

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

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

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

MYLAN PHARMACEUTICALS INC.,

Defendant.

**MEMORANDUM OF LAW IN SUPPORT OF NONPARTY AMGEN INC.'S MOTION
TO INTERVENE FOR THE LIMITED PURPOSE OF ASSERTING THE PUBLIC
INTEREST IN ACCESS TO JUDICIAL RECORDS**

Nonparty Amgen Inc. (“Movant”), by and through its undersigned counsel, hereby submits this Memorandum in Support of its “Motion to Intervene for the Limited Purpose of Asserting the Public Interest in Access to Judicial Records,” and seeks to intervene in this action pursuant to Fed. R. Civ. P. 24(b) for the limited purpose of unsealing certain judicial records (or portions thereof) currently unavailable to the public, in accordance with the public’s First Amendment and common law rights. In support of this Motion, the Movant states as follows:

INTRODUCTION

I. The Parties

Plaintiff Regeneron Pharmaceuticals, Inc. (“Regeneron”) developed and sells Eylea® (aflibercept) – a treatment for certain eye diseases. Defendant Mylan Pharmaceuticals Inc. (“Mylan”) is seeking FDA approval under the Biologics Price Competition and Innovation Act (“BPCIA”), 42 U.S.C. §§ 262(k)-(l), to commercialize “M710,” a proposed biosimilar of Eylea. Regeneron initiated this action (“Action”) seeking a judgment of patent infringement against Mylan to prevent M710 from coming to market and competing with Eylea. On April 20, 2023, the

parties filed motions for summary judgment. A 10-day bench trial is scheduled to begin on June 12, 2023.

II. The Movant

Movant, one of the world's leading biopharmaceutical companies, is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320. Movant's biosimilar business is committed to building on Amgen's experience in the development, manufacture, and distribution of biological medicines.

Movant has devoted considerable effort to developing a proposed biosimilar of Eylea, which is currently designated "ABP 938." For example, Movant has completed the primary analysis of a randomized, double-blind, active controlled Phase III study evaluating the efficacy and safety of ABP 938 compared with Eylea. The final analysis is expected to be completed by June 2023.

III. The Parties' Sealing Practices

During the course of the Action, the parties have filed numerous documents under seal. But, for the most part, the docket sheet does not list motions to seal with titles explaining what documents the party seeks to seal and the public cannot access the actual motions or pleadings: the motion and number where those pleadings or motions should be listed are absent from the docket sheet.¹ For example, ECF Nos. 106, 119, 122, 133, 135, 146, 173, 174, 226, 228, 246, 261, 286, 301, 305, 307, 309, 311, 313, 314, 322, 324, 335, 336, 337, 339, 342, 352, 353, 356, 357, 360, 375, 377, 389, 391, 392, 403, 410, 430, 440, 441, 443, 445, 448, 449, 454, 455, 463, 466, 467, 469, 470, 471, 472, 473, 474, 476, 477, 478, 479, 480 and 482 have been omitted from the

¹ The docket sheet for this Action is attached as Exhibit A.

docket sheet. The only place some of these submissions can be found is in the descriptions of orders granting various motions to seal. *See* ECF at Nos. 132, 134, 136, 185, 186, 227, 251, 263, 308, 310, 312, 334, 336, 338, 355, 359, 390, 405, 409, 411 and 464. Other orders state “SEALED,” but do not identify in the description what is being sealed or what motion is being granted. *See* ECF at Nos. 297, 298, 351, 361, 368, 376, 431, 442, 444, 462, 465 and 468. Moreover, each order granting the numerous motions to seal is itself sealed. Consequently, in general, no determination can be made as to what was sealed or the justification for sealing it.

The docket sheet does identify a few documents that the parties requested to be sealed or that were sealed:

- Regeneron requested that subpoenas to third-parties that supplied materials to Mylan be sealed. *See* ECF at Nos. 107, 120.
- Mylan requested that its Opening Claim Construction Brief be sealed. *See* ECF at No. 123.
- Mylan’s Responsive Claim Construction Brief, and the exhibits attached thereto, were sealed in their entirety. *See* ECF at No. 187.
- Regeneron’s Responsive Claim Construction Brief, and the exhibits attached thereto, were sealed in their entirety. *See* ECF at No. 188.
- Mylan’s Response in Opposition to Regeneron’s Motion for Judgment on the Pleadings as to Mylan’s Inequitable Conduct Defenses and Counterclaims and the exhibits attached thereto were sealed in their entirety. *See* ECF at No. 252.
- Mylan’s Motion to Strike Plaintiff’s Unauthorized Reply Brief on Claim Construction Issues or, Alternatively, for Leave to File Response, and the exhibits attached thereto, were sealed in their entirety. *See* ECF at No. 264.
- Regeneron’s Motion for Presumption Under 35 U.S.C. § 295 and the exhibits attached thereto, were sealed in their entirety. *See* ECF at No. 299.²
- Mylan’s Memorandum in support of its motion for summary judgment, and the exhibits attached thereto, were sealed in their entirety. *See* ECF at No. 429.

But no order justifying sealing these documents is available for review. Moreover, the parties have not filed redacted versions of these documents in the public record.

² On May 12, 2023, pursuant to Regeneron’s Motion (ECF 438), the Court denied Regeneron’s Motion for Presumption as moot. *See* ECF 456. Nonetheless, Regeneron’s Motion for Presumption and the exhibits attached thereto remain sealed.

ARGUMENT

I. Movant's Limited Intervention is Proper Under Fed. R. Civ. P. 24(b)

The Court should permit Movant to intervene in this action to assert the public's right of access to these judicial proceedings. Permissive intervention under Fed. R. Civ. P. 24(b) is the appropriate method for a nonparty to assert the public's right to access to judicial proceedings and seek access to protected or sealed documents. *See In re Grand Jury Subpoena*, 836 F.2d 1468, 1470 (4th Cir. 1988); *Kirby v. Res-Care, Inc.*, 596 F. Supp. 3d 588, 592 (S.D.W. Va. 2022) (“[P]ermissive intervention is an appropriate method for a nonparty to seek access to protected or sealed documents.”); *see also Grove Fresh Distributors, Inc. v. Everfresh Juice Co.*, 24 F.3d 893, 896 (7th Cir. 1994) (“[I]ntervention is the procedurally appropriate course for third-party challenges to protective orders.”).

“It is well settled that the public and press have a qualified right of access to [judicial documents and records] filed in civil and criminal proceedings.” *Doe v. Public Citizen*, 749 F.3d 246, 265 (4th Cir. 2014). Consistent with that well-settled principle, the Fourth Circuit has held that “the press has standing to intervene in actions in which it is not otherwise a party to seek review of a district court’s order sealing documents and court records.” *Rosenfeld v. Montgomery Cty. Public Schs.*, 25 F.App’x 123, 131 (4th Cir. 2011); *see also Stone v. Univ of Md. Med. Sys. Corp.*, 855 F.2d 178, 180-181 (4th Cir. 1988); *Virginia Dep’t of State Police v. Washington Post*, 386 F.3d 567, 572 (4th Cir. 2004).

The public’s standing to intervene is no different than that of the media. *Doe*, 749 F.3d at 263 (“We see no reason why the standing of news media to seek appellate review of a district court’s sealing order should differ from that of a member of the general public.”); *see also In re Greensboro News Co.*, 727 F.2d 1320, 1322 (4th Cir. 1984) (holding that the rights of access of the media “are co-extensive with and do not exceed those rights of members of the public in general”).

As explained by the Seventh Circuit, “every court of appeals to consider the matter has come to the conclusion that Rule 24 is sufficiently broad-gauged to support a request for intervention for the purposes of challenging confidential orders.” *Jessup v. Luther*, 227 F.3d 993, 997 (7th Cir. 2000); *see also Phenix Newspapers, Inc. v. U.S. Dist. Ct.*, 156 F.3d 940, 949 (9th Cir. 1998) (finding that it is well-established that nonparties have standing to intervene to gain public access to sealed court documents). The First Amendment’s protections to judicial documents would be meaningless without the ability for nonparties to intervene to seek access to withheld documents. *See CBS Inc. v. Young*, 522 F.2d 234, 237-38 (6th Cir. 1975). Movant has standing to intervene as a member of the public.

Movant’s motion for limited intervention is timely and will not unduly delay or prejudice the adjudication of the merits. Movant does not seek to adjust the case schedule or to participate in any aspect of the Action. Because access to judicial proceedings remains relevant even after a case ends, there is no particular time limit for a party to intervene for the limited purpose of seeking access to judicial proceedings. Courts, including the Third Circuit, “have allowed intervention by parties for the limited purpose of modifying a confidentiality or protective order even after the underlying dispute between the parties has been settled.” *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 779 (3d Cir. 1994); *Kirby*, 596 F. Supp. at 592 (finding that intervention for the purpose of asserting the right of access “can be appropriate even after entry of a final judgment”). By seeking to litigate only an issue of access under the protective order, Movant would not disrupt this case on the merits. *Pansy*, 23 F.3d at 780.

For these reasons, Movant should be permitted to intervene under Rule 24(b).

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