IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLIOIS
EASTERN DIVISION

FEDERAL TRADE COMMISSION STATE OF CALIFORNIA STATE OF ILLINOIS STATE OF MINNESOTA STATE OF NEW YORK STATE OF WASHINGTON and STATE OF WISCONSIN *Plaintiffs,* v. AMGEN INC. and HORIZON THERAPUETICS PLC, *Defendants*.	No.: 1:23-cv-03053 Judge John F. Kness

REGENERON PHARMACEUTICALS, INC.'S UNOPPOSED MOTION TO INTERVENE PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 24

Regeneron Pharmaceuticals, Inc. ("Regeneron") respectfully moves this Court to allow it to intervene in this case for the limited purpose of protecting the confidentiality of its proprietary and highly confidential information requested by and produced to the Plaintiffs and Defendants, Amgen, Inc. ("Amgen") and Horizon Therapeutics PLC ("Horizon"), in this litigation. Plaintiffs, Amgen, and Horizon do not oppose this Motion to Intervene.

At issue are the ***significant differences in protections*** afforded to Regeneron's proprietary and highly confidential information in this litigation, as compared to the protections afforded to both Amgen's and Regeneron's business information in the previously filed, competitor antitrust litigation between Regeneron and Amgen that Plaintiffs reference in their Complaint in this case, now pending in the District of Delaware. *See Regeneron Pharmas., Inc. v. Amgen Inc.*, 22-cv-00697-RGA-JLH (D. Del. May 27, 2022) ("private litigation"). If the Court permits Regeneron to intervene in this action for the limited purpose of seeking to protect its proprietary and highly

confidential information, its sole request will be that the Court deny the Defendants' pending motion or require Amgen abide by the terms of the Protective Order that govern the private litigation as it relates to any information Regeneron produces in this action.

As referenced in the Plaintiffs' Complaint, *see* Dkt. No. 66, ¶ 70, Regeneron sued Amgen on May 27, 2022 for anticompetitive bundling practices to exclude competition from Regeneron in the PCSK9i market.[1] Following several months of negotiation, Amgen and Regeneron filed a Stipulated Protective Order on April 24, 2023 ("Protective Order"), which the District of Delaware Court subsequently entered. The Protective Order includes three categories of confidential information—(1) Outside Counsel Only, (2) Attorneys' Eyes Only, and (3) Confidential. Ex. A, Protective Order, *Regeneron Pharmas, Inc. v. Amgen Inc.*, 22-cv-00697-RGA-JLH, Dkt. No. 75, ¶ 20 (D. Del. May 27, 2022).[2]

Amgen and Regeneron are competitors and their documents can cover current and future

[1] The PCSK9i market includes PCSK9 inhibitors approved by the FDA to treat certain cardiovascular conditions by reducing low-density lipoprotein cholesterol (LDL-C). *See Regeneron Pharmas.*, 22-cv-00697-RGA-JLH, Dkt. No. 1, ¶¶ 102-05. PCSK9 inhibitors have unique characteristics, including a novel mechanism of action for reducing LDL-C levels, and are used for a unique population. *Id.* ¶ 103. Until very recently, there were only two PCSK9 inhibitors approved in the United States, Amgen's Repatha® and Regeneron's Praluent®, and importantly these are still the only two drugs in a submarket for PCSK9i inhibitors that are dispensed through pharmacies. *Id.* ¶¶ 104-05.

[2] "Confidential" information is defined as "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)(l)(G), including but not limited to: scientific and technical information; financial, budgeting and/or accounting information; information about existing and potential customers; marketing and other business strategies, decisions, or negotiations; personnel compensation, evaluations, and other employment information; and includes such confidential and proprietary information about a Third Party, including parents, subsidiaries, and/or other Affiliates." *Id.* ¶ 3. "Attorneys' Eyes Only" means "any CONFIDENTIAL information that is of such a private, sensitive, competitive, or proprietary nature that present disclosure or dissemination to [certain individuals identified in the Order] would reasonably be expected to cause irreparable harm or materially impair the legitimate competitive position or interests of the Producing Party or create a substantial risk of serious harm that could not be avoided by less restrictive means." Ex. A ¶ 2. "Outside Counsel Only" materials are defined as "CONFIDENTIAL information that is not related to products at issue in this Litigation contained exclusively in: (1) materials or presentations given to, or prepared in connection with a meeting of, the Producing Party's Board of Directors, including all PowerPoint presentations or PDFs of such presentations; and (2) contracts for prescription drug coverage with third party payors." Ex. A ¶ 11.

business, commercial, and strategic plans, including about products (both launched and in development) beyond the ones at issue in the private litigation. Therefore, for easily identifiable categories of such documents covering products not at issue in the private litigation, the Protective Order in the private litigation has a highest tier designation of "Outside Counsel Only." Employees of Amgen and Regeneron, including in-house counsel, cannot access materials designated as "Outside Counsel Only." Ex. A at ¶ 11.

For "Attorneys' Eyes Only" materials, the Protective Order only allows up to five Amgen in-house counsel access to certain information so long as they "have no current involvement and will not have involvement for the duration of [the private litigation] in any marketing, financial, or other payor-access or business competitive decision-making (not including decision-making as an attorney in the litigation) relating to any products in" the private litigation. Ex. A at ¶ 33(b). This restriction begins once the individual receives the confidential information and extends for 18 months after termination of the private litigation or 18 months after notice is given to the other party that the individual "being replaced or otherwise removed from having access to" the confidential material. *Id.* Further, the Protective Order provides a process by which a party seeking access to "Attorneys' Eyes Only" material for in-house counsel must notify the other party and, if the opposing party objects, provides an opportunity for the objecting party to seek relief from the court before any confidential material is disclosed to the individual. *Id.* After ensuring in-house counsel met these qualifications and would abide by the future restrictions in their work responsibilities at Amgen, and after seeking Regeneron's approval, Amgen designated four in-house attorneys as recipients of certain confidential Regeneron materials.[3] Notably, Amgen did not designate Jonathan Graham.

[3] The Amgen in-house counsel requested include Melissa Pastrana, Will Diaz, Kimberly Dunne and Matt Bohn.

For the lowest tier of sensitive information, the parties agreed upon a designation of "Confidential" material. For "Confidential" materials, access to such Regeneron materials is additionally granted only to Amgen employees meaningfully "assisting in the preparation of this action for trial or other proceeding herein." *Id.* at ¶ 32.

Upon a joint motion by the parties in this matter (Dkt. No. 21), an Interim Confidentiality Order was entered on May 19, 2023 (Dkt. No. 25) ("Confidentiality Order"). That Confidentiality Order ***prohibits Amgen and Horizon employees*** from accessing any Confidential Material, including Regeneron's Confidential Material produced to the FTC as part of the FTC's pre-merger investigation. In relevant part, the Confidentiality Order defines Confidential Material as including "Competitively Sensitive Material," which is further defined as "refer[ing] to, but shall not be limited to, any trade secret or competitively sensitive research, analysis, technical, financial, development, or commercial information that has not been released into the public domain." A protective order was also issued in the FTC administrative proceeding that places similar restrictions on Amgen and Horizon's employees' access to confidential information. Ex. B, Protective Order Governing Confidential Material, *In re Amgen Inc. and Horizon Therapeutics plc*, FTC Dkt. No. 9414 (FTC June 23, 2023). Neither the Confidentiality Order nor the protective order in the FTC administrative proceeding provide restrictions on the future roles and responsibilities of Amgen or Horizon employees who receive confidential material in this litigation. Further, neither order provides a mechanism for third parties whose competitively sensitive information is subject to disclosure, such as Regeneron, to object to access by a competitor's employees.

In a motion filed on June 30, 2023 (Dkt. No. 79), Defendants now ask this Court to modify the Confidentiality Order to allow access to all Confidential Material by three Amgen in-house

attorneys and two Horizon in-house attorneys. Defendants' motion directly undermines the protections negotiated by Amgen and Regeneron in the Protective Order in the underlying private litigation—which covers some of the same products that will potentially be at issue in this action. The modifications Defendants request would circumvent the protections that Regeneron, and for their own materials, Amgen, carefully negotiated to protect its sensitive information from its competitor. The proposed provisions in particular would grant an additional Amgen in-house counsel and two Horizon in-house counsel access to sensitive Regeneron materials, while not providing any restrictions on their future roles and responsibilities at Amgen after receiving the materials as provided in the Protective Order in the private litigation. Further, the proposed provisions would allow Amgen in-house counsel to access Regeneron's competitively sensitive "Outside Counsel Only" materials in direct contrast to the restrictions in the private litigation—while Amgen would simultaneously be shielding those very same materials from Regeneron in the private litigation, providing it with an asymmetrical litigation advantage, as well as a potential competitive advantage (by giving its in-house attorneys access to some of Regeneron's most sensitive materials). Finally, the modifications would fail to provide an interested third party, like Regeneron, whose confidential and sensitive information would become accessible to Amgen and Horizon employees, an opportunity to object to the access provided to employees of its competitor.

As discussed in the attached brief in opposition (Ex. C), Regeneron seeks to intervene to oppose Defendants' motion as it relates to Regeneron's sensitive materials produced in this litigation and ensure that similar restrictions are maintained between this litigation and the private litigation. For the reasons explained below, this Court should enter an order granting Regeneron's Motion to Intervene. If the Court grants the Motion to Intervene, Regeneron respectfully requests that this Court order that Regeneron's brief in opposition to Defendants' request be deemed filed

instanter.

BACKGROUND

Regeneron is in the business of inventing, developing, manufacturing, and marketing a variety of innovative pharmaceutical products, including the marketing and distribution of Praluent® used to reduce high systematic levels of LDL-C or "bad cholesterol" that can lead to heart attacks, strokes, and certain types of chest pain conditions (unstable angina) requiring hospitalization. Regeneron's Praluent® competes directly with Amgen's Repatha®, both of which are PCSK9 inhibitors used to treat cardiovascular disease. During the FTC's investigation of Amgen's proposed acquisition of Horizon, Regeneron provided highly sensitive trade secrets and highly competitively sensitive information in response to requests by the FTC and subject to applicable laws and regulations designating the materials as confidential. *See* 15 U.S.C. § 57b-2(f); 16 C.F.R. § 4.10; 5 U.S.C. § 552 (exempting from disclosure under the Freedom of Information Act). The Plaintiff states who have joined the litigation also received access to Regeneron's confidential information subject to the Confidentiality Order and their own confidentiality restrictions.

In accordance with a Stipulated Order entered on May 17, 2023, the FTC agreed to produce its full investigative file no later than May 23, 2023. (Dkt. No. 3 at 3). This investigative file includes the competitively sensitive Regeneron information provided to the FTC during the course of its investigation. Further, Amgen served a subpoena on Regeneron to produce additional documents on June 27, 2023. Ex. D, Amgen's Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action. The FTC has likewise served a subpoena with similar specifications on Regeneron during the course of this litigation. Ex. E, The FTC's Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of

Premises in a Civil Action. These subpoenas similarly request documents containing highly sensitive Regeneron information, including its contracts and communications with third-party payors. *See, e.g.*, Ex. D at Request Nos. 3-4, 9. Without proper protection, the information previously produced to the FTC included in its investigative file and the additional documents that may be produced in response to the Parties' subpoenas—which remain subject to negotiation over scope and relevance—would not receive the protections that Amgen demanded and obtained in its litigation with Regeneron.

ARGUMENT

A party may intervene as of right pursuant to Rule 24(a)(2) if four requirements are met: "(1) timeliness, (2) an interest relating to the subject matter of the main action, (3) at least potential impairment of that interest if the action is resolved without the intervenor, and (4) lack of adequate representation by existing parties." *Planned Parenthood of Wis., Inc. v. Kaul*, 942 F.3d 793, 797 (7th Cir. 2019), *see also Zurich Capital Markets Inc. v. Coglianese*, 236 F.R.D. 379, 383 (N.D. Ill. 2006) (citing *Reid L. v. Ill. State Bd. of Educ.*, 289 F.3d 1009, 1017 (7th Cir. 2002)). Alternatively, in accordance with Rule 24(b), courts have discretion to grant permissive intervention "upon timely application[ ] 'when an applicant's claim or defense and the main action have a question of law or fact in common.'" *Sokaogon Chippewa Cmty. v. Babbitt*, 214 F.3d 941, 949 (7th Cir. 2000) (quoting Fed. R. Civ. P. 24(b)) (internal citations omitted). Before a court may permit permissive intervention under Rule 24(b)(2), a party "must demonstrate that there is (1) a common question of law or fact, and (2) independent jurisdiction." *Security Ins. Co. of Hartford v. Schipporeit, Inc.*, 69 F.3d 1377, 1381 (7th Cir. 1995) (citing *Reedsburg Bank v. Apollo*, 508 F.2d 995, 1000 (7th Cir. 1975)). Rule 24(b) also requires that "[i]n exercising its discretion the court must consider whether the intervention will unduly delay or prejudice the adjudication of the rights of the original parties."

Fed. R. Civ. P. 24(b)(2).

Regeneron meets these requirements. Regeneron files this motion promptly after Amgen filed its motion to expand the Confidentiality Order, which directly affects Regeneron's legitimate interest in protecting its confidential and competitively sensitive information from disclosure to Amgen and Horizon's in-house counsel. Further, no party in this litigation may adequately represent Regeneron's legitimate interest in preserving the confidentiality of its own commercially sensitive information. In the alternative, the Court should allow Regeneron permissive intervention because of its interest in the Confidentiality Order in this litigation as a third party who has submitted confidential materials afforded protection by its provisions.

I. Regeneron Should be Permitted to Intervene as of Right

Regeneron has satisfied the requirements outlined by Rule 24(a)(2). The Court should therefore grant its motion to intervene as of right.

(a) Regeneron's Motion is Timely

Regeneron has timely filed its motion to intervene. Courts have held that the "purpose of the [timeliness] requirement is to prevent a tardy intervenor from derailing a lawsuit within sight of the terminal. As soon as a prospective intervenor knows or has reason to know that his interests might be adversely affected by the outcome of the litigation he must move promptly to intervene." *Sokaogon*, 214 F.3d at 949 (quoting *United States v. South Bend Cmty. Sch. Corp.*, 710 F.2d 394, 396 (7th Cir. 1983)); *see also Lopez-Aguilar v. Marion Cnty. Sheriff's Dep't*, 924 F.3d 375, 389 (7th Cir. 2019) (quoting *Reich v. ABC/York-Estes Corp.*, 64 F.3d 316, 321 (7th Cir. 1995)) ("[W]e do not necessarily put potential intervenors on the clock at the moment the suit is filed or even at the time they learn of its existence. Rather, we determine timeliness from the time the potential intervenors learn that their interest might be impaired."). A court considers four factors to determine if a motion is timely: "(1) the length of time the intervenor knew or should have known

of his interest in the case; (2) the prejudice caused to the original parties by the delay; (3) the prejudice to the intervenor if the motion is denied; (4) any other unusual circumstances." *Sokaogon*, 214 F.3d at 949 (citing *Ragsdale v. Turnock*, 941 F.2d 501, 504 (7th Cir. 1991)).

Regeneron files this Motion to Intervene less than two weeks after Amgen and Horizon filed their motion to expand the Confidentiality Order and within the Court's briefing schedule. *See* Status Report, Dkt. No. 80 (June 30, 2023). Regeneron's prompt filing has allowed Amgen and Horizon an opportunity to respond as necessary. The Court's consideration of this Motion will also not cause undue delay as it aligns with the briefing schedule of the Parties. Finally, the unique circumstances of Regeneron's concurrent litigation with Amgen, and the Protective Order in the private litigation, provide unusual circumstances that justify intervention. Regeneron therefore has timely filed its Motion to Intervene.

(b) Amgen and Horizon's Motion to Expand the Confidentiality Order will Affect Regeneron's Ability to Protect its Confidential and Competitively Sensitive Information

Regeneron seeks intervention for the narrow purpose of ensuring adequate protection for its confidential and competitively sensitive information provided in this litigation. To satisfy the requirements for intervention, a potential intervenor's "interest [in the lawsuit] must be direct, significant, and legally protectable. . . . [Rule 24] does not define 'interest,' but the case law makes clear that more than the minimum Article III interest is required." *Lopez-Aguilar v. Marion Cnty. Sheriff's Dep't*, 924 F.3d 375, 391 (7th Cir. 2019) (internal citations and quotations omitted). Additionally, a third party need not have an interest in the underlying action to meet the requirements of Rule 24(a) if seeking to intervene for a narrow purpose such as a collateral discovery issue. *See United States v. American Tel. & Tel. Co.*, 642 F.2d 1285, 1291-92 (D.C. Cir. 1980) ("To bar intervention for collateral discovery issues merely because they do not concern the subject matter of the overall action would in many cases defeat the general purpose of

intervention."); *see also Wildcat Enters., LLC v. Weber*, 2016 WL 8711474, at *5 (N.D. Ill. March 4, 2016) (citing *American Tel. & Tel. Co.*, 642 F.2d at 1291-92). Moreover, to assess the sufficiency of an interest, courts "have interpreted 'statements of the Supreme Court as encouraging liberality in the definition of an interest.'" *Lopez-Aguilar*, 924 F.3d at 392 (quoting *Meridian Homes Corp. v. Nicholas W. Prassas & Co.*, 683 F.2d 201, 204 (7th Cir. 1982)). Indeed, "[t]he strongest case for intervention is not where the aspirant for intervention could file an independent suit, but where the intervenor-aspirant has no claim against the defendant yet a legally protected interest that could be impaired by the suit." *Solid Waste Agency of N. Cook Cnty. v. U.S. Army Corps of Eng'rs*, 101 F.3d 503, 506-07 (7th Cir. 1996) (internal citations omitted).

Regeneron has an interest in ensuring adequate protections are used to protect its confidential and competitively sensitive information from its competitors. Amgen and Horizon's motion to expand the Confidentiality Order will directly affect this interest by allowing Amgen and Horizon in-house counsel access to confidential materials they would not otherwise receive and subject to terms different than those that Regeneron and Amgen spent several months negotiating in the private litigation. Further, Regeneron is Amgen's competitor and adversary in a concurrent lawsuit. Regeneron's interest in protecting its confidential and competitively sensitive information from an adversarial party in a concurrent litigation is therefore heightened.

Further, no party in this litigation can adequately represent Regeneron's interest in protecting its own confidential information. As the Seventh Circuit held in *Planned Parenthood of Wisconsin, Inc. v. Kaul*, "[t]he default rule is a liberal one: 'The requirement of the Rule is satisfied if the applicant shows that representation of his interest may be inadequate.'" 942 F.3d 793 at 799 (7th Cir. 2019) (quoting and citing *Trbovich v. United Mine Workers of Am.*, 404 U.S. 528, 538 n.10 (1972); *Ligas ex rel. Foster v. Maram*, 478 F.3d 771, 774 (7th Cir. 2007)). Neither

the Plaintiffs nor the Defendants in this litigation have a comparable interest in protecting Regeneron's confidential and competitively sensitive information.

II. In the Alternative, The Court Should Allow Regeneron Permission to Intervene Pursuant to Rule 24(b)

In the alternative, the Court should grant Regeneron permission to intervene pursuant to Rule 24(b). A party need not meet all requirements of intervention as of right in order for a court to grant permission to intervene. *See City of Chi. v. FEMA*, 660 F.3d 980, 987 (7th Cir. 2011) ("[Courts] must be careful not to collapse the two inquiries—the inquiry under Rule 24(a) and the inquiry under Rule 24(b) . . ."); *see also Solid Waste Agency*, 101 F.3d 503, 509 (7th Cir. 1996). As explained above, Regeneron has timely filed its Motion and its interest in the protections afforded by the Confidentiality Order meets the requirements of Rule 24(b).

Although the "decision to permit intervention is 'wholly discretionary,'" *Planned Parenthood of Wisconsin*, 942 F.3d at 803, "every court of appeals to have considered the matter has come to the conclusion that Rule 24 is sufficiently broad-gauged to support a request of intervention for the purposes of challenging confidentiality orders." *Jessup v. Luther*, 227 F.3d 993, 997-98 (7th Cir. 2000) (further highlighting that the court "believe[s] that these circuits have employed sound reasoning"). In particular, even though "the interest asserted by someone challenging a protective order is not a 'claim' or 'defense'—the wording Rule 24(b)(1)(B) uses—the Seventh Circuit considers the language of the rule 'broad enough to encompass a third-party challenge to a protective order.'" *Cavelle v. Chi. Transit Auth.*, 2020 WL 6681344, at *5 (N.D. Ill. November 12, 2020) (quoting *Bond v. Utreras*, 585 F.3d 1061, 1070 (7th Cir. 2009)); *see also Grove Fresh Distrib. v. Everfresh Juice Co.* 24 F.3d 893 (7th Cir. 1994) (explaining that "[i]t is apparent, however, that intervention is the procedurally appropriate course for third-party challenges to protective orders").

Regeneron's timely intervention will not "unduly delay or prejudice the adjudication of the rights of the original parties," as required by Rule 24(b)(3). Regeneron seeks to intervene for the narrow purpose of ensuring adequate protection for its confidential and competitively sensitive information provided in this litigation—protections that Amgen has negotiated for and obtained for itself in the private litigation with Regeneron. This interest will not affect the rights of the Parties to this litigation. As discussed above, Regeneron has also filed a timely Motion to Intervene that will not unduly delay this litigation. For the above listed reasons, the Court should therefore grant Regeneron's motion for permissive intervention pursuant to Rule 24(b).

CONCLUSION

Regeneron seeks to intervene for the sole and limited purpose of protecting its highly confidential and competitively sensitive business information where the parties cannot adequately represent its interests. For the foregoing reasons, Regeneron requests that this Court grant its Motion to Intervene.

Dated: July 12, 2023

Respectfully submitted.

By: */s/ Lauren J. Caisman*

Lauren J. Caisman
BRYAN CAVE LEIGHTON PAISNER LLP
161 North Clark Street, Suite 4300
Chicago, Illinois 60601
Telephone: (312) 602-5000
Facsimile: (312) 602-5050
lauren.caisman@bclplaw.com

Eric S. Hochstadt (*pro hac vice pending*)
WEIL, GOTSHAL & MANGES LLP
767 Fifth Avenue
New York, NY 10153-0119
Telephone: (212) 310-8000
Fax: (212) 310-8007

Counsel for Regeneron Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

The undersigned, an attorney, certifies that a true and correct copy of the foregoing document was served to all counsel of record via the Court's ECF System on this 12th day of July 2023 and to the following via email:

Justin Moor
Office of the Attorney General, State of Minnesota
445 Minnesota Street, Suite 1400
St. Paul, Minnesota 55101-2130
justin.moor@ag.state.mn.us

/s/ Lauren J. Caisman
Lauren J. Caisman