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

Case No. 1:23-cv-89 (TSK)

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

CELLTRION, INC.,

Defendant.

REGENERON'S MEMORANDUM IN OPPOSITION TO DEFENDANTS' EMERGENCY MOTION TO COMPEL

Regeneron hereby responds to Defendant Celltrion, Inc.'s Emergency Motion to Compel,

filed on March 4, 2024. Celltrion seeks to compel production of materials from Regeneron

Pharms., Inc. v. Mylan Pharms. Inc. and Biocon Biologics Inc., No. 1:22-cv-00061, (the "Mylan

Action"), for purposes of the parties' preliminary injunction proceedings.

I. Regeneron Does Not Oppose Production Consistent With Its Obligations Under the Mylan Protective Order

As Regeneron has repeatedly informed Celltrion, Regeneron is more than willing to

produce the Mylan Litigation Materials¹ but cannot do so absent one of two things: (1) an Order

¹ The Mylan Litigation Materials include "Mylan Litigation Written Discovery" (the interrogatories and responses, requests for admission and responses, and statements pursuant to 42 U.S.C. § 262(1)(3)(B) and 42 U.S.C. § 262(1)(3)(C) served in the *Mylan* action relating to the PI Patents), Celltrion Ex. 2 (Regeneron Responses and Objections "R&O") at Definition No. 12; "Mylan Litigation Trial Demonstratives" (the trial demonstratives used by the parties during opening statements, closing arguments, and direct examinations in the 2023 trial in the *Mylan* action to the extent those demonstratives relate to the PI Patents), *id.* at Definition No. 13; "Mylan Litigation Deposition Materials" (transcripts of and exhibits from depositions in the *Mylan* action of Regeneron employees or experts and relating to the PI Patents), *id.* at Definition No. 14; and "Mylan Litigation Expert Reports" (the expert reports served in the *Mylan* action

of this Court, or (2) Mylan's consent. Upon receiving Celltrion's requests for documents, Regeneron promptly sought the latter. Ex. A at 7-10 (January 27, 2024 email from Regeneron counsel to Mylan counsel notifying them of Celltrion's document requests); *id.* at 3-4 (February 21, 2024 follow-up email). Mylan promptly, and adamantly, refused. *Id.* at 2-3 (February 22, 2024 email from Mylan counsel to Regeneron) ("Biocon and Mylan do <u>not</u> consent to Regeneron producing any of the documents identified in your list below." (emphasis in original)). Regeneron informed Celltrion of Mylan's position and the fact that Mylan represented that it was continuing to evaluate the documents implicated by Celltrion's request. *Id.* at 2-3 (February 22, 2024 email); Celltrion Ex. 4 at 2.

To be clear, Regeneron does not oppose an Order directing it to produce the Mylan Litigation Materials; as Celltrion knows, it is Mylan that does not consent. As Mylan is the company that has opposed the production of the requested materials, fairness would dictate that it has an opportunity to be heard in connection with Celltrion's motion. Yet Mylan (to Regeneron's knowledge) was not served with the motion and does not possess an unredacted version of the motion, which was filed only under seal. Regeneron provided Mylan with notice of the motion and a copy of the redacted version filed on the public docket.

To the extent that Mylan consents to the production of the requested materials upon receiving Celltrion's motion, or the Court hears Mylan's objections and rejects them, Regeneron will produce the requested materials consistent with the Protective Order in the Mylan Action. Accordingly, Regeneron has attached a proposed Order that would obligate it to produce the Mylan Litigation Materials one week from entry of the Order—thereby allowing Mylan (if the

relating to the PI Patents and excluding reports relating solely to the commercial success of the inventions claimed in such patents), *id.* at Definition No. 17.

Order issues) an opportunity to redact the materials as it deems appropriate. At the ordered time, Regeneron will produce the Mylan Litigation Materials either as redacted by Mylan (if Mylan has provided redacted copies), or in unredacted form (if Mylan has not) on an Outside-Counsel Eye's Only Basis (or at whatever designation the Court deems appropriate).

II. Regeneron Diligently Sought Mylan's Cooperation

Although Regeneron (unlike Mylan) does not oppose production of the materials at issue, Celltrion's aspersions improperly cast upon Regeneron and its counsel cannot go unanswered. Contrary to Celltrion's characterization, Regeneron did not simply "throw up its hands and default to inaction" or "fail[] to take any effort" with regard to producing the Mylan Litigation Materials. *See* Celltrion Motion at 2, 10. To the contrary, it has sought diligently Mylan's consent to produce materials that are not publicly available.

First, some background: Even before Regeneron's litigation with Celltrion commenced, and dating back to August 2023, Regeneron has sought Mylan's cooperation in improving the public accessibility of the docket in the Mylan Action, consistent with the Court's May 31, 2023 Order Granting Amgen's Motion to Intervene in the Mylan Action. *See* Mylan Action Dkt. No. 608. Celltrion likewise moved to intervene in the Mylan Action on August 10, 2023, and conferred with Regeneron to that end on August 22, 2023 regarding the sealed filings that Celltrion sought and the extent to which those documents differed from those sought by Amgen. *See* Mylan Action Dkt. No. 636. Ultimately, Celltrion agreed that Regeneron and Mylan should "diligently address Amgen's request" and "notify Celltrion upon completion so it may begin its independent review and supplementation." *See id.* Regeneron's coordination led to a joint proposal to unseal hundreds of filings, *see* Mylan Action Dkt. Nos. 608, 639-1, 675, and a joint effort to create redacted copies of relevant filings that could not be unsealed in their entirety, *see* Ex. B (Email chain between Regeneron's counsel and Mylan's counsel).

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Then, after litigation and formal discovery with Celltrion commenced, Regeneron promptly notified Mylan of Celltrion's requests for additional Mylan information. In particular, Regeneron asked Mylan for two things on January 27, 2024: (1) redacted copies removing Mylan's confidential information from a list of documents over which Regeneron expected Mylan to make claims of confidentiality, and (2) confirmation that the documents on a second list did not contain Mylan confidential information and so could be produced imminently in their current form. Ex. A at 7-10 (January 27, 2024 email from T. Gregory). On February 7, 2024, Regeneron followed up on this request. *Id.* at 7. Mylan responded that it would review the materials and would follow up once that review was complete. Id. at 6 (Feb. 11 email from L. Lesko.). Ten days later, Regeneron followed up on its requests, narrowed the list of documents for Mylan to review and notified Mylan that it would produce those documents it did not believe contained Mylan confidential information as early as February 23, 2024. Id. at 3-6 (Feb. 21, 2024 email from T. Gregory). Mylan's response was adamant: "Biocon and Mylan do not consent to Regeneron producing any of the documents identified." Id. at 3 (Email from L. Lesko on Feb. 22) (original emphasis). Mylan asserted that, because "Regeneron is seeking to produce documents that implicate Biocon/Mylan Confidential Information to direct competitors," Mylan would "require a reasonable amount of time to carefully review [the] voluminous requests in order to ensure that [Mylan's] information is properly maintained as confidential." Id. Hearing nothing further, Regeneron sent another email to Mylan days later, on February 27, 2024, asking for a time estimate for Mylan to complete its review. Id. at 2 (February 27, 2024 email from T. Gregory). More than two weeks later, at 10:19 PM last night (March 5, 2024), counsel for Mylan emailed Regeneron to confirm that a subset of the documents identified by Regeneron did not contain Mylan confidential information and could be produced. Id. at 1 (March 5, 2024

email from L. Lesko). Regeneron will produce those documents to Celltrion promptly, but Mylan still has not consented to the production of the remaining Mylan Litigation Materials. *See Id.* It is Regeneron's understanding, conveyed repeatedly to Celltrion, that Mylan continues to oppose the production of the remaining materials. However, to Regeneron's knowledge, Mylan has not received an unredacted version of Celltrion's motion and therefore has not been afforded an opportunity to oppose it. Regeneron shares Celltrion's frustration and thus seeks an Order permitting it to produce the remaining materials in a manner consistent with the Mylan Protective Order.² Ex. C at ¶ 30 (providing that if Mylan "takes steps to prevent disclosure" of information after being notified of a request for production, Regeneron "shall not produce" the information "before a determination by a court of appropriate jurisdiction unless [Regeneron] has obtained [Mylan's] permission.").

III. Regeneron Cannot Identify Documents Mylan Considers Public

Celltrion asserts that "[t]o the extent that the *Mylan* materials reference publicly available documents, Regeneron confidential information only, or documents shown in open court, Regeneron should be compelled to produce those documents." Celltrion Motion at 7. Unfortunately, as it has done throughout litigation, Mylan has asserted claims of confidentiality even over documents and portions of documents shown in open court. As this Court is aware, Mylan has a pending motion for sanctions against Regeneron with respect to inadvertent disclosures of information that was shown in open court but that Mylan claims is confidential. Mylan Action Dkt. No. 658. In view of this history, Regeneron is not in a position to share documents that Mylan has deemed confidential and as to which Mylan has affirmatively refused

 $^{^2}$ To simplify the discovery issues before the court, Regeneron no longer objects to producing the trial exhibits in the *Mylan* Action. However, these exhibits may contain Mylan confidential information and so they cannot be produced absent Mylan's consent or a court order.

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