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

REGENERON PHARMACEUTICALS, INC., Plaintiff, v. MYLAN PHARMACEUTICALS INC., and BIOCON BIOLOGICS INC., Defendants.	Case No. 1:22-cv-00061-TSK

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

Non-party Celltrion, Inc. ("Celltrion") is a company that, like the defendant Mylan, has filed a Biologics License Application ("BLA") with the U.S. Food & Drug Administration ("FDA") seeking approval of a biosimilar to plaintiff Regeneron's EYLEA product. Celltrion seeks to intervene in this action pursuant to Fed. R. Civ. P. 24(b) for the limited purpose of seeking the redaction and/or unsealing of docket entries (or portions thereof) that are currently unavailable to the public, in accordance with the public's First Amendment and common law rights.

The Court has granted similar relief to non-party Amgen, Inc. ("Amgen"), which filed a pre-trial motion to intervene in this action to seek the redaction and unsealing of various pre-trial pleadings. *See* ECF No. 485, 486. In granting Amgen's motion, the Court directed Amgen and the parties to "meet and confer after the bench trial takes place" to "determine which documents on the docket can be unsealed and/or redacted." ECF No. 516. The Court directed the parties to "submit a filing with the Court on or before August 25, 2023, indicating which documents can be unsealed and/or redacted." *Id.*

The bench trial is now complete. In this motion, Celltrion seeks the same relief granted to Amgen in order to protect Celltrion's interest should Amgen decline to press forward with the August 25, 2023 filing or otherwise fail to obtain the unsealing or redaction of materials on the docket. Celltrion also seeks to ensure that the parties and intervenors meet and confer to determine which of the sealed portions of the *trial transcript and post-trial docket entries*, including the parties' post-trial briefing concerning infringement and the parties' closing argument demonstratives, can be redacted to remove commercially-sensitive information and then unsealed.

In support of this Motion, Celltrion states as follows:

INTRODUCTION

I. The Parties

Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron") is the reference product sponsor of EYLEA, a biologic product that contains aflibercept as its active ingredient and which is approved by the FDA for the treatment of 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. A 10-day bench trial was held from June 12, 2023 to June 23, 2023. Closing arguments were held on August 3, 2023.

II. The Movant

Celltrion is a biopharmaceutical company organized and existing under the laws of Korea, with its principal place of business at 23, Academy-ro, Yeonsu-gu, Incheon, 22014, Republic of Korea. Celltrion has devoted considerable effort to developing its own proposed biosimilar of EYLEA, which is currently designated "CT-P42." On June 29, 2023, Celltrion filed with the FDA a BLA for CT-P42 that references EYLEA. At some point in the future, Regeneron may threaten or file a patent infringement suit against Celltrion asserting some or all of the patents asserted against

Mylan, to delay CT-P42 from coming to market and competing with EYLEA.

III. Non-Party Amgen's Motion to Intervene

On May 23, 2023, non-party Amgen, Inc. submitted a "Motion to Intervene for the Limited Purpose of Asserting the Public Interest in Access to Judicial Records" (ECF No. 485). Amgen argued that the public's right of access to judicial proceedings supported permissive intervention under Fed. R. Civ. P. 24(b). On May 31, 2023, Judge Kleeh granted Amgen's motion for good cause. *See* ECF No. 516. The parties and Amgen were ordered to meet and confer after the bench trial takes place, but on or before August 18, 2023, to determine which documents on the docket can be unsealed and/or redacted. The parties and Amgen were ordered to submit a filing with the Court on or before August 25, 2023, indicating which documents can be unsealed and/or redacted. *Id*.

IV. The Parties' Sealing Practices

Amgen's memorandum in support of its motion to intervene provides a detailed description of the documents that the parties filed under seal prior to trial, as well as the Court's Orders and docket entries concerning the sealing of those documents. ECF No. 486, Section III, 2-3. Celltrion incorporates that description by reference herein.[1] In addition to the documents identified in Amgen's memorandum, much of the trial and post-trial record remains under seal.

At the start of trial, Mylan made a motion to seal the courtroom for "limited portions of the trial proceedings" and "corresponding exhibits and portions of the trial transcript." ECF No. 526, 1. Mylan made clear that the information it sought to shield from public disclosure was very limited, and included only

> those portions of the trial that involve disclosure or discussion of (1) both the specific excipients or other constituents of the [Mylan YESALFI] product and the relative proportions and/or the specific amounts of each such constituent or excipient; (2) portions of Biocon's [BLA] containing other competitively sensitive research and development and/or product details; and (3) specific clinical trial data beyond that in the label, including individual patient data submitted to the [FDA]."

[1] Celltrion notes that since Amgen's motion was filed, additional docket entries are missing from the docket sheet. See ECF Nos. 487, 489, 491, 501, 503, 510, 530, 542, and 543.

Id. Mylan also promised to "provide a proposed redacted version of any relevant transcript volumes, for public filing, to further narrow the scope of information that is not publicly available." *Id.* at 4.

The Court did seal the courtroom for certain portions of the trial (*see, e.g.*, ECF No. 558 (Trial Tr. Day 1), 4, 10-20; ECF No. 560 (Trial Tr. Day 3), 581-711); ECF No. 564 (Trial Tr. Day 6), 1384-1416, 1451-80); ECF 566 (Trial Tr. Day 7), 1527-33, 1544-50; ECF 569 (Trial Tr. Day 9), 2121-22); *see also* ECF Nos. 557, 561, 565, 567, 570), however, Mylan has, to date, not proposed any redacted transcript volumes.

Regeneron also proposed that its opening post-trial brief regarding infringement, which presumably discloses or discusses information that falls into at least one of the three categories of information Mylan regards as sensitive, be sealed in its entirety. *See* ECF No. 577. The Court granted that motion, but again did not discuss or impose any requirement to redact those portions of the briefing papers that disclosed or discussed the narrow categories of information that Mylan is concerned about, so that the rest of the papers could be unsealed. ECF No. 580. Mylan also apparently requested sealing of its reply to Regeneron's post-trial brief concerning infringement, and the Court apparently granted that motion, since the reply does not appear on the public docket. There is no record of the Court requiring Mylan to file a redacted version of those reply papers.

Finally, during closing arguments, the Court again granted the parties' request to exclude the public from portions of the proceedings that risked disclosure of one or more of the three categories of allegedly sensitive information. At the conclusion of the parties' closing arguments, the Court also required the parties to file the demonstratives used during their arguments under seal.[2] No redacted transcript has yet been proposed, and the Court did not discuss or impose a requirement on the parties to prepare versions of the demonstratives with only information that falls into the three categories

[2] The transcript of the closing arguments is not yet available to Celltrion, but counsel for Celltrion attended the closing arguments and thus has firsthand knowledge of the parties' requests, and the

redacted, so that the remainder could be unsealed.

ARGUMENT

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

The Court should permit Celltrion 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.").

"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"). For the same reasons, the interests of one member of the general public, such as nonparty Amgen's, do not exceed

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