and understand the documents, whereas Regeneron has only to complete a computerized process for production, for which it says five days is insufficient. With the delay proposed by Regeneron, Mylan at best may have only one business day to review documents and, more likely, not be in receipt of highly relevant documents until after the close of expert discovery.

Mylan further reiterated that it would be willing to take documents on an attorney-eyes only basis to protect against confidentiality issues.

Regeneron could not explain any need for more time for the electronic production other than "document control"—that is, bates numbering. Mylan does not believe that bates numbering the documents for this litigation is necessary before document production (even so, Mylan told Regeneron that it would accept the documents now so Mylan could begin review, and let

Regeneron substitute the newly bates-numbered documents once available). Bates numbering is a purely electronic process, which Regeneron's document vendor has presumably performed countless times. The only human process involved is giving the proper software directions as to existing documents in the system. Mylan's experience is that this takes a matter of hours—or at most 24—for even the longest computer process for a previously-produced document set. Regeneron could not explain why this process could not be initiated over the weekend, let alone in time for the Court ordered deadline.

Mylan also explained its prejudice from further delay that would reduce its time (and more importantly its expert's time) to review and understand the documents, especially given the upcoming depositions and the upcoming Final Pretrial Order deadlines under the Scheduling Order. Regeneron, however, responded only that it would consider discussing such issues later, and refused to address any accommodations in deposition schedules, supplemental expert reports, or any other matter, to reduce the prejudice to Mylan. Moreover, while Regeneron claims time pressures, it ignores how each day of delay imposes more time pressures on Mylan; and the two pressures are not balanced. Mylan's review and assessment is far more human-intensive and time-consuming than the almost wholly automatic, electronic process Regeneron will undertake. In these circumstances, further compressing the very limited time Mylan has, which benefits Regeneron to Mylan's detriment, is grossly unfair and prejudicial, particularly with no commitment by Regeneron to give Mylan any relief on time pressures in exchange.

With regard to the subset of documents that Regeneron asserts are subject to a stipulated confidentiality order in other litigation, or to separate, specific orders in the "DOJ litigation," Mylan sought to understand how that could delay prompt production of the bulk of the documents. Mylan thus asked (1) for a copy of these orders; and (2) for Regeneron's counsel on Friday to

identify and preferably jointly communicate by e-mail that Regeneron had been ordered to produce documents to Mylan, which could facilitate Mylan ascertaining from the DOJ and/or any third-party counsel whether there were any potential objections in the first instance. That process did not need to await creation of a public version of the Court's order. Regeneron declined to undertake that effort or cooperate with Mylan in giving immediate notice, and even refused to provide Mylan with these counsel's contact information. Regeneron also did not explain why it has waited until now to resolve third-party or DOJ confidentiality concerns when it has been aware of Mylan's requests since December 2022.

Mylan also sought (in emails subsequent to the call) assurance that these separately-sealed documents Regeneron wanted to delay producing were not documents protected at the request of Regeneron, its present or former employees, or the Chronic Disease Fund and its predecessors or successors-in-interest (*e.g.*, Good Days). Mylan received no such assurances.

Accordingly, Mylan opposes any general modification of the Court's existing order because Regeneron has not given any explanation, much less a concrete or particularized explanation for why it cannot complete an electronic production by April 11. Any such change simply favors the needs of Regeneron and its counsel to complete a computerized process to the far more complex and timely human review Mylan and its experts must undertake under the current Scheduling Order.

Mylan also opposes any extension as to documents subject to protective orders, without confirmation that Regeneron is not using such orders to delay production of its own documents. Mylan further opposes delay absent (1) cooperation by Regeneron in giving immediate notice, which it can certainly do in general (even if it believes the Court's order cannot be sent due to the

sealing of the order), and (2) Regeneron's agreement to immediately and transparently involve Mylan's counsel in the process.

To the extent Your Honor believes an extension is necessary, Mylan submits a proposed order attached hereto as Exhibit A.<sup>2</sup> Mylan's proposed order requires Regeneron to substantially produce non-third-party information by April 11 (the Court ordered deadline) and complete said production by April 14; to expeditiously address any potential third party objections with Mylan's participation; and to explicitly provide for supplemental expert discovery with respect to the anti-kickback litigation documents, to alleviate the risk of prejudice to Mylan from Regeneron's latest delay.

Dated: April 10, 2023

Respectfully submitted,

STEPTOE & JOHNSON PLLC

Counsel for Defendant Mylan Pharmaceuticals Inc.

By: /s/ Gordon H. Copland

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<sup>2</sup> Regeneron confirmed to Mylan that the Court's sealed Order (ECF No. 405) contains no Regeneron confidential information. Mylan's proposed order accordingly asks the court to unseal the Order.

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**CERTIFICATE OF SERVICE**

I hereby certify that on April 10, 2023, I electronically filed the foregoing with the Clerk of the Court by using the Court's CM/ECF system, which will provide notice of the filing thereof to all counsel of record.

*/s/ Gordon H. Copland*

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**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 M M M M M , 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 hereby represents 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 is concurrently filing 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.

B. The Court hereby unseals ECF No. 405 such that it is publicly available.

C. The Court **ORDERS** that Regeneron substantially complete production of documents responsive to Mylan's RPD Nos. 144-151 by April 11, 2023.

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

E. The Court **ORDERS** that Regeneron shall produce documents responsive to Mylan's RPD Nos. 144-151 that have been designated Confidential by a party other than Regeneron, the Chronic Disease Fund, Good Days, former employees of same, and/or any successors-in-interest to same under the Stipulated Confidentiality Agreement and Protective Order, Dkt. 54, in *M v. M M M*, No. 1:20-cv-11217-FDS (D. Mass.), by April 14, 2023, absent a filing by the producing party contesting production. In the event the producing party contests production, Regeneron shall, jointly with Mylan's counsel, meet and confer within one (1) business day with counsel for the producing party to in good faith resolve any disputes.

F. 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 and that include information designated Confidential by a party other than Regeneron, the Chronic Disease Fund, Good Days, former employees of same, and/or any successors-in-interest, the Court **ORDERS** that by April 10, 2023, Regeneron shall, jointly with Mylan's counsel, meet and confer with parties whose confidential information is reflected in those sealed documents, and in the event agreement to production cannot promptly be obtained, Regeneron shall within one (1) business day file a

motion or motion(s) in the DOJ Litigation to modify the operative sealing orders to allow for production in this case.

G. The Court **ORDERS** that Regeneron provide Mylan the contact information for the primary attorney for each party producing documents responsive to Mylan's RPD Nos. 144-151 by April 10, 2023.

H. The Court **ORDERS** that any supplemental expert reports addressing documents produced pursuant to the Court's Sealed Order be served within ten (10) business days of Regeneron's certification to Mylan that all documents responsive to Mylan's RPD Nos. 144-151 have been produced.

I. The Court **ORDERS** that Regeneron's commercial success expert Dr. Richard Manning be made available for a two (2) hour supplemental deposition within ten (10) business days of Regeneron's certification that all documents responsive to Mylan's RPD Nos. 144-151 have been produced.

It is so **ORDERED**.

Dated: \_\_\_\_\_, 2023

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JAMES P. MA ONE  
UNITED STATES MAGISTRATE JUDGE