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IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

REGENERON PHARMACEUTICALS, INC., a New York corporation,

Plaintiff,

v.

AMGEN INC., a Delaware corporation,

Defendant.

Case No. 2:24-cv-00264-JWH-Ex
Hon. John W. Holcomb

FILED CONDITIONALLY UNDER SEAL

PLAINTIFF'S *EX PARTE* APPLICATION FOR SCHEDULING ORDER SETTING SCHEDULE FOR PRELIMINARY INJUNCTION PROCEEDINGS OR, IN THE ALTERNATIVE, AN EMERGENCY STATUS CONFERENCE; MEMORANDUM OF POINTS AND AUTHORITIES

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Attorneys for Plaintiff Regeneron Pharmaceuticals, Inc.

Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron" or "Plaintiff") hereby applies, *ex parte*, for an order setting a schedule for preliminary injunction proceedings necessitated by Defendant Amgen Inc.'s ("Amgen's") imminent plans to commercialize a biosimilar version of Regeneron's vision-saving drug, Eylea®. Five other cases are pending in the United States District Court for the Northern District of West Virginia against additional drug manufacturers seeking to commercialize biosimilar versions of Eylea®, with each such case pending before the Honorable Thomas S. Kleeh. Chief Judge Kleeh has already heard trial and issued an opinion in the first of those cases, holding that one of Regeneron's patents—which is also asserted against Amgen here—is not invalid and would be infringed by Defendants Mylan Pharmaceuticals Inc. and Biocon Biologics Inc. upon marketing their biosimilar version of Eylea®. Trask Decl., Ex. 4. The four other West Virginia cases have been set on a common schedule culminating in a combined preliminary injunction hearing before Chief Judge Kleeh on May 2, 2024. Trask Decl., Ex. 5. Those cases involve 13 of the same patents asserted against Amgen here.

In the interest of efficiency, Regeneron immediately filed a motion to transfer this case to the Northern District of West Virginia, so that preliminary injunction proceedings against Amgen may be joined with those underway in the four cases in West Virginia. Trask Decl., Ex. 6. That motion will be heard by the Judicial Panel on Multidistrict Litigation on March 28, 2024. Trask Decl., Ex. 7 at 2. In the interim, Regeneron respectfully and urgently requests that this Court enter a scheduling order that will keep this Amgen case on track with the West Virginia cases. Amgen agrees preliminary injunction proceedings are necessary but opposes Regeneron's requested schedule; Amgen instead insists its case should proceed separately to a hearing about two months later.

Pursuant to L.R. 7-19, the contact information for counsel for Defendant is as follows:

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The parties have conferred multiple times regarding the appropriate schedule for this action. *See* Trask Decl. ¶¶ 1-6. Pursuant to L.R. 7-19.1, counsel for Regeneron spoke most recently with counsel for Amgen on January 18, 2024. Amgen's counsel concurred the parties were at an impasse, and counsel for Regeneron stated its intention to file this application. *Id.* at ¶ 6. Amgen opposes the relief requested by this application.

This application is based upon this notice, the attached Memorandum of Points and Authorities, the attached declaration of Andrew V. Trask, all files and pleadings in this matter, and all other matters of which this Court may take judicial notice.

Dated: January 19, 2024

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Attorneys for Regeneron Pharmaceuticals, Inc.

This is a patent case concerning Eylea®, a market-leading drug for treating certain serious eye diseases that, if left untreated, can lead to permanent blindness. The Plaintiff, Regeneron Pharmaceuticals, Inc. ("Regeneron"), invented and developed Eylea® and markets it in the United States, along with other life-transforming medicines for diseases including Ebola, COVID-19, cancer, chronic inflammatory diseases, and cardiovascular and metabolic diseases. Compl. ¶¶ 1–2. Numerous Defendants—including the Defendant in this case, Amgen Inc. ("Amgen")—are currently seeking to market copies of Eylea®.[1] Each Defendant, including Amgen, has indicated an intent to commercialize their "biosimilar" copies of Eylea® before Regeneron's patents expire.

To vindicate its patent rights with respect to the proposed copies of Eylea®, Regeneron has filed six patent infringement suits against six Defendants. Other than this case against Amgen, all of the cases are pending before Chief Judge Thomas S. Kleeh in the United States District Court for the Northern District of West Virginia. Chief Judge Kleeh has already proceeded to trial in one of the five cases pending before him—the action against Mylan—in which the Court issued a decision and judgment on December 27, 2023. Declaration of Andrew Trask ("Trask Decl."), Ex. 4. Chief Judge Kleeh determined that one of the patents Regeneron has asserted in all six cases is not invalid and is infringed. *Id*. The four other cases before Chief Judge Kleeh were filed in late 2023 and now have ongoing preliminary injunction proceedings, with Regeneron's motions seeking to prevent commercialization of the Defendants' copies of Eylea® due February 22, 2024, and culminating in a

[1] There are six Defendants in total: Mylan Pharmaceuticals Inc., Biocon Biologics Inc. (*Regeneron Pharms., Inc. v. Mylan Pharms. Inc. and Biocon Biologics Inc.*, C.A. No. 1:22-cv-00061 (N.D. W. Va.) (Kleeh, C.J.)), Celltrion, Inc. (*Regeneron Pharms., Inc. v. Celltrion, Inc.*, C.A. No. 1:23-cv-00089 (N.D. W. Va.) (Kleeh, C.J.)), Samsung Bioepis Co., Ltd. (*Regeneron Pharms., Inc. v. Samsung Bioepis Co., Ltd.*, C.A. No. 1:23-cv-00094 (N.D. W. Va.) (Kleeh, C.J.) and *Regeneron Pharms., Inc. v. Samsung Bioepis Co., Ltd.*, C.A. No. 1:23-cv-00106 (N.D. W. Va.) (Kleeh, C.J.)), Formycon AG (*Regeneron Pharms., Inc. v. Formycon AG*, C.A. No. 1:23-cv-00097 (N.D. W. Va.) (Kleeh, C.J.)), and Amgen Inc.

combined preliminary injunction hearing on May 2, 2024. Trask Decl., Ex. 5 at 3–4 (Order Setting Briefing Schedule, entered in four cases simultaneously). The court set that hearing date recognizing that Regeneron's FDA regulatory exclusivity for Eylea® (during which the FDA cannot approve any of Defendants' biosimilar copies of Eylea®) will expire on May 18, 2024—and thus that maintaining the marketplace status quo requires entry of preliminary injunctions prior to that date. *Id*. at 4. To conserve judicial resources, Regeneron filed a motion to transfer this case for pre-trial proceedings to Chief Judge Kleeh in the Northern District of West Virginia. *See* Trask Decl. Ex. 6 (Motion to Transfer, *In Re Aflibercept Patent Litig.*, C. MDL No. 3103 (JPML Jan. 11, 2024)); Notice of Mot. to Transfer, ECF No. 6.

To maintain this case on a schedule that would allow it to be positioned for the consolidated preliminary injunction hearing on May 2, Regeneron respectfully and urgently requests that, while Regeneron's transfer motion is pending, this Court enter a preliminary injunction schedule that tracks the schedule in West Virginia. A proposed schedule for this Court's consideration is attached as Exhibit A. Amgen agrees that preliminary injunction proceedings are necessary and should commence this month, but instead proposes that this Court (or Chief Judge Kleeh, in the event of a transfer) hold duplicative proceedings about two months after Chief Judge Kleeh adjudicates many of the same issues on many of the same patents.[2] Trask Decl., Ex. 3. Regeneron respectfully submits that such a proposal would be wasteful and inefficient, as detailed below. In the alternative to entry of Regeneron's proposed preliminary injunction schedule, Regeneron respectfully

[2] Counsel for Regeneron conferred with counsel for Amgen by videoconference on Friday, January 12, 2024, and again on January 18, 2024. On both calls, counsel for Amgen indicated that they disagree that the Amgen case should proceed on the same preliminary injunction schedule as the one entered in the West Virginia cases. *See* Trask Decl., ¶¶ 3, 6. After the videoconference on January 12, counsel for Regeneron emailed the proposed schedule reflected in Exhibit A to counsel for Amgen. Trask Decl., Ex. 2 at 2–4. Amgen's counsel responded that Amgen does not agree that the parties should proceed on that proposed schedule, *Id.* at 2, and proposed its own preliminary injunction schedule, Trask Decl., Ex. 3.

requests a status conference at the Court's earliest convenience to discuss the need for entry of Regeneron's proposed schedule.

I. Background

This action for patent infringement arises under the Biologics Price Competition and Innovation Act ("BPCIA"). The BPCIA provides a framework for adjudicating patent disputes relating to efforts to market a nearly identical version of a branded pharmaceutical product before the product is commercialized. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. 1, 7–8 (2017). In order to effectuate that goal, the BPCIA (like its corollary for a different class of pharmaceutical products, the Hatch-Waxman Act) deems the filing of an FDA application to market a biosimilar version of a product before patent expiry an act of infringement under 35 U.S.C. § 271(e), so that claims of infringement may be initiated and resolved before infringement by commercialization. *Id.*, 582 U.S. at 7. Where multiple generic or biosimilar applications are filed under the BPCIA or Hatch-Waxman Act, multiple lawsuits commonly ensue. Those lawsuits—all involving applications related to the same branded product—typically are coordinated to preserve judicial resources, including through multidistrict litigation transfer. *See, e.g.*, *In re Sitagliptin Phosphate ('708 & '921) Pat. Litig.*, 402 F. Supp. 3d 1366, 1367 (J.P.M.L. 2019); *In re Kerydin (Tavaborole) Topical Sol. 5% Pat. Litig.*, 366 F. Supp. 3d 1370 (J.P.M.L. 2019).

That is the scenario here. In addition to this case against Amgen, Regeneron has sued five other Defendants in the Northern District of West Virginia. All complaints, including in this case against Amgen, allege patent infringement in response to the Defendants' applications to commercialize biosimilar versions of Regeneron's Eylea® product.

Regeneron filed its first suit on August 2, 2022, against Defendants Mylan Pharmaceuticals Inc. and Biocon Biologics Ltd., following FDA acceptance of Mylan's abbreviated Biologics License Application ("aBLA") and the parties'

completion of pre-suit requirements under the BPCIA, 42 U.S.C. § 262(*l*). In the action against Mylan, Chief Judge Kleeh issued a claim construction order addressing claim terms of four of Regeneron's asserted patents. Order on Claim Construction, *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, C.A. No. 1:22-cv-00061 (N.D. W. Va. Apr. 19, 2023) (Kleeh, C.J.) (ECF No. 427). Regeneron is asserting each of those four patents in every subsequently filed case against every Defendant, including in this case against Amgen. Compl. ¶ 6; Trask Decl., Ex. 6, ¶ 11. In addition, Chief Judge Kleeh presided over a two-week bench trial in June 2023 regarding the validity and infringement of three of Regeneron's patents, all of which are asserted in all subsequently filed actions, including in this case against Amgen. Compl. ¶ 6; Trask Decl., Ex. 6, ¶ 11. On December 27, 2023, Chief Judge Kleeh issued an opinion and judgment holding that one of the three trial patents is not invalid and will be infringed by Mylan and Biocon if they market their biosimilar Eylea® product.[3] Trask Decl., Ex. 4.

Regeneron filed the next three West Virginia actions in November 2023, alleging that the Defendants' proposed marketing and sale of their respective biosimilar products upon receiving FDA approval would infringe Regeneron's patents. *Regeneron Pharms., Inc. v. Celltrion, Inc.*, ECF No. 1, C.A. No. 1:23-cv-89 (N.D. W. Va. Nov. 11, 2023); *Regeneron Pharms., Inc. v. Samsung Bioepis*, Co., Ltd., ECF No. 1, C.A. No. 1:23-cv-94 (N.D. W. Va. Nov. 21, 2023); *Regeneron Pharms., Inc. v. Formycon AG*, ECF No. 1, C.A. No. 1:23-cv-97 (N.D. W. Va. Nov. 29, 2023). In those pending lawsuits, Regeneron seeks, *inter alia*, declarations of validity and infringement of its patents and injunctive relief against the manufacture,

[3] The four patents addressed in the claim construction order are U.S. Patent Nos. 11,084,865 ("the '865 patent"); 10,888,601 ("the '601 patent"); 11,253,572 ("the '572 patent"); and 11,104,715 ("the '715 patent"). Order on Claim Construction, *Regeneron Pharms., Inc. v. Mylan Pharms. Inc. and Biocon Biologics Inc.*, C.A. No. 1:22-cv-00061 (N.D. W. Va. Apr. 19, 2023) (Kleeh, C.J.) (ECF No. 427). Validity and infringement of the '865 patent, '572 patent, and '601 patents were tried at the two-week bench trial. Trask Decl., Ex. 4. The '865 patent was found to be infringed and not invalid. *Id.*

importation, use, sale, offer for sale of the Defendants' biosimilar products. Regeneron filed an additional lawsuit against Samsung on December 27, 2023, asserting infringement of many of the same patents pursuant to another provision of the BPCIA, 42 U.S.C. § 262(*l*)(6). *Regeneron Pharms., Inc. v. Samsung Bioepis, Co, Ltd*., ECF No. 1, C.A. No. 1:23-cv-106 (N.D. W. Va. Dec. 27, 2023). On January 10, 2024, Regeneron filed this suit against Amgen, also pursuant to 42 U.S.C. § 262(*l*)(6).

In all six actions, Regeneron has asserted 13 of the same patents against the six biosimilar Defendants and seeks the same relief. Thus, on January 11, 2024, immediately following the filing of this case against Amgen, Regeneron sought transfer of this action to West Virginia for consolidated pre-trial proceedings with the actions pending before Chief Judge Kleeh. Trask Decl., Ex. 6; Notice of Mot. to Transfer, ECF No. 6. As explained in Regeneron's motion to the Judicial Panel on Multidistrict Litigation ("JPML"), this case and the West Virginia actions involve many common questions of fact; transfer is in the interest of the parties and witnesses; and centralization will promote the just and efficient conduct of the actions. Trask Decl., Ex. 6. Regeneron's motion for transfer will be heard by the JPML on March 28, 2024. *See* Trask Decl., Ex. 7 at 2 (Minute Order, *In Re Aflibercept Patent Litig.*, C. MDL No. 3103 (JPML Jan. 12, 2024) (ECF No. 7)).

In all actions other than the action against Mylan tried last year, Regeneron is urgently seeking preliminary injunctions to prevent the Defendants from marketing their proposed biosimilar products upon expiry of FDA regulatory exclusivity on May 18, 2024. In the four West Virginia actions against Samsung, Celltrion, and Formycon, Chief Judge Kleeh issued an Order on January 9, 2024, setting a briefing schedule for Regeneron's Motion for a Preliminary Injunction, as well as for dispositive motion practice. Trask Decl., Ex. 5. Pursuant to the preliminary injunction schedule, document discovery is now underway; document production will be complete on February 2; Regeneron will file its preliminary injunction

motion on February 22; Defendants will file their opposition on March 21; Regeneron will file its reply on April 18; and the Court will hold a preliminary injunction hearing on May 2, 2024. *Id.* at 3–4.

For the same reasons that Regeneron is seeking preliminary injunctions against the Defendants in West Virginia, Regeneron intends to seek a preliminary injunction against Amgen as well. Regeneron already has advised Amgen of the documents it seeks in connection with its intended preliminary injunction motion. *See* Trask Decl. ¶ 7. As explained below, Regeneron respectfully submits that the proper course is to commence preliminary injunction proceedings against Amgen in this Court on a schedule tracking that in the West Virginia actions, while the JPML considers Regeneron's request to transfer this case to West Virginia.

II. Regeneron's Proposed Preliminary Injunction Schedule Is Optimal for the Courts and the Parties

A single preliminary injunction proceeding against all Defendants, including Amgen, is optimal for the Courts and the parties. All actions against all Defendants, including Amgen, will entail resolution of whether each Defendant may be permitted to sell a biosimilar version of Eylea® in the face of Regeneron's patents. And in all actions against all Defendants, Regeneron has asserted 13 of the same patents, alleged overlapping substantive claims, and seeks the same relief. Indeed, of the eight patents identified for preliminary injunction proceedings in West Virginia, six are asserted against Amgen here. Thus, a single proceeding will promote judicial efficiency and avoid the potential for inconsistent rulings—regarding, for example, the meaning of patent claim terms, the validity of the asserted patents, and Regeneron's irreparable harm.

To effectuate that objective, Regeneron promptly sought consolidation of this action with those pending in West Virginia. As explained above, however, preliminary injunction proceedings are now underway in the West Virginia actions, with a hearing date of May 2, 2024. Regeneron thus respectfully submits that the

most efficient course is for this Court to enter a preliminary injunction schedule tracking that of the West Virginia schedule, so that following MDL consolidation, the preliminary injunction proceeding against Amgen may be joined with the preliminary injunction proceedings against the other Defendants, and Regeneron's preliminary injunction motions against each Defendant may be heard together by Chief Judge Kleeh on May 2, 2024. As previously stated, a proposed schedule for this action largely tracking the preliminary injunction schedule entered by Chief Judge Kleeh in West Virginia is attached as Exhibit A for this Court's consideration.

Situating the preliminary injunction proceedings against Amgen to proceed on the same schedule as the other Defendants will facilitate the efficient coordination of those proceedings in the event of the requested transfer. Amgen, like each of the Defendants in West Virginia, has filed a pending application with the FDA seeking approval to market a biosimilar version of Regeneron's Eylea® product. Amgen, like the other Defendants, intends to launch its biosimilar product before the expiration of Regeneron's patents relating to Eylea® and related technologies. Each of the other Defendants notified Regeneron under 42 U.S.C. § 262(*l*)(8)(A) that it may market its biosimilar product following FDA approval and at least 180 days after it provided notice of commercial marketing under the BPCIA (the "180-day clock" referenced in Chief Judge Kleeh's Scheduling Order). [redacted] Indeed, Amgen *agrees* preliminary injunction proceedings are necessary; it would just prefer to hold them in parallel, trailing behind the West Virginia schedule by only a couple of months. Trask Decl., Ex. 3. Thus, Regeneron needs preliminary injunctive relief against each Defendant,

including Amgen, due to the otherwise imminent launch of their biosimilar products.

Preliminary injunction proceedings in this Court should proceed alongside the proceedings in West Virginia so that, following MDL consolidation in West Virginia, Amgen will be on track to join the May 2, 2024 preliminary injunction hearing with the rest of the similarly situated Defendants. As noted above, judicial efficiency is best served by hearing all of the preliminary injunctions together because of the numerous common facts and issues. This will be facilitated by the Amgen case proceeding at the same pace as the similarly situated West Virginia cases while the JPML considers Regeneron's motion to transfer. Should that motion be granted, Amgen's proposed schedule would require Chief Judge Kleeh to hold duplicative hearings barely more than two months apart—one for Formycon, Celltrion, and Samsung in early May, and a second (covering overlapping issues on overlapping patents) solely to accommodate Amgen's preference for June or early July. *Compare* Trask Decl., Ex. 3 (Amgen's Proposed Schedule for Preliminary Injunction Proceedings) *with* Trask Decl., Ex. 5 (Order Setting Briefing Schedule, entered in four cases simultaneously). That arrangement would result in a tremendous waste of judicial resources and impose unnecessary burdens on witnesses such as repetitive travel and duplicative depositions.

Regeneron's case for pre-trial consolidation is strong, given the substantial overlap of the Amgen case and the West Virginia cases, combined with the precedent for consolidating such actions. *See* Trask Decl., Ex. 6. But even if the JMPL were to deny transfer, the preliminary injunction discovery and briefing contemplated by Regeneron's proposed schedule will be used productively in this Court. Because Regeneron will be seeking a preliminary injunction against Amgen irrespective of the venue for those proceedings, the requested discovery and briefing will be necessary without regard to whether the ultimate hearing occurs in California or West Virginia.

III. Amgen's Proposed Schedule Is Inefficient and Prejudicial

Amgen's proposed schedule, Trask Decl., Ex. 3, is inefficient and prejudicial. Amgen is not materially differently situated from the other Defendants, and there is no compelling reason for Amgen to have a unique preliminary injunction schedule. Amgen may argue that it is situated differently because the 180-day clock has already begun to run for the other Defendants, [redacted] Amgen may also argue that it has particularly preferred arguments on the merits for some of the commonly asserted patents. There is no dispute, however, that Amgen plans to commercialize its biosimilar on a schedule requiring imminent preliminary injunction proceedings, and that the merits issues of claim construction, validity, public interest, and irreparable harm are overlapping, and likely identical. There is nothing so unique about Amgen that warrants the judicial inefficiencies and prejudice to Regeneron that would result from duplicative preliminary injunction proceedings against Amgen offset by about two months from the same proceedings against the other Defendants.

Amgen's own proposed scheduling order recognizes the relationship and substantial overlap between the Amgen preliminary injunction proceedings and the West Virginia preliminary injunction proceedings. For example, Amgen's scheduling order contains unusual provisions requiring Regeneron to produce to Amgen the same documents Regeneron produced to the West Virginia Defendants, and to produce to Amgen sealed filings submitted and filed in West Virginia under the West Virginia protective order. Trask Decl., Ex. 3. In other words, Amgen seeks all the privileges of being a party to the West Virginia proceeding without accepting any of the costs.

One such purported cost to Amgen is that the preliminary injunction decision under Regeneron's proposed schedule may be rendered [redacted] before Amgen's potential commercialization. Amgen mistakes a feature for a bug. Time

between a preliminary injunction decision and Amgen's planned date of commercialization will permit both parties to plan accordingly and, if they so choose, seek expedited appellate review of the preliminary injunction decision before commercialization would begin.

Amgen's proposed schedule also unnecessarily drags out the preliminary injunction proceeding—a proceeding that, by its very nature, is accelerated. For example, Amgen's proposed schedule includes about an extra month for document production as compared to Regeneron's proposed schedule. *Compare* Trask Decl., Ex. 3, *with* Ex. A. Such a long discovery period is not needed. Regeneron is prepared to produce the overwhelming majority of the Regeneron documents relevant to the preliminary injunction proceedings within one business day of entry of the scheduling order. *See* Ex. A. Further, Regeneron's document requests to Amgen are narrow—they are largely the same documents that three other Defendants are producing in essentially the same amount of time as would be provided to Amgen under Regeneron's proposed schedule. Regeneron has already sent these document requests, Trask Decl., ¶ 7, and is prepared to confer about prioritization of those requests to ensure timely production of the most important documents. There is no reason that Celltrion, Formycon, and Samsung can produce relevant documents within the time period set forth in Regeneron's proposed schedule, but Amgen cannot. Amgen's proposed schedule also gives Amgen nearly two months to respond to Regeneron's preliminary injunction motion. Trask Decl., Ex. 3. Amgen's proposal is needlessly lengthy, as demonstrated by the one-month response deadline ordered by Chief Judge Kleeh for each of the Defendants in West Virginia. *See* Trask Decl., Ex. 5. Indeed, in a recent case in the District of New Jersey in which Amgen is *seeking* a preliminary injunction, the defendants likewise had one month to respond. Trask Decl., Ex. 8.

Finally, Amgen's proposed schedule is prejudicial to Regeneron. In Amgen's proposed schedule, for example, the deadline for Amgen's depositions of

Regeneron's declarants is the day after the West Virginia preliminary injunction hearing. This is not practical, because in the final days before the deposition deadline, counsel and witnesses for Regeneron are likely to be physically located in West Virginia, preparing for and attending that hearing. Amgen's proposed schedule also demands Regeneron file its opening motion against Amgen during the month between Regeneron's receipt of the West Virginia Defendants' opposition to Regeneron's preliminary injunction motion(s) and the date Regeneron must file its reply. While Amgen wishes to proceed on a preliminary injunction schedule about two months behind the schedule in West Virginia, doing so would introduce unnecessary complexity and hardship for Regeneron, including for witnesses likely to participate in both proceedings.

Based on the foregoing, Regeneron respectfully requests that the Court grant this *ex parte* Application and enter Regeneron's proposed scheduling order or, in the alternative, convene a status conference at the Court's earliest convenience to discuss the need for entry of Regeneron's requested preliminary injunction schedule.

Dated: January 19, 2024

BIENERT KATZMAN LITTRELL WILLIAMS LLP

By: */s/Anthony R. Bisconti*
Anthony R. Bisconti

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Attorneys for Regeneron Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

I am employed in the County of Orange, State of California. I am over the age of 18 and not a party to the within action. My business address is 903 Calle Amanecer, Suite 350, San Clemente, CA 92673. I declare that I am employed in the office of a member of the bar of this Court at whose direction the service was made.

On January 20, 2024, I served the foregoing documents described as **PLAINTIFF'S EX PARTE APPLICATION FOR SCHEDULING ORDER SETTING SCHEDULE FOR PRELIMINARY INJUNCTION PROCEEDINGS OR, IN THE ALTERNATIVE, AN EMERGENCY STATUS CONFERENCE; MEMORANDUM OF POINTS AND AUTHORITIES** all interested parties in this action as stated as follows:

[X] BY ELECTRONIC TRANSMISSION: by electronically filing the foregoing with the Clerk of the District Court using its CM/ECF System pursuant to the Electronic Case Filing provision of the United States District Court General Order and the E-Government Act of 2002, which electronically notifies all parties in this case.

[X] **BY UNITED STATES MAIL** – I enclosed the document(s) in a sealed envelope addressed to the person(s) at the address(es) listed in the attached service list and placed the envelope for collection and mailing, following our ordinary business practices. I am readily familiar with this business's practice for collecting and processing correspondence for mailing. On the same day that correspondence is placed for collection and mailing, it is deposited in the ordinary course of business with the United State Postal Service, in a sealed envelope with postage fully paid. I am employed in the county where the mailing occurred. The envelope was placed in the mail at Los Angeles, California. I am aware that on motion of the party served, service is presumed invalid if postal cancellation date or postage meter date is more than one (1) day after date of deposit for mailing in affidavit.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on January 20, 2024 at Santa Maria, California.

/s/ Leah Thompson
Leah Thompson

SERVICE LIST

MARSHALL GERSTEIN
John R. Labbe
labbe@marshallip.com
Kevin M. Flowers
kflowers@marshallip.com
233 South Wacker Drive, Suite 6300
Chicago IL 60606-6357

EXHIBIT A

BIENERT KATZMAN LITTRELL WILLIAMS LLP
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Thomas S. Fletcher, State Bar No. 262693
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Teagan J. Gregory (*pro hac vice* forthcoming)
Shaun P. Mahaffy, State Bar No. 296001
Kathryn S. Kayali (*pro hac vice* forthcoming)
Arthur J. Argall III (*pro hac vice* forthcoming)
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Attorneys for Plaintiff Regeneron Pharmaceuticals, Inc.

Counsel's information continued on page i

IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

REGENERON PHARMACEUTICALS, INC., a New York corporation,

Plaintiff,

v.

AMGEN INC., a Delaware corporation,

Defendant.

Case No. 2:24-cv-00264-JWH-Ex
Hon. John W. Holcomb

EXHIBIT A TO PLAINTIFF'S EX PARTE APPLICATION FOR ORDER ENTERING PRELIMINARY INJUNCTION SCHEDULE: REGENERON'S PROPOSED PRELIMINARY INJUNCTION SCHEDULE

KELLOGG, HANSEN, TODD, FIGEL
& FREDERICK, P.L.L.C.
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Jacob E. Hartman (*pro hac vice* forthcoming)
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Anish R. Desai (*pro hac vice* forthcoming)
Natalie C. Kennedy (*pro hac vice* forthcoming)
Tom Yu (*pro hac vice* forthcoming)
Yi Zhang (*pro hac vice* forthcoming)
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Telephone (202) 682-7000

Attorneys for Plaintiff Regeneron Pharmaceuticals, Inc.

REGENERON'S PROPOSED PRELIMINARY INJUNCTION SCHEDULE

Event	Deadline
Regeneron delivers targeted requests for production	January 12, 2024 [Completed]
Regeneron identifies no more than eight patents that may be included in a motion for preliminary injunction; Defendants deliver targeted requests for production	Within two business days of the entry of this order.
Regeneron makes initial production of documents	Within one business day of entry of this order. Regeneron's documents shall be maintained on an outside-counsel's-eye's only basis until a protective order is entered, absent further agreement of the parties.
Defendant produces documents responsive to Regeneron's requests	January 26, 2024
Regeneron completes production of documents related to preliminary injunction, including documents related to patents it may assert in preliminary injunction motion	February 2, 2024
Regeneron identifies patents it may assert in preliminary injunction motion	February 2, 2024
Regeneron to file motion for preliminary injunction and supportive memorandum	February 22, 2024
Depositions of any Regeneron declarants complete	March 13, 2024
Defendant files opposition to motion for preliminary injunction	March 21, 2024
Deposition of Defendant's declarants complete	April 10, 2024

Regeneron files reply in support of preliminary injunction	April 18, 2024
Hearing on Regeneron's motion for preliminary injunction	May 2, 2024,[1] at 10:00 a.m.
In-person status conference with lead counsel ahead of May 18, 2024 expiration of regulatory exclusivity	May 13, 2024,[2] at 12:00 p.m.

Dated: January 19, 2024

BIENERT KATZMAN LITTRELL WILLIAMS LLP

By: */s/Anthony R. Bisconti*
Anthony R. Bisconti

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David I. Berl, State Bar No. 211761
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Jennalee Beazley* (*pro hac vice* forthcoming)

[1] In the event that Regeneron's motion to transfer the matter to the Northern District of West Virginia is not granted by April 20, 2024, the parties will confer regarding a date for the preliminary injunction hearing.

[2] In the event that Regeneron's motion to transfer the matter to the Northern District of West Virginia is not granted by April 20, 2024, the parties will confer regarding a date for the status conference.

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Attorneys for Plaintiff Regeneron Pharmaceuticals, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

REGENERON PHARMACEUTICALS, INC., a New York corporation, Plaintiff, v. AMGEN INC., a Delaware corporation, Defendant.	Case No. 2:24-cv-00264-JWH-Ex Hon. John W. Holcomb FILED CONDITIONALLY UNDER SEAL **DECLARATION OF ANDREW V. TRASK**

I, Andrew V. Trask, make the following Declaration based on personal knowledge of the matters set forth herein. I am a partner at Williams & Connolly LLP, counsel to Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron") in this matter. I am a member in good standing with the State Bars of New York and Washington, D.C., and my pro hac vice motion to represent Regeneron in this action in the United States District Court for the Central District of California is forthcoming. I submit this declaration in support of Regeneron's Ex Parte Application for Entry of Schedule. I have personal knowledge of the facts set forth in this declaration, and if called upon I could and would testify competently to the following:

1. David Berl and Kathryn Kayali are partners at Williams & Connolly LLP. On January 10, 2024, Mr. Berl, Ms. Kayali, and I spoke by videoconference with John Labbé, counsel for Defendant Amgen Inc. ("Amgen"). On that call, Mr. Labbé was unable to confirm that Amgen [redacted]

2. Attached hereto as Exhibit 1 is a true and correct copy of the email sent by Ms. Kayali to Mr. Labbé and others on Wednesday, January 10, 2024 memorializing Regeneron's understanding of the videoconference call, as well as the responsive email sent by Mr. Labbé to Ms.

Kayali and others on Thursday, January 11, 2024 regarding the January 10, 2024 videoconference call.

3. On Friday, January 12, 2024, Mr. Berl and I spoke with Mr. Labbé and others by videoconference. On that call, Mr. Berl asked Mr. Labbé if Amgen would be willing to proceed on the same preliminary injunction schedule as the one entered in the West Virginia cases. Mr. Labbé responded that Amgen disagrees that the preliminary injunction proceeding against Amgen should proceed on the same schedule as the preliminary injunction proceeding in West Virginia.

4. Attached hereto as Exhibit 2 is a true and correct copy of an email chain between Mr. Berl and Mr. Labbé. Immediately after the January 12, 2024 call, Mr. Berl emailed Mr. Labbé a proposed schedule with the same dates as those in the proposed schedule reflected in Exhibit A to Regeneron's *Ex Parte* Application for Entry of Schedule. The next day, Mr. Labbé responded by email that Amgen does not agree that the parties should proceed on the proposed schedule. On January 16, 2024, Mr. Labbé replied in the same email chain and attached Amgen's proposal for a preliminary injunction schedule. Mr. Labbé's email also stated that "[t]he information in this correspondence is confidential under 42 U.S.C. § 262(*l*)(1)."

5. Attached hereto as Exhibit 3 is a true and correct copy of the attachment to Mr. Labbé's January 16, 2024 email to Mr. Berl. The attachment is entitled "Amgen's Proposed Schedule for Preliminary Injunction Proceedings."

6. On Thursday, January 18, 2024, I joined a videoconference call with Rhochelle Krawetz, who is an associate at Williams & Connolly LLP, Mr. Labbé, and others regarding the preliminary injunction schedule and the confidentiality of Mr. Labbé's prior correspondence. Mr. Labbé agreed that the parties were at an impasse on the issue of an appropriate preliminary injunction schedule. He also stated that Amgen considers information regarding the timeframe of its commercialization plans to be Amgen confidential information. During the conversation, I told

Mr. Labbé that Regeneron intends to file an ex parte application seeking entry of its proposed preliminary injunction schedule. Mr. Labbé stated that Amgen will oppose the relief requested by Regeneron's application.

7. On January 12, 2024, Regeneron transmitted its first set of requests for production to Amgen.

8. Attached hereto as Exhibit 4 is a true and correct copy of the judgement in *Regeneron Pharms., Inc. v. Mylan Pharms. Inc. and Biocon Biologics Inc.*, C.A. No. 1:22-cv-00061 (N.D. W. Va. Dec. 27, 2023 N.D. W. Va.) (Kleeh, C.J.) (ECF No. 665).

9. Attached hereto as Exhibit 5 is a true and correct copy of the "Order Setting Briefing Schedule" in *Regeneron Pharms., Inc. v. Celltrion, Inc.*, C.A. No. 1:23-cv-00089 (N.D. W. Va.) (Kleeh, C.J.); *Regeneron Pharms., Inc. v. Samsung Bioepis Co., Ltd.*, C.A. No. 1:23-cv-00094 (N.D. W. Va.) (Kleeh, C.J.); *Regeneron Pharms., Inc. v. Samsung Bioepis Co., Ltd.*, C.A. No. 1:23-cv-00106 (N.D. W. Va.) (Kleeh, C.J.); and *Regeneron Pharms., Inc. v. Formycon AG*, C.A. No. 1:23-cv-00097 (N.D. W. Va.) (Kleeh, C.J.).

10. Attached hereto as Exhibit 6 is a true and correct copy of Regeneron's motion to transfer this action to the Northern District of West Virginia for pretrial proceedings. *In re: Aflibercept Patent Litig.*, C. MDL No. 3103 (JPML Jan. 11, 2024) (ECF No. 1).

11. Attached hereto as Exhibit 7 is a true and correct copy of the docket as of January 19, 2024, in *In re: Aflibercept Patent Litig.*, C. MDL No. 3103 (JPML Jan. 11, 2024).

12. Attached hereto as Exhibit 8 is a true and correct copy of the July 21, 2023 amended scheduling order in *Amgen Inc. v. Sandoz Inc.*, C.A. 23-2406 (D.N.J. July 21, 2023).

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 19th day of January, 2024 in Alexandria, Virginia.

Andrew V. Trask

EXHIBIT 1

(Filed Conditionally Under Seal)

EXHIBIT 2

(Filed Conditionally Under Seal)

EXHIBIT 3

Amgen's Proposed Schedule for Preliminary Injunction Proceedings
Case No. 2:24-cv-00264-JWH-E

Event	Deadline
Regeneron identifies no more than 3 patents and 15 total claims that may be included in a motion for preliminary injunction[1]	January 19, 2024
Regeneron makes initial document production, including all documents produced in *Regeneron v. Mylan* (N.D. W. Va.) litigation[2, 3]	January 19, 2024
Parties serve targeted document requests	January 26, 2024
Parties serve responses and objections to targeted document requests	February 9, 2024
Parties complete production of documents responsive to targeted document requests	March 8, 2024
Regeneron to file motion for preliminary injunction and supportive memorandum and declarations	April 5, 2024
Amgen's depositions of any Regeneron declarants completed	May 3, 2024
Amgen files opposition to motion for preliminary injunction and supportive declarations	May 31, 2024
Regeneron's depositions of any Amgen declarants complete	June 21, 2024
Regeneron files reply in support of motion for preliminary injunction	June 28, 2024
Hearing on Regeneron's motion for preliminary injunction	TBD at the Court's convenience

NOTES

[1] Amgen's proposed schedule assumes that Regeneron will identify no more than 3 patents (and 15 claims) for its PI motion at the outset of the schedule. If Regeneron proceeds with more than 3 patents or more than 15 claims (Regeneron proposes 8 patents), Amgen would request more time for discovery and to prepare its opposition.

[2] Regeneron shall produce to Amgen any documents that Regeneron has produced or produces in the future to any of the defendants in any of *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc. and Biocon Biologics Inc.*, No. 1:22-cv-00061 (N.D. W. Va.) (Kleeh, C.J.); *Regeneron Pharmaceuticals, Inc. v. Celltrion, Inc.*, No. 1:23-cv-00089 (N.D. W. Va.) (Kleeh, C.J.); *Regeneron Pharmaceuticals, Inc. v. Samsung Bioepis Co., Ltd.*, No. 1:23-cv-00094 (N.D. W. Va.) (Kleeh, C.J.); *Regeneron Pharmaceuticals, Inc. v. Samsung Bioepis Co., Ltd.*, No. 1:23-cv-00106 (N.D. W. Va.) (Kleeh, C.J.); and *Regeneron Pharmaceuticals, Inc. v. Formycon AG*, No. 1:23-cv-00097 (N.D. W. Va.) (Kleeh, C.J.) (collectively, "Other Aflibercept Matters") that are relevant to the issues in this case, by this deadline or at the same time those documents are produced in these other matters.

[3] Upon request by Amgen, Regeneron shall provide to Amgen redacted versions of any court filings in any of the Other Aflibercept Matters within 3 business days of any such request, which versions redact confidential information of the defendants in those cases that the West Virginia court has ordered to be kept under seal.

EXHIBIT 4

UNITED STATES DISTRICT COURT

for the

Northern District of West Virginia

Regeneron Pharmaceuticals, Inc.

Plaintiff(s)

v.

Civil Action No. 1:22-cv-61

Mylan Pharmaceuticals, Inc., et al.

Defendant(s)

JUDGMENT IN A CIVIL ACTION

The court has ordered that:

☐ Judgment award ☐ Judgment costs ☒ Other

other: The Court concludes that Regeneron has demonstrated by a preponderance of the evidence that the Defendants have infringed claims 4, 7, 9, 11, 14, 15, 16, and 17 of the ’865 Patent; Regeneron has demonstrated by a preponderance of the evidence that the Defendants will induce infringement of claims 6 and 25 of the ’572 Patent and claims 11 and 19 of the ’601 Patent; (continued below)

This action was:

☐ tried by jury ☐ tried by judge ☒ decided by judge

decided by Judge Thomas S. Kleeh

Mylan has not demonstrated by clear and convincing evidence that claims 4, 7, 9, 11, 14, 15, 16, and 17 of the ’865 Patent are anticipated or obvious in light of the prior art or invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, or indefiniteness. Mylan has not demonstrated by clear and convincing evidence that claim 6 of the ’572 Patent is invalid as anticipated; Mylan has demonstrated by clear and convincing evidence that claim 6 of the ’572 Patent is invalid as obvious; Mylan has not demonstrated by clear and convincing evidence that claim 25 of the ‘572 patent is invalid as anticipated; Mylan has demonstrated by clear and convincing evidence that claim 25 of the ‘572 patent is invalid as obvious; Mylan has not demonstrated by clear and convincing evidence that Claim 11 of the ‘601 Patent is invalid as anticipated; Mylan has demonstrated by clear and convincing evidence that Claim 11 of the ‘601 patent is invalid as obvious; Mylan has demonstrated by clear and convincing evidence that Claim 19 of the ‘601 Patent is invalid as obvious.

Date: December 27, 2023

CLERK OF COURT

Cheryl Dean Riley

/s/ D. Kinsey

Signature of Clerk or Deputy Clerk

EXHIBIT 5

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

REGENERON PHARMACEUTICALS, INC.,
Plaintiff,

v. **CIVIL NO. 1:23-CV-89**

CELLTRION, INC.,
Defendant.

REGENERON PHARMACEUTICALS, INC.,
Plaintiff,

v. **CIVIL NO. 1:23-CV-94**

SAMSUNG BIOEPIS, CO., LTD.,
Defendant.

REGENERON PHARMACEUTICALS, INC.,
Plaintiff,

v. **CIVIL NO. 1:23-CV-97**

FORMYCON AG,
Defendant.

REGENERON PHARMACEUTICALS, INC.,
Plaintiff,

v. **CIVIL NO. 1:23-CV-106**

SAMSUNG BIOEPIS, CO., LTD.,
Defendant.

ORDER SETTING BRIEFING SCHEDULE ON MOTIONS TO DISMISS AND SETTING SCHEDULE FOR PRELIMINARY INJUNCTION PROCEEDINGS

Pending before the Court is a motion to dismiss for lack of personal jurisdiction filed by Defendant Samsung Bioepis, Co., LTD. [ECF No. 47 in Case No. 1:23-CV-94 and ECF No. 14 in 1:23-

CV-106]. On January 5, 2024, the Court held a status conference that was prompted by Plaintiff Regeneron's "emergency motion" requesting either a schedule for preliminary injunction proceedings or an emergency status conference. During the status conference, Regeneron reiterated its request for the Court to enter a schedule governing preliminary injunction proceedings and also requested that the Court allow it to conduct jurisdictional discovery. Regeneron requests that the preliminary injunction proceedings run parallel to the resolution of the jurisdictional issue. Defendants disagree and ask the Court to decide the jurisdictional issue first.

Assuming that all Defendants will have filed a motion to dismiss on or before January 17, 2024, as represented, the following briefing schedule shall govern the motions to dismiss:

- Regeneron shall file an omnibus response to the motions to dismiss on or before **February 19, 2024**; and

- Any replies shall be filed on or before **February 26, 2024.**

The parties agree that preliminary injunction proceedings must ultimately take place within the 180 days set forth under the BPCIA. The 180-day clock has already begun to tick, and even if this Court would ultimately determine that it lacks jurisdiction, the 180 days would not restart when this action is transferred to or filed in a different court. Given the unique timeline in this

case, the Court finds that it is appropriate here to allow preliminary injunction proceedings to take place at the same time as the briefing and resolution of the motions to dismiss.[1] The Court finds good cause to set forth and hereby does set forth the following schedule for preliminary injunction proceedings:

Event	**Deadline**
Regeneron identifies no more than eight patents that may be included in a motion for preliminary injunction; Defendants deliver targeted requests for production	Within two business days of entry of this order
Regeneron makes initial production of documents	Within one business day of agreement by counsel for a Defendant to maintain such documents on an outside-attorney's-eyes-only basis until a protective order has been entered
Defendant produces documents responsive to Regeneron's requests	January 26, 2024
Regeneron completes production of documents related to preliminary injunction, including documents related to patents it may assert in preliminary injunction motion	February 2, 2024
Regeneron identifies patents it may assert in preliminary injunction motion	February 2, 2024
Regeneron to file motion(s) for preliminary injunction and supportive memoranda against all defendants in the above-captioned cases	February 22, 2024
Depositions of any Regeneron	March 13, 2024

[1] The Court takes under advisement the request for jurisdictional discovery, finding it premature to decide at this time.

declarants complete[2]	
Defendants file opposition(s) to motion(s) for preliminary injunction	March 21, 2024
Deposition of Defendants' declarants complete	April 10, 2024
Regeneron files reply/replies in support of preliminary injunction	April 18, 2024
Hearing on Regeneron's motion(s) for preliminary injunction	May 2, 2024, at 10:00 a.m.
In-person status conference with lead counsel ahead of May 18, 2024 expiration of regulatory exclusivity	May 13, 2024, at 12:00 p.m.

It is so **ORDERED.**

The Clerk is **DIRECTED** to transmit copies of this Order to counsel of record.

DATED: January 9, 2024

Tom S Kleeh

THOMAS S. KLEEH, CHIEF JUDGE
NORTHERN DISTRICT OF WEST VIRGINIA

[2] The parties shall present any declarant for deposition in the continental United States.

EXHIBIT 6

BEFORE THE UNITED STATES JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

In re Aflibercept Patent Litigation	MDL No. _____

MOTION OF PLAINTIFF FOR TRANSFER OF ACTION TO THE NORTHERN DISTRICT OF WEST VIRGINIA PURSUANT TO 28 U.S.C. § 1407 FOR COORDINATED PRETRIAL PROCEEDINGS

Regeneron Pharmaceuticals, Inc. ("Regeneron"), by and through undersigned counsel, respectfully moves the Judicial Panel on Multidistrict Litigation to enter an order pursuant to 28 U.S.C. § 1407 and Rule 6.2 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, transferring *Regeneron Pharmaceuticals, Inc. v. Amgen Inc.*, C.A. No. 2:24-cv-00264, currently pending in the United States District Court for the Central District of California (judge not yet assigned), to Chief Judge Thomas S. Kleeh in the United States District Court for the Northern District of West Virginia, for coordinated pretrial proceedings with the five cases filed by Regeneron that are already pending before Chief Judge Kleeh in the Northern District of West Virginia.

Transfer for pretrial coordination is proper and necessary for the following reasons, as set forth more fully in the accompanying memorandum:

1. Regeneron is the Plaintiff in six actions for patent infringement brought under the patent laws of the United States, Title 35, United States Code, against six defendants:[1]

- *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc. and Biocon Biologics Inc.*, C.A. No. 1:22-cv-00061 (N.D. W. Va.) (Kleeh, C.J.)

[1] Mylan Pharmaceuticals Inc. ("Mylan"); Biocon Biologics Inc. ("Biocon"); Celltrion, Inc. ("Celltrion"); Formycon AG ("Formycon"); Samsung Bioepis Co. Ltd. ("Samsung"); and Amgen Inc. ("Amgen") (collectively, "Defendants").

- *Regeneron Pharmaceuticals, Inc. v. Celltrion, Inc.*, C.A. No. 1:23-cv-00089 (N.D. W. Va.) (Kleeh, C.J.)
- *Regeneron Pharmaceuticals, Inc. v. Samsung Bioepis Co., Ltd.*, C.A. No. 1:23-cv-00094 (N.D. W. Va.) (Kleeh, C.J.)
- *Regeneron Pharmaceuticals, Inc. v. Samsung Bioepis Co., Ltd.*, C.A. No. 1:23-cv-00106 (N.D. W. Va.) (Kleeh, C.J.)
- *Regeneron Pharmaceuticals, Inc. v. Formycon AG*, C.A. No. 1:23-cv-00097 (N.D. W. Va.) (Kleeh, C.J.)
- *Regeneron Pharmaceuticals, Inc. v. Amgen Inc.*, C.A. No. 2:24-cv-00264 (C.D. Cal.) (judge not yet assigned)

This motion seeks coordination of these six actions by transferring the *Amgen* action to West Virginia.

2. Five of the six above-listed actions are pending before Chief Judge Kleeh in the Northern District of West Virginia.

3. In the sixth action, Regeneron sued Amgen Inc. in the Central District of California (the "Amgen Action"); that case has not yet been assigned to a judge.

4. All six actions arise out of Defendants' filings of abbreviated Biologics License Applications ("aBLAs") with the United States Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, or import biosimilar versions of Regeneron's Eylea® (aflibercept) product, prior to the expiration of patents owned by Regeneron. Each action involves numerous asserted patents, 13 of which overlap across all six actions: U.S. Patent Nos. 9,222,106; 9,254,338; 9,816,110; 10,130,681; 10,415,055; 10,464,992; 10,669,594; 10,888,601; 11,066,458; 11,084,865; 11,104,715; 11,253,572; and 11,306,135 (the "patents-in-suit").

5. Each Defendant's submission of its aBLA constitutes an act of patent infringement under 35 U.S.C. § 271(e). Each Defendant has indicated that it disputes the validity and/or

infringement of all asserted patents and that it does not intend to await patent expiry to commercialize its biosimilar product. Pursuant to 42 U.S.C. § 262(k)(7)(A), Defendants' aBLAs may be approved as soon as Eylea's regulatory exclusivity expires on May 18, 2024.

6. Regeneron filed the first of the above-listed actions, *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc. and Biocon Biologics Inc.* (the "Mylan Action"), in August 2022, after the FDA accepted Mylan's aBLA filing and the parties completed the pre-suit requirements set forth in 42 U.S.C. § 262(*l*). In June 2023, Chief Judge Kleeh presided over a two-week bench trial involving the infringement and validity of three of Regeneron's patents-in-suit. The Court issued its post-trial decision on December 27, 2023, finding that one of Regeneron's patents-in-suit is valid and infringed by Mylan and Biocon.

7. Regeneron filed suits against Celltrion, Formycon, and Samsung in the Northern District of West Virginia in November 2023 after each sent notice letters to Regeneron indicating that they would begin marketing and selling their respective biosimilar products upon receiving approval from the FDA. 42 U.S.C. § 262(*l*)(8)(A). On December 27, 2023, Regeneron filed a second suit against Samsung pursuant to 42 U.S.C. § 262(*l*)(6). On January 10, 2024, Regeneron also filed a suit in the Central District of California against Amgen pursuant to 42 U.S.C. § 262(*l*)(6).

8. All of the above-listed actions therefore involve the same core issue: whether, by seeking approval of its Eylea biosimilar product, the Defendant has infringed and/or will infringe any valid claim of Regeneron's asserted patents.

9. The above-listed actions present numerous common issues of fact and law, including without limitation the technologies underlying the patents-in-suit; the prosecution histories of the patents-in-suit; the proper construction of claim terms in the patents-in-suit; the

scope and content of the prior art; and any secondary indicia of non-obviousness associated with the products embodying the patents-in-suit. The above-listed actions also present common issues of fact and law with respect to issues of remedies, including injunctive relief.

10. All of the above-listed actions except for the Mylan Action are in their earliest stages. As of the filing of this motion, in all the actions other than the Mylan Action, only a single scheduling conference has occurred, discovery is just beginning, and no substantive orders have issued. On January 9, 2024, Chief Judge Kleeh issued an Order scheduling preliminary injunction proceedings in the Celltrion, Formycon, and Samsung Actions, culminating in a combined preliminary injunction hearing on May 2, 2024. That Order is attached as Exhibit 7 to this motion.

11. In the Mylan Action, Regeneron provided extensive discovery as to six patents from three patent families, and the Court issued a claim construction opinion on 12 claim terms of the six patents and a decision following a two-week trial on 12 asserted claims from three of the patents-in-suit. Four of the six patents construed by the Court in the Mylan Action are asserted in all six actions.

12. Regeneron intends to seek an injunction against each of the Defendants to prevent them from marketing their proposed biosimilars before patent expiry in each of the above-listed actions. As mentioned above, a preliminary injunction hearing has been scheduled for May 2, 2024, in four of the cases currently pending before Chief Judge Kleeh. Ex. 7. As the Mylan Action has already proceeded to trial, Regeneron will seek permanent injunctive relief from Chief Judge Kleeh in that case.

13. Transfer and coordination of the above-listed action is necessary to: (a) eliminate the potential for inconsistent rulings on pretrial motions, including but not limited to any claim construction rulings; (b) eliminate the burden of duplicative discovery on common issues; (c) avoid

the unnecessary use of judicial resources; and (d) reduce the overall costs and burdens for all of the parties.

14. Because each of the above-listed actions asserts infringement through the submission of an aBLA, the effect of having inconsistent rulings regarding FDA procedures, claim construction, injunctions, validity, and aBLA-based infringement would be significant, deleterious, and an unnecessary strain on judicial resources.

15. Chief Judge Kleeh is already familiar with the issues in these cases, having presided over more than a year of litigation and two weeks of trial in the Mylan Action, culminating in a 313-page opinion issued on December 27, 2023. The Court does not currently have any other multidistrict litigations on its docket.

Based on the foregoing, Regeneron respectfully requests that the action against Amgen Inc. pending in the Central District of California, *Regeneron Pharmaceuticals, Inc. v. Amgen Inc.*, C.A. No. 2:24-cv-00264, be transferred to Chief Judge Kleeh in the Northern District of West Virginia for coordinated pretrial proceedings with the five other cases filed by Regeneron that are already pending in that District.

Dated: January 11, 2024

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EXHIBIT 7

United States Judicial Panel on Multidistrict Litigation
CIVIL DOCKET FOR CASE #: MDL No. 3103

IN RE: Aflibercept Patent Litigation
Assigned to: Not Assigned

Date Filed: 01/11/2024
MDL Status: Pending

Date Filed	#	Docket Text
01/11/2024	1	MOTION TO TRANSFER (INITIAL MOTION) with Brief in Support. −− 6 Action(s) −− from California Central District Court (2:24−cv−00264) −− from West Virginia Northern District Court (1:22−cv−00061,1:23−cv−00089,1:23−cv−00094,1:23−cv−00097,1:23−cv−00106) **Suggested Transferee Court:** Northern District of West Virginia **Filed by:** Regeneron Pharmaceuticals, Inc. (Attachments: # 1 Brief in Support of Motion, # 2 Schedule of Actions, # 3 Proof of Service, # 4 Exhibit 1 Complaint 22−cv−00061, # 5 Exhibit 2 Complaint 23−cv−00089, # 6 Exhibit 3 Complaint 23−cv−00094, # 7 Exhibit 4 Complaint 23−cv−00106, # 8 Exhibit 5 Complaint 23−cv−00097, # 9 Exhibit 6 Complaint 24−cv−00264, # 10 Exhibit 7 ND WVA Order Setting Briefing Schedule)(Berl, David) Modified on 1/12/2024 (DLD). ADDED ADDITIONAL CASES AND REMOVE DUPLICATE ATTACHMENT NAMES (Entered: 01/11/2024)
01/11/2024	2	MOTION TO TRANSFER (AMENDED) (re: pldg. 1) −− 5 Additional Action(s) −− from West Virginia Northern District Court (1:22−cv−00061,1:23−cv−00089,1:23−cv−00094,1:23−cv−00097,1:23−cv−00106) Filed by: *Plaintiff Regeneron Pharmaceuticals, Inc.* (Berl, David) (Entered: 01/11/2024)
01/11/2024	3	MOTION TO EXPEDITE (re: pldg. 1 in MDL No. 3103) Filed by David Isaac Berl on behalf of Plaintiff Regeneron Pharmaceuticals, Inc. (Attachments: # 1 Proof of Service) Associated Cases: Pending No. 5, CAC/2:24−cv−00264, WVN/1:22−cv−00061, WVN/1:23−cv−00089, WVN/1:23−cv−00094, WVN/1:23−cv−00097, WVN/1:23−cv−00106 (Berl, David) Modified on 1/12/2024 (DLD). REMOVED DUPLICATE PARTIES Modified on 1/16/2024 (DLD). REMOVED DUPLICATE ATTACHMENT NAME AND ADDED MDL LINK. (Entered: 01/11/2024)
01/12/2024	4	MOTION TO TRANSFER (CORRECTED) −− *(re: pldg. 1)* Correcting the following items: **Proof of service,** −− Filed by: *Plaintiff Regeneron Pharmaceuticals, Inc.* (Berl, David) (Entered: 01/12/2024)
01/12/2024	5	MDL Number 3103 Assigned −− MOTION FOR TRANSFER ACCEPTED FOR FILING re: pldg. (1 in Pending No. 5) Associated Cases: Pending No. 5, CAC/2:24−cv−00264, WVN/1:22−cv−00061, WVN/1:23−cv−00089, WVN/1:23−cv−00094, WVN/1:23−cv−00097, WVN/1:23−cv−00106 (DLD) (Entered: 01/12/2024)
01/12/2024	6	*****TEXT ONLY NOTICE***** NOTICE OF FILING AND PUBLICATION OF BRIEFING SCHEDULE *re: pldg. (1 in MDL No. 3103)* BRIEFING SCHEDULE IS SET AS FOLLOWS: Notices of Appearance due on or before **1/26/2024**. Corporate Disclosure Statements due on or before **1/26/2024**. Responses due on or before **2/2/2024**. Reply, if any, due on or before **2/9/2024**. **In their briefs, the parties should address what steps they have taken to pursue alternatives to centralization (including, but not limited to, engaging in informal coordination of discovery and scheduling, and seeking Section 1404 transfer of**

		one or more of the subject cases). Appearance forms (JPML form 18) and Corporate Disclosure forms can be downloaded from our website. **Important**: A Corporate Disclosure Form, if required, must be filed, even if one has previously been filed in this MDL. Please visit the CM/ECF Filing Guidelines & Forms page of our website for additional information. Attorneys must be registered to file in the JPML. Please visit our website for Registration Information. Signed by Clerk of the Panel Tiffaney D. Pete on 1/12/2024. Associated Cases: MDL No. 3103, CAC/2:24−cv−00264, WVN/1:22−cv−00061, WVN/1:23−cv−00089, WVN/1:23−cv−00094, WVN/1:23−cv−00097, WVN/1:23−cv−00106 (DLD) (Entered: 01/12/2024)
01/12/2024	7	***TEXT ONLY ENTRY*** MINUTE ORDER (re: pldg. (3 in MDL No. 3103)) Plaintiff has moved to expedite consideration of its motion to transfer. The Panel considers all motions in due course and is not persuaded to depart from its long−standing practice. The motion for expedited consideration is DENIED. This matter will be set for the March 28, 2024 Hearing Session Order. Signed by Clerk of the Panel Tiffaney D. Pete on 1/12/2024. Associated Cases: MDL No. 3103, CAC/2:24−cv−00264, WVN/1:22−cv−00061, WVN/1:23−cv−00089, WVN/1:23−cv−00094, WVN/1:23−cv−00097, WVN/1:23−cv−00106 (DLD) Modified on 1/12/2024 (DLD). (Entered: 01/12/2024)

EXHIBIT 8

THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

AMGEN INC., et al., **Plaintiffs,** **v.** **SANDOZ INC., et al.,** **Defendants.**	**Civil No. 23-2406 (CPO/EAP)**

AMENDED SCHEDULING ORDER

This matter comes before the Court by way of the parties' July 3, 2023 joint letter, presenting disputes on the proposed case management schedule, as well as the proposed Joint Discovery Plan and Appendix A, outlining the issues at impasse; Defendant Sandoz Inc.'s July 3, 2023 letter outlining various disputes concerning the proposed consent injunction and Plaintiffs' July 5, 2023 letter in response thereto; and the parties' pre-motion letters, ECF Nos. 74, 77, directed to the Hon. Christine P. O'Hearn, U.S.D.J., regarding Defendant Sandoz Inc.'s proposed motion to dismiss. The Court has considered the parties' submissions, the numerous disputes between the parties, and for good cause shown;

IT IS this **21st** day of **July 2023**, hereby **ORDERED**:

1. The previously proposed early trial date of March 5-8 and 11-13, 2024, is **DENIED**.

2. **Preliminary Injunction Motion.** The Court **GRANTS** Plaintiffs' request for a schedule for preliminary injunction briefing, including expedited discovery that might be necessary for the motion.

3. **Briefing Schedule.** Plaintiffs shall file their motion for a preliminary injunction by **September 1, 2023**. Defendant Sandoz Inc. shall file its opposition by **October 1, 2023**. Plaintiffs shall file their reply brief by **October 16, 2023**.

4. The Court will conduct a preliminary injunction hearing on the motion in **November 2023**. No later than **July 27, 2023**, the parties shall submit a letter to the Court identifying the approximate number of days required for this hearing. The Court will schedule the hearing upon receipt of this information.

5. No later than **August 1, 2023,** the parties shall submit a revised proposed case management order without reference to an early trial date. If the parties seek expedited discovery for purposes of the preliminary injunction motion, they should include dates for such discovery in the proposed case management order.

6. The Court will conduct an **in-person** initial conference on **August 16, 2023, at 10:00 a.m.** Counsel shall report to the **Mitchell H. Cohen Building & U.S. Courthouse, 4th & Cooper Streets, Courtroom 5C, Camden, New Jersey 08101**.

THE FAILURE OF A PARTY OR ATTORNEY TO OBEY THIS ORDER MAY RESULT IN IMPOSITION OF SANCTIONS UNDER FED. R. CIV. P. 16(f).

s/ Elizabeth A. Pascal
ELIZABETH A. PASCAL
United States Magistrate Judge

cc: Hon. Christine P. O'Hearn, U.S.D.J.

IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

REGENERON PHARMACEUTICALS, INC., a New York corporation,

Plaintiff,

v.

AMGEN INC., a Delaware corporation,

Defendant.

Case No. 2:24-cv-00264-JWH-Ex
Hon. John W. Holcomb

[PROPOSED] ORDER ENTERING PRELIMINARY INJUNCTION SCHEDULE

The Court has reviewed and considered the *Ex Parte Application for Order Entering Preliminary Injunction Schedule,* filed by Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron") on January 19, 2024. The Court has determined that good cause exists to grant the Application. Accordingly,

IT IS ORDERED THAT:

1. The Application is GRANTED.

2. Pursuant to Federal Rules of Civil Procedure 16(b) and 26(f) and the Local Rules of Civil Procedure and 42 U.S.C. § 262(*l*)(8)(C), the Court enters the following Case Management and Scheduling Order.

WHEREAS Plaintiff Regeneron Pharmaceuticals, Inc. initiated this civil action with the filing of a Complaint against Defendant Amgen Inc. ("Amgen");

WHEREAS the United States Food and Drug Administration is currently reviewing Defendant's Biologic License Applications seeking approval to market a biosimilar version of Regeneron's aflibercept (Defendant's "Aflibercept aBLA");

WHEREAS Regeneron has sought multi-district litigation transfer of this action for pre-trial purposes, including for preliminary injunction proceedings, to the Northern District of West Virginia;

WHEREAS the Parties shall reasonably cooperate to expedite these proceedings and facilitate the Court's resolution of the Parties' disputes.

Event	Deadline
Regeneron delivers targeted requests for production	January 12, 2024 [Completed]
Regeneron identifies no more than eight patents that may be included in a motion for preliminary injunction; Defendants deliver targeted requests for production	Within two business days of the entry of this order.

Regeneron makes initial production of documents	Within one business day of entry of this order. Regeneron's documents shall be maintained on an outside-counsel's-eye's only basis until a protective order is entered, absent further agreement of the parties.
Defendant produces documents responsive to Regeneron's requests	January 26, 2024
Regeneron completes production of documents related to preliminary injunction, including documents related to patents it may assert in preliminary injunction motion	February 2, 2024
Regeneron identifies patents it may assert in preliminary injunction motion	February 2, 2024
Regeneron to file motion for preliminary injunction and supportive memorandum	February 22, 2024
Depositions of any Regeneron declarants[1] complete	March 13, 2024
Defendant files opposition to motion for preliminary injunction	March 21, 2024
Deposition of Defendant's declarants complete	April 10, 2024
Regeneron files reply in support of preliminary injunction	April 18, 2024

[1] The parties shall present any declarant for deposition in the continental United States.

Hearing on Regeneron's motion for preliminary injunction	May 2, 2024,[2] at 10:00 a.m.
In-person status conference with lead counsel ahead of May 18, 2024 expiration of regulatory exclusivity	May 13, 2024,[3] at 12:00 p.m.

To the extent that the Parties have any discovery disputes, such disputes will be resolved on an expedited basis consistent with the principles outlined in 42 U.S.C. § 262(*l*)(8)(C).

SO ORDERED this _____ of January, 2024.

_____

United States District Judge

[2] In the event that Regeneron's motion to transfer the matter to the Northern District of West Virginia is not granted by April 20, 2024, the parties will confer regarding a date for the preliminary injunction hearing.

[3] In the event that Regeneron's motion to transfer the matter to the Northern District of West Virginia is not granted by April 20, 2024, the parties will confer regarding a date for the status conference.