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**

MEMORANDUM IN SUPPORT OF REGENERON'S EXPEDITED MOTION TO COMPEL COMPLIANCE WITH THE PROTECTIVE ORDER

Regeneron seeks expedited relief from this Court for Mylan's ongoing violation of the Stipulated Protective Order, Dkt. No. 91, pursuant to which it has designated the entire 1,000,000+ pages of its biosimilar application and regulatory file as "Outside Counsel's Eyes Only" ("OCEO"). Mylan made these designations despite the fact that Regeneron's designated In-House Counsel had access to a substantial portion of this material earlier this year during the pre-litigation "patent dance." Mylan's overuse of the OCEO designation in this litigation prevents Regeneron's designated In-House Counsel—who are subject to all the constraints of the Protective Order—from meaningfully participating in this litigation. Mylan's tactics also interfere with Regeneron's outside counsel's ability to communicate with their client, forcing Regeneron's outside counsel to self-censor their discussions about nearly every aspect of this case.

Mylan's designation of its entire aBLA regulatory file and related regulatory correspondence (which is 98% of its produced pages) as "OCEO" constitutes a flagrant abuse of the Protective Order and is indefensible under its plain language. Mylan has argued that the Protective Order authorizes it to designate anything related to its biosimilar aflibercept program as

OCEO, but that reading of the Protective Order is flatly wrong. It runs counter to the language of the Protective Order, the BPCIA itself, the parties' pre-suit agreement as to who could view Mylan's documents, and the substantial body of case law that provides OCEO designations are to be used sparingly because of the significant constraints they impose on a company to obtain legal advice about the subject matter of its case.

Regeneron has made extensive efforts to persuade Mylan to reverse it position, but Mylan has refused. Resolution of this issue is urgent. Depositions are about to begin, meetings with experts are ongoing, and Mylan's tactical abuse of the Protective Order is depriving Regeneron's In-House Counsel of the opportunity to fully participate in these events and to evaluate the case.

Regeneron respectfully requests that the Court order Mylan to de-designate its abbreviated Biologics License Application ("aBLA") immediately to the level of Confidential, and to correct the remainder of its designations to come into compliance with the Protective Order, as set forth in the accompanying Proposed Order.

BACKGROUND

Below, Regeneron sets forth a brief background to the present dispute, the backdrop for which is the mandatory pre-suit exchange of information provided for in the BPCIA. As a result of the BPCIA, Regeneron's In-House Counsel ***were previously permitted to have access*** to the information Mylan now designates as OCEO pursuant to a pre-suit Agreement that the parties executed in January 2022. The parties contemplated that if a patent infringement case were filed, a Protective Order would be entered so that the parties could avail themselves of the Court to supervise and adjudicate confidentiality issues.

A. The Parties' BPCIA Section 262(l) Confidentiality Agreement

Mylan first submitted a regulatory application seeking approval of a biosimilar version of Regeneron's Eylea® product in October 2021, pursuant to the BPCIA. That statute provides

would-be biosimilar drug companies a roadmap for securing expedited regulatory approval of a potential biosimilar product, but that process comes with conditions: the BPCIA contains numerous provisions designed to protect the rights of patent owners and innovators (like Regeneron), whose successful products the biosimilar companies wish to copy.

Those protections include mandatory document and information exchange provisions (the "patent dance"), pursuant to which a biosimilar applicant like Mylan and a patent owner like Regeneron (referred to as the "reference product sponsor") can evaluate each other's positions. The BPCIA provides that the applicant "shall" provide confidential access to its application to a list of mandatory recipients, including both outside counsel and at least one in-house counsel who satisfies certain conditions:

> (I) Outside counsel
> One or more attorneys designated by the reference product sponsor who are employees of an entity other than the reference product sponsor (referred to in this paragraph as the "outside counsel"), provided that such attorneys do not engage, formally or informally, in patent prosecution relevant or related to the reference product.
>
> [and]
>
> (II) In-house counsel
> One attorney that represents the reference product sponsor who is an employee of the reference product sponsor, provided that such attorney does not engage, formally or informally, in patent prosecution relevant or related to the reference product.

42 U.S.C. § 262 (*l*)(1).

Pursuant to this provision, Regeneron and Mylan entered into a "Section 262(l) Confidentiality Agreement" in January 2022 to allow Regeneron's in-house and outside counsel to review Mylan's aBLA. Ex. 1 (Section 262(*l*) Agreement). Regeneron asked, and Mylan agreed, that three of its In-House Counsel be permitted to review Mylan's information. These In-House Counsel were Larry Coury, Vice President and Associate General Counsel; Petra Scamborova, Senior Director and Assistant General Counsel; and James Evans, Director of Dispute Resolution.

Regeneron certified to Mylan that none of the three In-House Regeneron attorneys engage in patent prosecution relevant to Eylea®, or communications with regulatory agencies relevant to Mylan's proposed aflibercept product. *Id.* at ¶ C(1).

B. The Protective Order Entered in This Case

Following commencement of this case, Regeneron and Mylan negotiated a Stipulated Protective Order ("the Order"), which they filed on November 1, 2022, Dkt. No. 89, and the Court entered the next day. Dkt. No. 91 (November 2, 2022).

The Stipulated Protective Order is "two-tiered," permitting the parties to designate sensitive materials produced during discovery as either "Confidential" or "Outside Counsel's Eyes Only" ("OCEO"), as appropriate. "Confidential" is the lower—but still highly protective—tier, and includes "information that constitutes, contains, reveals, or reflects trade secrets or other confidential research, development, business, or commercial information within the meaning of Fed. R. Civ. P. 26(c)(1)(G)." Dkt. No. 91 at ¶ 1(d). The tier of "Outside Counsel's Eyes Only" is narrower, covering only those disclosures that both contain certain categories of "highly sensitive information" and as to which "production on a confidential basis, even to In-House Counsel, would create a serious risk of harm to the Designating Party that could not be avoided by less restrictive means." *Id.* at ¶ 1(m) (emphasis added).

Information the parties designated as "Confidential" may be viewed by both outside counsel and up to three designated In-House Counsel. Material designated OCEO may not be shared with In-House Counsel. *Id.* at ¶ 7 (information designated OCEO "may be disclosed by the Receiving Party only to Qualified Persons identified in Subparagraphs (a)-(h) of Paragraph 6"). The ability of outside counsel to provide anything other than conclusory legal advice based on facts learned from OCEO materials thus is severely constrained.

In view of the limitations imposed by OCEO designations, Regeneron and Mylan agreed that an OCEO designation may only be used where "less restrictive means"—such as a "Confidential" designation—will not suffice. *Id.* at ¶ 1(m). Such circumstances should be comparatively rare, because the "Confidential" level of protection already is quite protective. For example, Paragraph 5 of the Protective Order provides restrictions on the use of any designated information, whether "Confidential" or "OCEO," and that such information may only be used for purposes of the current case absent modification of the Protective Order. *Id.* at ¶ 5. That Paragraph also calls out a number of specific prohibitions on the use of either category of material. *Id.* Paragraph 6 of the Protective Order also protects information that is produced at the "Confidential" level, because it contains restrictions on the types of job duties that In-House Counsel with access to the other side's information may have. *Id.* at ¶ 6.

During the negotiation of the Protective Order, Mylan did not say or even hint that it intended to interpret the Order as withdrawing access to its documents from Regeneron's In-House counsel, or that it believed the parties could designate documents OCEO at will.[1]

C. Mylan's Protective Order Designations

On November 4, 2022, Mylan produced 2,106 documents comprised of 1,081,205 pages to Regeneron as part of fact discovery, consisting of its aBLA and some additional regulatory file materials. It produced 100% of these documents under the designation of OCEO.

The material Mylan designated OCEO includes many categories of documents as to which such a designation cannot possibly be supported. For example, Mylan's OCEO designations

[1] To the contrary, Mylan participated in the drafting and editing the provisions governing both sides' In-House Counsel access to information. Ex. 2 at14-19 (Mylan 9/13/22 Protective Order edits); Ex. 3 at 11-13 (Mylan 10/6/22 Protective Order edits).

include published scientific articles,[2] non-substantive transmittal correspondence from Mylan to the FDA,[3] and Regeneron's own documents, including some that are public like the Complaint in this case and the prescribing label for Eylea®.[4] The OCEO material also includes the entirety of Mylan's aBLA—more than half a million pages of documents, bates-stamped MYL-AFL-BLA0000001 to MYL-AFL-BLA0565369—which undersigned counsel previously could share and discuss with Regeneron's In-House Counsel. Mylan's blanket OCEO designations also span an additional 515,835 pages of regulatory correspondence that discusses the same subject matter as the aBLA.

Regeneron has engaged in extensive efforts to persuade Mylan to change its abusive, blanket OCEO designations, but Mylan has refused. Ex. 4 at 1 (Nov. 17, 2022 Letter from T. Fletcher); Ex. 5 (Nov. 23, 2022 Email from E. Oberwetter); Ex. 6 (Dec. 2, 2022 Email from E. Oberwetter). Mylan has simply said that it will not amend the OCEO designations because the documents are all "relevant to Mylan's prospective product" and a confidentiality review would not be "feasible." Ex. 5 (Nov. 23, 2022 Email from L. Lesko).

ARGUMENT

Mylan's blanket OCEO designations are improper. They are indefensible as a matter of the BPCIA and, even apart from the BPCIA, Mylan's indiscriminate designation of documents as

[2] To avoid having to file a motion to seal that would encompass documents that Regeneron does not believe should be sealed, Regeneron cites exemplary documents from Mylan's production here, and they are available to the Court upon request. *E.g.*, MYL-AFL-BLA0562563; MYL-AFL-BLA0562800; MYL-AFL-BLA0563141.

[3] *E.g.*, MYL-AFL-BLA0565438; MYL-AFL-BLA0565500; MYL-AFL-BLA0565787.

[4] *E.g.*, MYL-AFL-BLA1080322 (Regeneron's Complaint); MYL-AFL-BLA1079868 (Regeneron-FDA correspondence released to Mylan pursuant to FOIA); MYL-AFL-BLA0562176 (Eylea Prescribing Information).

OCEO is the kind of protective order abuse that courts routinely hold to be improper. The Stipulated Protective Order certainly does not countenance such tactics, as it only permits such designations as to "highly sensitive information" where the less restrictive designation of "Confidential"—with all of that designation's attendant restrictions—will not suffice to avoid a "substantial risk of serious harm." Dkt. No. 91 at ¶ 1(m).

A. BPCIA Framework and Parties' Prior January 2022 Agreement

While there is ample case law concerning protective orders and abusive OCEO designations that supports Regeneron's position, *see* below, at 9-11, this protective order dispute is simpler and does not even require that case law. The BPCIA on its own renders absurd Mylan's self-serving interpretation of the Order.

It is unusual to find an expression of congressional intent on a protective order issue, but there is one here: the BPCIA itself presumes that a designation of "Confidential" suffices to protect the production of an aBLA to a reference product sponsor like Regeneron. Congress did not include in the BPCIA any "OCEO" level of designation for a biosimilar applicant's application. To the contrary, it affirmatively said that In-House Counsel for the reference product sponsor ***shall*** have access to the aBLA of the biosimilar company that wants to copy its patented product, so long as the In-House Counsel is not doing patent prosecution work related to the patents at issue. Congress also provided that that right of access should continue even after litigation commences. 42 U.S.C. § 262(*l*)(1)(F) (in the event of a lawsuit, "the use of confidential information shall continue to be governed by the terms of this paragraph until such time as a court enters a protective order regarding the information"). Congress plainly thought a designation of "Confidential" would adequately protect the aBLA and—by extension—the type of information contained in it.

These provisions of the BPCIA run counter to Mylan's argument that its aBLA is too competitively sensitive to share with Regeneron's In-House Counsel. Congress said otherwise,

even though it is obvious that the biosimilar applicant intends to have its product compete with that of the reference product sponsor. Congress mandated that applicants like Mylan—who want the benefits of the BPCIA to achieve expedited approval of a copied drug—must share their aBLA with In-House Counsel for the reference product sponsor so that it can assess the applicant's potential infringement of its patents. 42 U.S.C. § 262(*l*)(1).

Mylan's own prior § 262(*l*) Agreement with Regeneron reflected a recognition that Regeneron's (obvious) status as a competitor was no basis for not providing access to qualifying In-House Counsel, because Mylan agreed that the same three In-House Counsel who are still at issue could review its information. Mylan did not even insist that they have no responsibility for commercial decision-making about Eylea®. Instead, consistent with the standards set forth in the BPCIA, the parties' § 262(*l*) Agreement simply provided that they could not have responsibility for prosecuting patents, and could not have responsibility for communicating with regulatory agencies about Mylan's aflibercept. Ex. 1 at ¶ B(3).

In light of the foregoing, Mylan's present interpretation of the Protective Order is so outlandish that it cannot possibly be advancing it in good faith. Why would Regeneron have agreed to a Stipulated Protective Order that excludes the same three In-House Counsel at Regeneron who could previously view Mylan's documents, when the BPCIA mandates by statute that at least one such attorney should have access, and Mylan had already voluntarily agreed that three of Regeneron's attorneys could review its information? Of course, Regeneron would not have done so, it did not do so, and Mylan cannot genuinely think that it did. Mylan's position appears calculated to throw a wrench in the schedule—a schedule Mylan opposed and has continued to complain about—or worse, to impede Regeneron's ability to communicate effectively with its outside counsel.

B. Mylan's Interpretation and Designations Would Be Abusive Even Were It Not for the BPCIA.

Mylan's blanket designation of every aflibercept-related document would be improper even apart from the special BPCIA considerations discussed above.

When a party designates a document as confidential under an existing protective order, that party "must have good cause" to do so and bears the burden of demonstrating good cause when the designation is disputed. *Marietta Area Healthcare, Inc. v. King*, 2022 WL 4596672, at *2 (N.D.W. Va. June 30, 2022); *see also Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 787-88 (3d Cir. 1994) ("The burden of justifying the confidentiality of each and every document sought to be covered by a protective order remains on the party seeking the order.").

Mylan has not even attempted to meet this standard. Instead, it contends that ¶ 1(m) permits it to designate OCEO anything that relates to aflibercept. Ex. 5 (Nov. 23, 2022 Email from L. Lesko). That reading of ¶ 1(m) ignores the limiting language that an OCEO designation can only be made where "production on a confidential basis, even to In-House Counsel, would create a substantial risk of serious harm … that could not be avoided by less restrictive means." *See id.* Mylan cannot plausibly contend that disclosing again to Regeneron's In-House Counsel documents that they previously could and have seen would create a "substantial risk of serious harm" to Mylan, much less has Mylan attempted to satisfy that standard as to individual documents. Instead, Mylan pretends that the standard articulated in ¶ 1(m) does not exist.

Mylan's interpretation of the Order also runs counter to the large body of caselaw providing that protective order designations at the level of OCEO (or Attorneys' Eyes Only) are to be used only sparingly. *K.I.S.S. Pharm LLC v. Becker Prof. Dev't Corp.*, 2020 WL 8093507, *1 (N.D. Ill. Nov. 30, 2020) (AEO designations should only be used "on a relatively small and select number of documents where a genuine threat of competitive or other injury dictates such extreme

measures"); *see also Phoenix Process Equipment Co. v. Capital Equipment & Trading Corp.*, 2022 WL 3365069, *3 (W.D. Ky. Aug. 15, 2022) (AEO designations are considered "the most restrictive (and thus least often justified) tier of discovery" (internal citations omitted)).

Excessive OCEO designations are abusive, interfere with a client's preference for having In-House Counsel advise it, and inhibit the litigation process. As one federal district court explained in a widely cited case:

> The indiscriminate use of 'attorney's eyes only' protective orders … pose[s] a significant handicap on the restricted litigant. Discovery, trial preparation, and trial are made more difficult and expensive if an attorney cannot make complete disclosure of the facts to the litigant….A litigant who is not in possession of all relevant facts, furthermore, is in a poor position to assess its obligation to maintain only arguably meritorious actions at every stage of the case. Although imposition of these and other handicaps upon a litigant is justifiable in some circumstances, such action by the court must be supported by a showing that disclosure will work a clearly defined and serious injury to the party seeking extraordinary confidential treatment.

Arvco Container Corp. v. Weyerhaeuser Co., 2009 WL 311125, at *6 (W.D. Mich. Feb. 9, 2009); *see also In re American Med. Sys., Inc. (Pelvic Repair Sys. Prods. Liability Litig.)*, 2012 WL 2601880, *6 (S.D. W.Va. July 5, 2012) (document over-designations "gum up the works"); *CellTrust Corp. v. ionLake, LLC*, 2022 WL 1553558, at *4 (D. Minn. May 17, 2022) (Attorneys' Eyes Only designations caused "logistical restraints" and were "possibly obstructionist").

OCEO designations at the rate Mylan has applied them are self-evidently abusive. One federal district court evaluating a production where more than 95% of the documents had been designated Attorneys' Eyes Only ("AEO") observed that blanket designations of that sort have "frequently been condemned. In fact, many courts confronted with this level of designations (and lower designations) brand the percentage as 'absurd.'" *Procaps S.A. v. Patheon, Inc.*, 2015 WL

4430955, *7 (S.D. Fla. July 20, 2015) (collecting cases).[5] Misuse of an OCEO designation is not appropriate simply because it is expedient, *Marietta Area Healthcare*, 2022 WL 4596672, at *2 (while material was "cumbersome to sift through," that did not excuse compliance with discovery obligations), although Mylan has proffered that as a justification here. Ex. 5 (Nov. 23, 2022 Email from L. Lesko).

Mylan's flagrant over-designation of materials as OCEO is creating the problems that courts warn about. Regeneron's outside counsel have been unable to communicate freely with In-House Counsel about the merits of the case or decisions about discovery and what witnesses to depose. Indeed, Mylan has designated OCEO the documents containing lists of Mylan and Viatris employees who worked on its clinical trials. *E.g.*, MYL-AFL-BLA00552829-32. Meetings with expert witnesses are also being disrupted. Regeneron's outside counsel already has had to ask the company's In-House Counsel not to sit in on particular expert meetings, or to leave for significant portions of them so that Mylan's documents can be discussed. Regeneron's outside counsel cannot even presently discuss with Regeneron the details of Mylan's Phase III clinical trial—even though it serves as the basis for the product Mylan wants to put on the market.

These problems are about to get worse. Depositions are about to begin and Regeneron's In-House Counsel—who are counsel of record in this matter—are entitled to and plan to attend them. Mylan's interpretation of the Stipulated Protective Order would result in constant interruptions of the depositions, as Regeneron's In-House Counsel would need to leave the room

[5] *See also THK Am., Inc. v. NSK Co. Ltd.*, 157 F.R.D. 637, 645 (N.D. Ill. 1993) (designating 79% of produced documents AEO was "a blatant misuse" of the protective order); *Paradigm Alliance, Inc. v. Celeritas Techs., LLC*, 248 F.R.D. 598 (D. Kan. 2008) (high percentage of AEO designations was inconsistent with good faith designations); *Acuity Brands Lighting, Inc. v. Bickley*, 2015 WL 12976102, at *4 (E.D. Ky. Sept. 4, 2015) (blanket AEO designation "fundamentally misapprehended" the standard for AEO designations).

for many exhibits. The problems will be even worse when the parties are drafting expert reports. Regeneron's outside counsel will become bogged down in having to redact draft reports, and Regeneron will be impeded in having its In-House Counsel understand the issues and how they are developed.

Mylan's conduct is improper, plain and simple. The Court should order Mylan to de-designate its aBLA immediately to the level of Confidential so that Regeneron's same three In-House Counsel who could see it before can continue to see it. And the court should order Mylan to undertake a proper confidentiality review of its other documents to comply with the Stipulated Protective Order. *See, e.g.*, *Penn Eng'g & Mfg. Corp.*, 2021 WL 4192038, at *1 (ordering this remedy for over-designation); *Paradigm All., Inc.*, 248 F.R.D. at 606 (D. Kan. 2008) (same)

CONCLUSION

For the foregoing reasons, Regeneron requests that the Court order expedited consideration of this Motion, direct Mylan to respond to this Motion within three business days, and grant the relief requested in the accompanying Proposed Order.

Date: December 6, 2022

CAREY DOUGLAS KESSLER & RUBY, PLLC

/s/ Steven R. Ruby

Steven R. Ruby (WVSB No. 10752)
David R. Pogue (WVSB No. 10806)
707 Virginia Street East
901 Chase Tower (25301)
P.O. Box 913
Charleston, West Virginia 25323
(304) 345-1234
sruby@cdkrlaw.com
drpogue@cdkrlaw.com

Attorneys for Plaintiff Regeneron Pharmaceuticals, Inc.

Of Counsel:

David I. Berl (admitted *PHV*)
Ellen E. Oberwetter (admitted *PHV*)
Thomas S. Fletcher (admitted *PHV*)
Andrew V. Trask (admitted *PHV*)
Teagan J. Gregory (admitted *PHV*)
Shaun P. Mahaffy (admitted *PHV*)
Arthur J. Argall III (admitted *PHV*)
Adam Pan (admitted *PHV*)
Nicholas Jordan (admitted *PHV*)
Renee M. Griffin (admitted *PHV*)
Sean M. Douglass (admitted *PHV*)

Haylee Bernal Anderson (admitted *PHV*)
WILLIAMS & CONNOLLY LLP
680 Maine Avenue, SW
Washington, DC 20024
(202) 434-5000

Attorneys for Plaintiff Regeneron Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on December 6, 2022, 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/ Steven R. Ruby
Steven R. Ruby