**BEFORE THE UNITED STATES JUDICIAL PANEL**
**ON MULTIDISTRICT LITIGATION**

| In re: Aflibercept Patent Litigation | MDL No. 3103 |
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**SAMSUNG BIOEPIS CO., LTD.'S, CELLTRION, INC.'S, AND FORMYCON AG'S OPPOSITION TO PLAINTIFF'S MOTION TO TRANSFER**

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## I. INTRODUCTION

Defendants Samsung Bioepis Co., Ltd. ("SB"), Celltrion, Inc. ("Celltrion"), and Formycon AG ("Formycon") (collectively, the "PI Defendants") respectfully oppose Regeneron Pharmaceuticals, Inc.'s ("Regeneron") Motion to Transfer *Regeneron Pharmaceuticals, Inc. v. Amgen Inc.*, C.A. No. 2:24-cv-00264, pending in the Central District of California, to Judge Thomas S. Kleeh in the United States District Court for the Northern District of West Virginia, for coordinated pretrial proceedings pursuant to 28 U.S.C. § 1407 ("Regeneron's Motion").

As set forth below in further detail, the PI Defendants were sued in separate actions in the Northern District of West Virginia. Each of them is a foreign corporation with no physical presence in West Virginia. Each has contested personal jurisdiction in the district from the start and communicated their intentions to file motions to dismiss on that basis to Regeneron. In fact, on January 4, exactly a week before Regeneron filed the instant Motion, SB filed a motion to dismiss for lack of personal jurisdiction. Ex. 1. And in a January 9 Order, the West Virginia Court ordered briefing to be complete on the PI Defendants' personal jurisdiction challenges by February 26, 2024. Regeneron filed its Motion to establish an MDL two days after the West Virginia Court's order, without once mentioning to the Panel that the PI Defendants were seeking dismissal. Recognizing the possibility that the West Virginia Court could dismiss the PI Defendants before the Panel's decision, Regeneron also sought expedited consideration of its Motion, which this Panel properly denied.

As set out further below, Regeneron's failure to inform the Panel of the pending motions challenging personal jurisdiction is indicative of its improper purpose in establishing an MDL: to "circumvent a possible unfavorable decision on a motion to dismiss for lack of personal jurisdiction." *In re: Klein*, 923 F. Supp. 2d 1373 (J.P.M.L. 2013). Regeneron's Motion should be denied on this ground alone. And, even putting aside that improper purpose, it is Regeneron's

burden to show that an MDL should be established. By failing to address the effect of the PI Defendants' motions, Regeneron has failed to carry that burden.

Finally, notwithstanding the motions to dismiss, transfer is inappropriate under the standard factors. Any overlap between the cases is nominal at best and outweighed by their myriad differences. Regeneron's asserted patents span a wide array of technologies—from method of manufacture to cell culture to formulation and beyond—that will require different analyses for each PI Defendant based on that defendant's unique confidential information. Each PI Defendant independently developed their biosimilar, including their accused manufacturing processes, formulation, and available presentations and indications. Each PI Defendant's information is highly confidential and commercially sensitive vis-à-vis one another and as Regeneron has not yet narrowed its case, this will require, to an unknown degree, separate proceedings.

Moreover, of Regeneron's 63 asserted patents from 20 families, only 13 are common among all defendants. Four patents in one of the families are subject to instituted IPRs, with three having been found invalid by the PTAB and/or the West Virginia Court. Of the three patents in a second family, one was recently disclaimed by Regeneron after a successful IPR, and the other two are essentially duplicates of each other. That second family relates to the product's formulation, which is likely to differ amongst all defendants. And the remaining patents relate to aspects of each PI Defendant's confidential manufacturing process and cell lines, where it is highly likely that there are significant differences in each PI Defendant's individually developed methods. Thus, even if the cases were limited to the 12 common, non-disclaimed patents—they are not—there is little reason for consolidation.

And, even if all of the PI Defendants remain in West Virginia, transferring Amgen and centralizing the actions during the ongoing PI proceedings would be pointless and disruptive. As part of the Court-directed preliminary injunction process, the PI Defendants are already informally coordinating their four pending cases as much as possible. All of the PI Defendants already are on a common schedule for preliminary injunction proceedings, and the present Motion will not be decided until those proceedings are at an advanced stage. By the time Amgen would be added, any benefits from consolidation already would have dissipated as the West Virginia Court will not be able to incorporate Amgen into the proceedings while ruling on Regeneron's proposed preliminary injunction motion within the 180-day statutory window.[1] No matter what happens, the PI Defendants and Amgen will be on a completely separate schedule (as will Mylan, which has already had one trial on the merits).

For the foregoing reasons, and those set forth further below, the PI Defendants respectfully request denial of Regeneron's Motion.

## II. BACKGROUND

Regeneron initiated the first lawsuit regarding a proposed aflibercept biosimilar product in August 2022 when it sued Mylan Pharmaceuticals Inc. in its home state of West Virginia. *See* Brief in Support of Motion to Transfer to the Northern District of West Virginia Pursuant to 28 U.S.C. § 1407 ("Reg. Br.") at 2. Over fifteen months later, beginning in November 2023, Regeneron sued three additional defendants in West Virginia—Celltrion, SB, and Formycon. *Id.* at 2-3. On December 27, 2023, the Court in the Mylan case issued a written decision holding

[1] The BPCIA provides that a biologics license applicant must provide the reference product sponsor (here, Regeneron) with 180 days' notice before commercially marketing their product. 42 U.S.C. § 262(l(8)(A). Upon receipt of the notice, the reference product sponsor may seek a preliminary injunction. 42 U.S.C. § 262(l(8)(B).

that one of the three tried patents was infringed and not invalid. *Id.* at 3. It found the other two asserted patents invalid. *Id*.

All three PI Defendants contested personal jurisdiction from each suit's inception and communicated their intentions to challenge it to both Regeneron and the West Virginia Court. On January 4, 2024, SB moved to dismiss Regeneron's lawsuit for lack of personal jurisdiction. Ex. 1. At a hearing the day later, Celltrion and Formycon represented that their motions to dismiss would be filed on or before January 17. On January 9, 2024, the West Virginia Court entered (1) a briefing schedule on SB's filed and Celltrion/Formycon's forthcoming motions to dismiss, and (2) a schedule for preliminary injunction proceedings against those same defendants. *See* Reg. Br., Ex. 7.

On January 10, 2024, Regeneron sued Amgen Inc. in the Central District of California. Reg. Br. at 3. One day later, Regeneron filed the present Motion to transfer and centralize the Amgen case with the other actions tried or currently pending in West Virginia. Regeneron's Motion was accompanied by a motion to expedite the Panel's decision, which was denied the following day. *In re: Aflibercept Pat. Lit.*, MDL No. 3103, ECF No. 4 (J.P.M.L. 2024).

On January 20, 2024, Regeneron requested that the Central District of California "enter a scheduling order that will keep this Amgen case on track with the West Virginia cases." Ex. 2 at 1. Three days later, that Court denied Regeneron's request and, instead, set a scheduling conference in that case for April 5, 2024. Ex. 3.

## III. REGENERON'S MOTION IMPROPERLY SEEKS TO CIRCUMVENT THE PI DEFENDANTS' CHALLENGE TO PERSONAL JURISDICTION

Regeneron's Motion should be denied as it improperly seeks to circumvent the PI Defendants' challenge to personal jurisdiction in West Virginia.

As set forth above, the PI Defendants were sued in separate actions in the Northern District of West Virginia. Each PI Defendant contested personal jurisdiction in the district from the outset. *See* Reg. Br., Ex. 7 at 2. For instance, a week before Regeneron filed the instant Motion, SB filed a motion to dismiss for lack of personal jurisdiction. Ex. 1. And both Celltrion and Formycon told the West Virginia Court at a hearing a day later that they would file their motions to dismiss by January 17. In a January 9 Order, the West Virginia Court directed Celltrion and Formycon to file their motions by January 17, and set Regeneron's response to those motions and the PI Defendants' replies on February 19 and February 26, 2024, respectively.

Regeneron filed its Motion to establish an MDL two days after the West Virginia Court's order, without once mentioning to the Panel these facts.[2] Recognizing that the schedule set by the West Virginia Court meant it would likely rule before the Panel's March 25, 2024 hearing date, Regeneron also sought expedited consideration of its Motion to transfer, which was denied.

While the PI Defendants acknowledge that personal jurisdiction is not generally a pertinent factor in the Section 1407 analysis, it is also the case that the Panel has frequently noted that a "desire to circumvent obstacles of personal jurisdiction . . . amounts to an attempted misuse of the statute" and has denied transfer on those grounds. *See*, *e.g.*, *In re Highway Acc. Near Rockville, Connecticut, on Dec. 30, 1972*, 388 F. Supp. 574 (J.P.M.L. 1975); *In re Truck Acc. Near Alamagordo, New Mexico*, on June 18, 1969, 387 F. Supp. 732 (J.P.M.L. 1975).

[2] While SB's motion was filed under seal, all of the PI Defendants indicated in publicly available filings as well as in open court during the January 5, 2024 hearing that they either had or would file motions to dismiss for lack of personal jurisdiction. Additionally, the Court's order setting a schedule on the motions to dismiss was public and attached to Regeneron's motion to transfer.

For instance, in *In re: Klein*, 923 F. Supp. 2d 1373 (J.P.M.L. 2013), the Panel denied a motion for centralization. There, the plaintiff filed two complaints—the first in the District of the District of Columbia, where the defendant challenged personal jurisdiction, and the second in the Middle District of Florida. The plaintiff acknowledged that it filed the second complaint to seek consolidation into the District of Columbia action in response to the claim by the defendant that there was no personal jurisdiction there. The Panel denied the motion on these grounds, stating that "circumvent[ing] a possible unfavorable decision on a motion to dismiss for lack of personal jurisdiction" was an improper purpose under the statute. *Id*.

The rationale of *In re: Klein*—that the MDL process should not be utilized as a mechanism to upend pending personal jurisdiction challenges—applies here, despite acknowledged differences in the facts. That the *In re: Klein* plaintiff filed two different cases against the same defendant is of no moment. If the West Virginia Court had already dismissed cases against the PI Defendants for lack of personal jurisdiction, and Regeneron filed and sought consolidation with the Mylan action, the improper purpose and effect would be the same as it is here. Whether the transfer involves the same defendant or multiple defendants is irrelevant—the key, as the *In re: Klein* Panel made clear, is that using the MDL process to defeat personal jurisdiction challenges does not "achieve the purposes for which Section 1407 was designed." *Id*.

Similarly, that Regeneron has not expressly acknowledged its improper purpose does not distinguish *In re: Klein*. Despite the substantial impact the PI Defendants' pending motions have on the Section 1407 analysis (*see infra* Section IV), Regeneron failed to inform the Panel about the motions and instead sought to expedite consideration of its Motion ahead of the West Virginia Court's decision on personal jurisdiction. This is sufficiently indicative of an improper

purpose to circumvent those motions. Regeneron should not be rewarded merely because it was less direct than the *In re: Klein* plaintiff regarding its purpose in seeking consolidation.

Regeneron's Motion should be denied on this ground alone.

## IV. BY FAILING TO ADDRESS THE PI DEFENDANTS' MOTIONS, REGENERON FAILS TO CARRY ITS BURDEN

Even putting aside Regeneron's improper purpose in seeking consolidation, by failing to address the PI Defendants' motions and their impact on the Panel's three-factor analysis, Regeneron has failed to carry its burden to show that centralization is proper. *In re: Select Retrieval, LLC, ('617) Pat. Litig.*, 883 F. Supp. 2d 1353, 1354 (J.P.M.L. 2012).

For instance, Regeneron fails to address whether consolidation would be "just and efficient" in view of the pending motions to dismiss. As just one example, preliminary injunction proceedings are currently on-going in West Virginia over the PI Defendants, pending rulings on their motions to dismiss. In MDL cases, the MDL court's authority to coordinate pre-trial proceedings flows from the personal jurisdiction of the court transferring the action—it otherwise has no authority over the defendant. *See* 15 Fed. Prac. & Proc. Juris. § 3862 n.12 (4th ed.); *see In re Agent Orange Prod Liab. Litig.*, 818 F.2d 145, 163 (2d Cir. 1987) (quoting *In re FMC Corp. Patent Litig.*, 422 F.Supp. 1163, 1165 (J.P.M.L.1976)) (transferee court "has all the jurisdiction and powers over pretrial proceedings in the actions transferred to [it] that the transferor judge would have had in the absence of transfer").

Here, if an MDL were established but the West Virginia Court were to find it lacked personal jurisdiction, its authority over the PI Defendants would disappear, as there would be neither a transferor court from which to derive jurisdiction nor a transferee court with personal jurisdiction in the first instance. With an MDL established but no authority for the Court to act, Regeneron presumably would have to file a second action against each Defendant in a venue in

which personal jurisdiction is appropriate and then seek to transfer each action back to West Virginia, consistent with establishment of the MDL. But refiling and transfer would neither be efficient given the time it would take nor would it be just given that the purpose of such transfers would be expressly improper under *In re: Klein*.

Similarly, Regeneron also fails to address whether consolidation in West Virginia would be proper without the PI Defendants in West Virginia. By the time the Panel hears Regeneron's Motion, the PI Defendants may be in separate jurisdictions. In that case, to the extent the Panel finds consolidation proper, it might choose Delaware instead, where two defendants (SB and Celltrion) have acknowledged personal jurisdiction would be proper, where Amgen is incorporated, and where Formycon has indicated it would accept consolidation if its preference of Seattle is not accepted. But Regeneron fails to address this in its Motion.

By its willful blindness as to the motions to dismiss, Regeneron has failed to carry its burden. Its Motion should be denied on this ground as well.

## V. NOTWITHSTANDING THE MOTIONS TO DISMISS, TRANSFER OF AMGEN AND CENTRALIZATION ARE INAPPROPRIATE

As the party "seeking centralization," Regeneron bears "the burden of demonstrating the existence of common questions of fact such that centralization will serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation." *In re: Select*, 883 F. Supp. 2d at 1354. "[W]here only a minimal number of actions are involved, the proponents of centralization bear a heavier burden to demonstrate that centralization is appropriate." *In re: JumpSport, Inc., ('845 & '207) Pat. Litig.*, 338 F. Supp. 3d 1356, 1357 (J.P.M.L. 2018) (denying motion to centralize six patent cases in two districts despite "undoubtedly . . . some factual overlap among these actions").

"[C]entralization is not a cure-all for every group of complicated cases." *In re: Uniloc USA, Inc., & Uniloc Luxembourg, S.A., HPE Portfolio Pat. Litig.*, 304 F. Supp. 3d 1356, 1357 (J.P.M.L. 2018) (internal quotation marks omitted). "Centralization of any litigation—including patent cases—is not automatic, and will necessarily depend on the facts, parties, procedural history and other circumstances in a given litigation." *In re: Select*, 883 F. Supp. 2d at 1354.

Regeneron makes none of the showings required to justify transfer and centralization and thus fails to carry its burden. As explained below, there are insufficient common questions of fact to warrant transfer and centralization, and transfer and centralization will neither serve the convenience of the parties and witnesses nor further the just and efficient conduct of the actions.

**1. The Actions Involve Distinct Questions of Fact**

The litigations at issue each involve myriad unique questions of law and fact.

*First*, defendants' respective accused products "vary considerably," which "weigh[s] against centralization here." *See In re: Blue Spike, LLC, Pat. Litig.*, 278 F. Supp. 3d 1379, 1380 (J.P.M.L. 2017); *see also In re: Genetic Techs. Ltd. ('179) Pat. Litig.*, 883 F. Supp. 2d 1337, 1338 (J.P.M.L. 2012); *In re: Uniloc*, 304 F. Supp. 3d at 1357 (denying transfer despite "[a]ll actions involv[ing] some common factual questions regarding the alleged infringement of one or more of seven Uniloc patents" in part because "the products at issue also vary significantly").

Here, Regeneron's accusations of infringement are premised on five unique Biologics License Applications ("BLA") that will implicate idiosyncratic noninfringement defenses. The details of each defendant's product are highly confidential at this stage, but there will likely be little to no overlap as to most of the patents, given each PI Defendant independently developed their biosimilar and their complex manufacturing processes. For instance, the defendants' cell cultures and manufacturing processes are almost certain to be different, as are their formulations. And, because of the highly confidential nature of their processes and product details, even if

there were similarities, they cannot be shared among the defendants nor made part of consolidated proceedings.

That the validity of the 12 common, non-disclaimed patents asserted against all defendants will be challenged in each case also does not counsel in favor of consolidation. Each patent has a number of claims, and Regeneron has given no guarantee that it will assert the same claims against each PI Defendant. Consequently, because claims within the same patent can differ in scope, each PI Defendant may present different theories of invalidity depending on the asserted claims, the nature of their manufacturing processes and products, and their evaluation of the prior art and relevant legal doctrines. While certain factual issues associated with validity may be common, for those limited issues, the discovery they engender is "unlikely to be unusually burdensome or time-consuming." *In re: Kohl's Tel. Consumer Prot. Act (TCPA) Litig.*, 220 F. Supp. 3d 1363, 1364 (J.P.M.L. 2016). "In contrast, the amount of individualized discovery into such matters as the" preparation and content of defendants' unique BLAs is "likely to be quite significant." *Id.* Accordingly, even though "[t]he actions possess a degree of factual commonality," transfer is not appropriate because "[t]here are . . . significant differences among the actions," including that, "[i]n each action, . . . [t]he defendants make different 'accused products.'" *In re: Alexsam, Inc. ('608 & '787) Pat. & Cont. Litig.*, 437 F. Supp. 3d 1374, 1375 (J.P.M.L. 2020).

*Second*, "the degree of overlap among [Regeneron's 63] asserted patents varies widely among the cases." *In re: Blue Spike*, 278 F. Supp. at 1379. Centralization is not necessary simply because certain patents overlap between cases. *See id.* (denying motion to transfer despite "[a]ll actions involv[ing] some common facts surrounding the alleged infringement of a total of 34 Blue Spike patents, which share a common inventor"). Of the 63 total asserted

patents from 20 families, only 12 are common and non-disclaimed among all defendants, from seven families. Of those 12, four are subject to instituted IPRs, three of which already have been found invalid by the PTAB or the West Virginia Court, and one has been disclaimed. And the remaining patents relate to aspects of each PI Defendant's confidential manufacturing processes, cell lines, and formulation, where it is highly likely there are significant differences in each PI Defendant's individually-developed methods and formulation.

Moreover, there will eventually be a second stage of litigation against each PI Defendant after the PI phase that will address the 50-plus patents Regeneron asserts against each of them. These massive cases will have limited factual overlap between them as to questions of infringement and will not involve the same sets of patents. For instance, Regeneron asserts 52 patents against SB across two cases, but it only asserts 26 of those 52 patents against Amgen. *See* Ex. 4. Similarly, Regeneron only asserts 34 of those patents against Formycon and 37 against Celltrion. *Id.* And, as to the Mylan case, there is almost no factual overlap: of those patents, only ***a single patent*** overlaps with those addressed in the Mylan decision. *Id*. The same is true for the preliminary injunction proceedings—of the 8 patents asserted therein, not all patents overlap for all defendants, and only ***one*** patent overlaps with those addressed in the Mylan decision. *Id*.

Regeneron contends that centralization is warranted because Judge Kleeh "is already well-versed in the issues common to the cases." Reg. Br. at 9. But the Panel has previously held that "the efficiency benefits of litigating . . . ***eight*** patents from ***three*** different patent families before a single judge are insufficient to justify centralization" where "[e]ach defendant is accused of infringing a varying number of . . . patents." *In re: Realtime Adaptive Streaming LLC*

*Pat. Litig.*, 326 F. Supp. 3d 1374, 1375 (J.P.M.L. 2018) (emphasis added). Here, where the variations vastly exceed those in *In re: Realtime*, the efficiencies are virtually non-existent.

Moreover, that the patents all relate to the same industry or product is not sufficient to warrant centralization. Even when "all . . . patents raised in the[] actions relate to the [same] industry," centralization is not appropriate where the patents "involve a wide range of technologies and do not descend from a common patent 'family' (*i.e.,* the patents have many different inventors)." *In re: Constellation Techs. LLC Pat. Litig.*, 38 F. Supp. 3d 1392, 1393 (J.P.M.L. 2014); *see also In re: Uniloc*, 304 F. Supp. 3d at 1357. Regeneron's asserted patents descend from at least 24 different families (with a host of different inventors) and span a large number of technologies. Even categorizing the patents by the broad, general characterizations in Exhibit 4, there are roughly 20 different technologies, ranging from composition of matter and cell culture to packaging and design patents.

Finally, Regeneron attempts and fails to analogize to the Hatch-Waxman context, where it contends consolidation is prevalent. BPCIA cases are meaningfully different from Hatch-Waxman cases. As an initial matter, the BPCIA contemplates preliminary injunction proceedings within a 180-day period after receipt of the commercial marketing notice. *See supra* p. 3, n. 1. This makes BPCIA cases uniquely difficult to consolidate given the tight timeframe for a preliminary injunction. Indeed, because of a mere month delay in filing against Amgen, it is impossible to add Amgen to the PI proceedings in West Virginia without substantial disruption. In the Hatch-Waxman context, by contrast, there is a 30-month stay after the commercial marketing notice, making Hatch-Waxman proceedings substantially easier and more desirable to consolidate. Additionally, process/manufacturing patents may not be listed by a reference product sponsor in the Hatch-Waxman context, but they constitute the majority of

Regeneron's asserted patents here. This difference is significant as there are likely to be little to no common questions of fact as to each PI Defendant's confidential manufacturing process, each of which is complex and individually developed. Finally, as the cases cited by Regeneron show, in the Hatch-Waxman context, defendants often do not oppose consolidation because there often are, in fact, numerous common issues (as was the case in 5 of the 7 cases cited by Regeneron). That is not the case in the BPCIA context, where bringing a biologic to market requires substantially more complex manufacturing processes.

*Third*, the possibility of inconsistent pretrial rulings with respect to claim construction does not necessitate transfer. Regeneron argues that Judge Kleeh's prior claim construction ruling supports centralization. *See* Reg. Br. at 8. Not so. Judge Kleeh's claim construction experience was limited to only four of the commonly-asserted patents, two of which have since been declared invalid and a third to which Regeneron stipulated to noninfringement and dropped before trial. As this Panel previously noted when denying a patentee's motion to transfer and centralize five infringement actions, previous "claim construction rulings are available to the parties and the presiding judges ***regardless*** of centralization." *In re: Alexsam*, 437 F. Supp. 3d at 1376 (emphasis added). Moreover, Regeneron's speculation as to potential future claim construction issues does not necessitate centralization, at least because "the involved courts may . . . allow a claim construction hearing to proceed in one action in advance of the others." *In re: High Quality Printing Inventions, LLC, ('070) Pat. Litig.*, 176 F. Supp. 3d 1381, 1384 (J.P.M.L. 2016).

*Fourth*, whether Regeneron is entitled to a preliminary injunction does not involve common questions of fact. Regeneron is correct that the availability of a preliminary injunction will turn on certain questions—namely, "likelihood of success on the merits; the prospect of

harm to Regeneron; a balancing of the equities; and whether injunctive relief is in the public interest." Reg. Br. at 8. But, just because those inquiries form the basis for any preliminary injunction proceeding, does not mean that they necessarily involve common questions of fact. For example, whether Regeneron can demonstrate a likelihood of success on infringement will be unique to the particular facts of each defendant's individual BLA. Moreover, the prospect of harm to Regeneron will differ depending on each defendant's marketing and pricing strategy, indications, presentations, and market timing—facts that are not only different, but also unknown and sensitive as to each defendant. *See, e.g., Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1375 (Fed. Cir. 2012) (causal nexus requires showing that the allegedly "infringing feature drives consumer demand for the accused product"). Other factors will differ too, including the balancing of the equities, which will be defendant-specific, and questions of public interest, which can turn on, for instance, pricing, availability, and use.

Accordingly, Regeneron has failed to demonstrate that common questions of fact warrant transfer and centralization.

**2. Centralization in the Northern District of West Virginia Will Not Convenience the Parties and Witnesses**

Regeneron provides the Panel only with reasons why consolidation would be convenient to itself. If that were sufficient to show convenience, this factor would be met any time a plaintiff seeks consolidation. It is not. The second factor addresses the convenience of "the parties and witnesses," not just the party seeking consolidation. *See In re: CVS Caremark Corp. Wage & Hour Emp. Pracs. Litig.*, 684 F. Supp. 2d 1377, 1379 (J.P.M.L. 2010) ("Nevertheless, where a Section 1407 motion appears intended to further the interests of particular counsel more than those of the statute, [the Panel] would certainly find less favor with it."); *see also In re: ArrivalStar S.A. Fleet Mgmt. Sys. Pat. Litig.*, 802 F. Supp. 2d 1378, 1379 (J.P.M.L. 2011)

(denying transfer because Panel "not persuaded that centralization would serve the convenience of the parties and witnesses"); *In re: Dietgoal Innovations, LLC ('561) Pat. Litig.*, 999 F. Supp. 2d 1380, 1381 (J.P.M.L. 2014) (same). Here, for everyone other than Regeneron, centralization in West Virginia would not be convenient.

*First*, centralization in the Northern District of West Virginia will inconvenience the PI Defendants (as well as their witnesses), who contest the propriety of the forum. Regeneron contends that centralization in West Virginia will minimize the burdens on the parties and the witnesses because "[f]ive of the actions are already pending before Chief Judge Kleeh in West Virginia." Reg. Br. at 9. But, notably missing from Regeneron's Motion is any mention of the pending dispute over whether the Northern District of West Virginia has personal jurisdiction over the PI Defendants.

Instead, Regeneron self-servingly assumes that the Court will rule in its favor on this hotly contested issue and, therefore, that the actions against the PI Defendants will proceed in West Virginia. But, by failing to acknowledge this issue, Regeneron fails to account for the very real possibility that the Court reaches the opposite conclusion—a result that would vitiate any argument that West Virginia is convenient. Because this is a live issue, the Panel should afford no weight to the fact that certain actions are ***presently*** pending in West Virginia. Nor should Regeneron's lack of transparency find favor with the Panel. *See In re: CVS*, 684 F. Supp. 2d at 1379.

*Second*, litigating complex patent actions in the Northern District of West Virginia is, as a general matter, less convenient than in other districts. For example, the Northern District of West Virginia lacks local patent rules, which in turn increases the burden on parties and witnesses (as well as their counsel) by reducing the predictability of the various deadlines and

exchanges present in a complex patent litigation. Additionally, the Northern District of West Virginia requires that local counsel attend all depositions in person—even those occurring outside of West Virginia. Moreover, the Northern District of West Virginia is relatively inaccessible to the parties, requiring a flight into Pittsburgh and a roughly two-hour drive to Clarksburg, West Virginia. Each of the PI Defendants is a foreign corporation whose witnesses will be coming from abroad, and the required travel to West Virginia will be particularly burdensome for these witnesses.

*Third*, centralization is not necessary to adequately convenience Regeneron because the parties can and will informally coordinate in order to minimize duplicative discovery. "[I]nformal coordination among the two involved courts and cooperation by the parties [is] both practicable and preferable to centralization." *In re: Constellation*, 38 F. Supp. 3d at 1393; *In re: Plastic Injection Molding Mfg. Process ('184) Pat. Litig.*, 706 F. Supp. 2d 1376, 1377 (J.P.M.L. 2010) (denying centralization because "the parties can continue to avail themselves of alternatives to Section 1407 transfer to minimize whatever possibilities may arise of duplicative discovery and/or inconsistent pretrial rulings"). In fact, the PI Defendants are coordinating briefing efforts where (as here) possible. *See In re: Oplus Techs., Ltd., Pat. Litig.*, 899 F. Supp. 2d 1373, 1373–74 (J.P.M.L. 2012) ("We note that defendants appear to be amenable to cooperative efforts to reduce costs in this litigation, given that they filed a single consolidated brief on the issue of centralization."). And the PI Defendants have conferred with Amgen and have confirmed that they are prepared and willing to coordinate wherever it is feasible and in particular with respect to the extensive discovery that is expected to occur after the preliminary injunction proceedings.

Accordingly, Regeneron has failed to demonstrate that transfer and centralization will serve the convenience of the parties and witnesses.

### 3. Centralization in the Northern District of West Virginia Will Hinder the Just and Efficient Conduct of the Actions

Regeneron's Motion also should be denied because centralization would not further the just and efficient conduct of this litigation. *See In re: Blue Spike*, 278 F. Supp. 3d at 1380.

*First*, even if Amgen is transferred to West Virginia, given the schedule the Court has entered there and the timing of transfer, the PI Defendants and Amgen will continue on separate schedules at least through the PI phase. Specifically, after denying Regeneron's motion to expedite consideration of the present Motion, the Panel set a hearing date for March 28, 2024. *See In re: Aflibercept Pat. Lit.*, MDL No. 3103, ECF No. 4 (J.P.M.L. 2024). Thus, even assuming that the Panel promptly reaches a decision, it would not come until, at best, after the PI Defendants have filed oppositions to Regeneron's PI motions. As set out below, this would mean Amgen would not have participated in substantial document production, briefing on the PI, or depositions of the Regeneron declarants:

| Event | Deadline |
|---|---|
| Regeneron makes initial production of documents | January 10, 2024 |
| Regeneron identifies patents for motion for preliminary injunction; Defendants deliver targeted requests for production | January 11, 2024 |
| Defendant produces documents responsive to Regeneron's requests | January 26, 2024 |
| Regeneron completes production of documents related to preliminary injunction | 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 | February 22, 2024 |
| Depositions of any Regeneron declarants complete | March 13, 2024 |

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| Defendants to file opposition(s) to motion(s) for preliminary injunction | March 21, 2024 |
| Deposition of Defendant's 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 |
| In-person status conference with lead counsel ahead of May 18, 2024 expiration of regulatory exclusivity | May 13, 2024 |

*See* Reg. Br., Ex. 7 at 3-4. Trying to add Amgen into the above schedule at this late stage would be extremely disruptive and likely to delay resolution of the PI proceedings. Accordingly, it is highly likely that Amgen's PI proceedings will move on a completely separate schedule, whether in the Central District of California or West Virginia.

*Second*, the advanced stage of the Mylan litigation minimizes any alleged efficiencies. "The presence of procedural disparities among constituent cases is another factor that can weigh against centralization." *In re: Select*, 883 F. Supp. 2d at 1354 (denying motion to transfer despite "all actions alleg[ing] that defendants infringe the [same] patent"). As Regeneron notes, the Mylan case began in August 2022. Reg. Br. at 2. The Court issued a claim construction decision in April 2023, and it was not until November 2023 that Regeneron commenced the next litigation. *Id.* The Court in the Mylan case issued a decision in December 2023, and Regeneron sued Amgen in January 2024. *Id.* at 2-3.

Centralization is "unlikely to produce significant efficiencies" where "some of the actions have been commenced only within the past several months" but "others have been pending far longer." *In re: Kohl's*, 220 F. Supp. 3d at 1364; *see also In re: Droplets, Inc., Pat. Litig.*, 908 F. Supp. 2d 1377, 1378 (J.P.M.L. 2012) (denying motion to transfer where "not all actions are in their 'infancy'" where one action, "for example, has been pending" for at least a year); *In re: PilePro Antitrust & Pat. Litig.*, 140 F. Supp. 3d 1350, 1351 (J.P.M.L. 2015) (denying motion to

transfer actions "in vastly different procedural postures"). That is the case here, where the Mylan case was initiated ***fifteen months*** before any of the actions pending in West Virginia were even filed, and the ***decision*** in the Mylan case predates Regeneron's complaint against Amgen.

Moreover, as addressed above, any alleged efficiencies from proceeding in West Virginia are limited to the patents that have been litigated there—which, because two of the three patents asserted at trial were invalidated, amounts to a single patent. The Court's written decision on that patent is available to judges in other forums.

*Third*, informal coordination is preferable to transfer in light of the minimal number of pending actions. "[W]here only a minimal number of actions are involved, the moving party generally bears a heavier burden of demonstrating the need for centralization." *In re: Transocean Ltd. Sec. Litig. (No. II)*, 753 F. Supp. 2d 1373, 1374 (J.P.M.L. 2010). For purposes of a motion to transfer, the Panel views litigations before the same judge or with coordinated pretrial proceedings as effectively a single proceeding. *See In re: JumpSport*, 338 F. Supp. 3d at 1357 (finding that, where four actions had been consolidated in one district and two in another, "there effectively are only two actions pending here in only two districts"); *see also In re: Zeroclick, LLC*, 437 F. Supp. 3d 1362 (J.P.M.L. 2020) (treating multiple actions before same judge as essentially one proceeding); *see also In re Sumatriptan Succinate Pat. Litig.*, 381 F. Supp. 2d 1378, 1378 (J.P.M.L. 2005) (same); *In re: Samsung Galaxy Smartphone Mktg. & Sales Pracs. Litig.*, 273 F. Supp. 3d 1371, 1373 (J.P.ML. 2017) (same); *In re: Quest Integrity USA, LLC, ('874) Pat. Litig.*, 148 F. Supp. 3d 1356, 1357 (J.P.M.L. 2015) (same).

Here, if Regeneron is correct that West Virginia has personal jurisdiction over the PI Defendants, five of the six actions will remain before Judge Kleeh, with all four pending PI

proceedings coordinated already and the other having completed trial.[3] Thus, this litigation would effectively involve two actions pending in two districts: (1) the already-tried Mylan action and the four pending actions in the Northern District of West Virginia, and (2) the Amgen action in the Central District of California. "With so few involved defendants and only a limited number of common claims and patents in dispute, . . . informal cooperation among the parties and coordination among the involved judges is a feasible alternative to transfer." *In re: Oplus*, 899 F. Supp. 2d at 1373; *see also In re: Constellation*, 38 F. Supp. 3d at 1393 (denying transfer and finding "informal coordination among the two involved courts and cooperation by the parties seems both practicable and preferable to centralization").

Indeed, Regeneron's "request in [the Amgen] case [for] preliminary injunction proceedings on the same schedule as . . . . West Virginia" acknowledges as much. Reg. Br. at 4. While Regeneron's request was denied, this type of informal coordination remains as available to the parties as it would be in consolidated proceedings, minimizing any need for centralization.

Accordingly, Regeneron has failed to demonstrate that transfer and centralization will further the just and efficient conduct of the actions.

## VI. CONCLUSION

For the foregoing reasons, the PI Defendants respectfully request that the Panel deny Regeneron's Motion to Transfer the California Action to West Virginia.

[3] As previously explained, a determination by the Court that it lacks personal jurisdiction would vitiate any argument that West Virginia is convenient, and by failing to address this very real possibility, Regeneron has failed to meet its burden. *Supra* pp. 15, 7-8.

Respectfully submitted,

Dated: February 2, 2024

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# EXHIBIT 1

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

| | |
|---|---|
| REGENERON PHARMACEUTICALS, INC.,<br>Plaintiff,<br>v.<br>SAMSUNG BIOEPIS CO., LTD.,<br>Defendant. | Civil Action No. 1:23-cv-106-TSK |

**DEFENDANT SAMSUNG BIOEPIS CO., LTD.'S**
**MOTION TO DISMISS PURSUANT TO FED. R. CIV. P. 12(b)(2)**

Defendant Samsung Bioepis Co., Ltd. hereby moves the Court for an order to dismiss Plaintiff Regeneron Pharmaceuticals, Inc.'s Complaint for lack of personal jurisdiction pursuant to Rule 12(b)(2) of the Federal Rules of Civil Procedure.

The specific grounds for this motion are contained in the Memorandum filed herewith and any other materials which may in the future be filed in support of this motion.

Dated: January 4, 2024

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*Attorneys for Defendant Samsung Bioepis Co., Ltd. appearing for the limited purpose of contesting jurisdiction*

**CERTIFICATE OF SERVICE**

I hereby certify that, on January 4, 2024, I electronically filed the foregoing document with the Clerk of the Court by using the Court's CM/ECF, which will send notification of such filing to all registered participants. In addition, I certify that I caused copies of the foregoing document to be served on January 4, 2024, by email upon all of the following counsel, as well as by U.S. Mail on David R. Pogue at the address indicated below:

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# EXHIBIT 2

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***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,<br><br>Plaintiff,<br><br>v.<br><br>AMGEN INC., a Delaware corporation,<br><br>Defendant. | Case No. 2:24-cv-00264-JWH-Ex<br>Hon. John W. Holcomb<br><br>FILED CONDITIONALLY UNDER SEAL<br><br>**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

**WILLIAMS & CONNOLLY LLP**
David I. Berl, State Bar No. 211761
Ellen E. Oberwetter (*pro hac vice* forthcoming)
Thomas S. Fletcher, State Bar No. 262693
Andrew V. Trask (*pro hac vice* forthcoming)
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)
Adam Pan, State Bar No. 330253
Rebecca A. Carter (*pro hac vice* forthcoming)
Haylee N. Bernal Anderson (*pro hac vice* forthcoming)
Renee M. Griffin (*pro hac vice* forthcoming)
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**KELLOGG, HANSEN, TODD, FIGEL & FREDERICK, P.L.L.C.**
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**WEIL GOTSHAL & MANGES LLP**
Elizabeth S. Weiswasser (*pro hac vice* forthcoming)
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)
Kathryn Leicht (*pro hac vice* forthcoming)
Rocco Recce (*pro hac vice* forthcoming)
Zhen Lin (*pro hac vice* forthcoming)
Kellie Van Beck (*pro hac vice* forthcoming)
Christopher M. Pepe (*pro hac vice* forthcoming)
Priyata Y. Patel (*pro hac vice* forthcoming)
Matthew Sieger (*pro hac vice* forthcoming)

*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

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# EXHIBIT 3

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
CIVIL MINUTES—
GENERAL

| Case No. | 2:24-cv-00264-JWH-E | Date | January 23, 2024 |
|---|---|---|---|
| Title | *Regeneron Pharmaceuticals, Inc. v. Amgen, Inc.* | | |

| Present: The Honorable | JOHN W. HOLCOMB, UNITED STATES DISTRICT JUDGE |
|---|---|

| Clarissa Lara | Not Reported |
|---|---|
| Deputy Clerk | Court Reporter |
| Attorney(s) Present for Plaintiff(s): None Present | Attorney(s) Present for Defendant(s): None Present |

**Proceedings: ORDER GRANTING IN PART AND DENYING IN PART PLAINTIFF'S *EX PARTE* APPLICATION [ECF No. 38]**

Before the Court is the *ex parte* application of Plaintiff Regeneron Pharmaceuticals, Inc. for an order setting a schedule for preliminary injunction proceedings.[1] The Court finds this matter appropriate for resolution without a hearing. *See* Fed. R. Civ. P. 78; L.R. 7-15. After considering the papers filed in support and in opposition,[2] the Court orders that the Application is **GRANTED in part** and **DENIED in part**, for the reasons set forth herein.

As an initial matter, the Court addresses the timing of Regeneron's Application by reminding the parties of the Court's Standing Order:

[1] Pl.'s *Ex Parte* App. for Scheduling Order Setting Schedule for Preliminary Injunction Proceedings or, in the alternative, an Emergency Status Conference (the "Application") [ECF No. 38].

[2] The Court considered the documents of record in this action, including the following papers: (1) Application (including its attachments); and (2) Def.'s Opp'n to the Application (the "Opposition") [ECF No. 39].

> The other parties' opposition . . . to an *ex parte* application is due 24 hours—***not*** the next ***court day***—after the other parties' receipt of the *ex parte* application. ***In view of that 24-hour deadline for opposition papers, in the absence of a true emergency, the Court takes a dim view of applicants who file their* ex parte *applications on Fridays or on the day before a court holiday.***[3]

"The opportunities for legitimate *ex parte* applications are extremely limited." *Lum v. Mercedes-Benz USA, LLC*, 2012 WL 13012454, at *4 (C.D. Cal. Jan. 5, 2012) (citation omitted). To justify *ex parte* relief, the moving party must make two showings: (1) "the evidence must show that the moving party's cause will be irreparably prejudiced if the underlying motion is heard according to regular noticed motion procedures"; and (2) "it must be established that the moving party is without fault in creating the crisis that requires *ex parte* relief, or that the crisis occurred as a result of excusable neglect." *Mission Power Engineering Co. v. Continental Cas. Co.*, 883 F. Supp. 488, 492 (C.D. Cal. 1995).

Regeneron argues that *ex parte* relief is warranted because the Court should "urgently" enter a scheduling order to keep this action on track with four other cases pending in the United States District Court for the Northern District of West Virginia against drug manufacturers seeking to commercialize biosimilar versions of Eyelea.[4]

A preliminary injunction schedule will indeed promote judicial economy. But Regeneron has not made a sufficient showing regarding why this Court should adopt the same schedule set in the West Virginia cases. In view of the fact that this case was filed after the Western Virginia cases, the Court concludes that it is appropriate for this case to trail the Western Virginia cases.

---

[3] Standing Order [ECF No. 48] 13:7-12 (emphasis in original). The Court hastens to note that its Standing Order was entered after Regeneron filed its Application. Nevertheless, Defendant Amgen, Inc. complied with the Court's requirement. *See* Opposition 1:7-10 ("Amgen apologizes for burdening the Court with this filing on a Saturday evening. Amgen understands that a response to an *ex parte* application is typically due within 24 hours, so it responds today to ensure compliance with the Court's procedures.").

[4] *See generally* Application.

The Court appreciates Amgen's willingness "to discuss a reasonable schedule,"[5] and, therefore, the Court **SETS** a Scheduling Conference on April 5, 2024, in this case to discuss preliminary injunction proceeding briefing.

The parties agree that the Application discusses information that Amgen has designated as confidential under 42 U.S.C. § 262(*l*)(1).[6] Accordingly, the Court **ORDERS** that the Application for Leave to File Under Seal [ECF No. 37] and the Application (including its attachments) are **SEALED**.

Therefore, for the foregoing reasons, the Court **ORDERS** as follows:

1. The Application is **GRANTED in part**, to the extent it requests setting a preliminary injunction proceeding schedule, and the Application is **DENIED in part**, to the extent it requests the specific schedule proposed by Regeneron.

2. The Court **SETS** a Scheduling Conference on April 5, 2024, at 11:00 a.m. in Courtroom 9D of the Ronald Reagan Federal Building and U.S. Courthouse, 411 W. 4th Street, Santa Ana, California, to discuss the preliminary injunction proceedings.

3. The Application for Leave to File Under Seal and the Application (including its attachments) are **SEALED**.

**IT IS SO ORDERED.**

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[5] Opposition 2:25.

[6] App. for Leave to File Under Seal Unredacted *Ex Parte* App (the "Application for Leave to File Under Seal") [ECF No. 37] 2:9-12; Opposition 2:10-12.

# EXHIBIT 4

| No. | Patent | Subject Matter | Family | Mylan Complaint | Celltrion Complaint | Amgen Complaint | Formycon Complaint | SB Nov. 21 Complaint | SB Dec. 27 Complaint | PI Patents |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 7,070,959 | Aflibercept composition of matter (expired) | Papadopoulos | Yes | Yes | No | Yes | Yes | No | No |
| 2 | 9,222,106 | Expression/EESYR | Chen | Yes | Yes | Yes | Yes | Yes | Yes | No |
| 3 | 9,254,338 | Method of treatment | Yancopoulos | Yes | Yes | Yes | Yes | Yes | Yes | No |
| 4 | 9,315,281 | Container fill | Dissanayake | No | Yes | Yes | No | Yes | Yes | No |
| 5 | 9,562,238 | Expression/EESYR | Chen | No | No | No | Yes | Yes | Yes | No |
| 6 | 9,669,069 | Method of treatment | Yancopoulos | Yes | No | No | No | No | No | No |
| 7 | 9,816,110 | Expression/EESYR | Shen/Chen | Yes | Yes | Yes | Yes | Yes | Yes | No |
| 8 | 10,130,681 | Method of treatment | Yancopoulos | Yes | Yes | Yes | Yes | Yes | Yes | No |
| 9 | 10,406,226 | Method of manufacturing/ expression + stability | Dix | Yes | No | No | No | No | No | No |
| 10 | 10,415,055 | Expression/EESYR | Chen | Yes | Yes | Yes | Yes | Yes | Yes | No |
| 11 | 10,464,992 | Formulation | Furfine | Yes | Yes | Yes | Yes | Yes | Yes | No |
| 12 | 10,669,594 | Method of detecting biological contaminant | Monpoeho | Yes | Yes | Yes | Yes | Yes | Yes | No |
| 13 | 10,828,345 | Method of treatment (12-week tertiary doses) | Yancopoulos | No | Yes | Yes | Yes | Yes | Yes | No |
| 14 | 10,857,205 | Method of treatment | Yancopoulos | Yes | No | No | No | No | No | No |
| 15 | 10,888,601* | Method of treatment | Yancopoulos | Yes | Yes | Yes | Yes | Yes | Yes | No |
| 16 | 10,905,786 | Sterilization | Shodder | No | No | Yes | No | Yes | Yes | No |
| 17 | 10,918,754 | Sterilization | Shodder | No | No | Yes | No | Yes | Yes | No |
| 18 | 10,927,342 | Cell culture | Johnson | Yes | Yes | No | Yes | Yes | Yes | No |
| 19 | 10,973,879 | Method of treatment | Vitti | Yes | No | No | No | No | No | No |
| 20 | 11,053,280 | Oxo-aflibercept | Tustian | Yes | Yes | No | Yes | Yes | Yes | Yes |
| 21 | 11,066,458 | Formulation | Furfine | Yes | Yes | Yes | Yes | Yes | Yes | No |
| 22 | 11,084,865* | Formulation | Furfine | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| 23 | 11,104,715 | Cell culture | Lawrence | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| 24 | 11,174,283 | Oxo-aflibercept | Tustian | Yes | Yes | No | Yes | Yes | Yes | No |
| 25 | 11,186,625 | Oxo-aflibercept | Wang | Yes | No | No | No | No | No | No |
| 26 | 11,253,572* | Method of treatment | Yancopoulos | Yes | Yes | Yes | Yes | Yes | Yes | No |
| 27 | 11,299,532 | Oxo-aflibercept | Tustian | Yes | Yes | No | Yes | Yes | Yes | Yes |
| 28 | 11,306,135 | Oxo-aflibercept | Wang | Yes | Yes | Yes | Yes | Yes | Yes | No |
| 29 | 11,312,936 | Cell culture | Lawrence | No | Yes | No | Yes | Yes | Yes | No |
| 30 | 11,332,771 | Cell culture | Oshodi | Yes | Yes | No | Yes | Yes | Yes | No |
| 31 | 11,472,861 | Cell culture | Lawrence | No | Yes | Yes | Yes | Yes | Yes | Yes |
| 32 | 11,485,770 | Oxo-aflibercept | Wang | No | Yes | No | Yes | Yes | Yes | No |
| 33 | 11,535,663 | Cell culture | Lawrence | No | Yes | Yes | Yes | Yes | Yes | Yes |
| 34 | 11,542,317 | Oxo-aflibercept | Wang | No | Yes | Yes | Yes | Yes | Yes | No |
| 35 | 11,548,932 | Oxo-aflibercept | Wang | No | Yes | Yes | Yes | Yes | Yes | No |
| 36 | 11,555,176 | Cell culture | Xue | No | Yes | Yes | Yes | Yes | Yes | No |

| No. | Patent | Subject Matter | Family | Mylan Complaint | Celltrion Complaint | Amgen Complaint | Formycon Complaint | SB Nov. 21 Complaint | SB Dec. 27 Complaint | PI Patents |
|---|---|---|---|---|---|---|---|---|---|---|
| 37 | 11,559,564 | Method of treatment | Yancopoulos | No | Yes | Yes | Yes | Yes | Yes | No |
| 38 | USD 858,754 | Design patent | Grygus | No | No | No | No | No | Yes | No |
| 39 | USD 906,102 | Design patent | Cook | No | No | No | No | No | Yes | No |
| 40 | USD 934,069 | Design patent | Cook | No | No | No | No | No | Yes | No |
| 41 | USD 961,376 | Design patent | Cook | No | No | No | No | No | Yes | No |
| 42 | USD 961,377 | Design patent | Cook | No | No | No | No | No | Yes | No |
| 43 | 11,577,025 | PFS/overfill | Dix | No | No | No | No | No | Yes | No |
| 44 | 11,505,593 | PFS/oxo-aflibercept | Wang | No | Yes | Yes | No | No | Yes | No |
| 45 | 11,433,186 | PFS | Ulla | No | No | No | No | No | Yes | No |
| 46 | 11,439,758 | PFS | Langley | No | No | No | No | No | Yes | No |
| 47 | 11,459,374 | PFS/oxo-aflibercept | Tustian | No | Yes | Yes | No | No | Yes | Yes |
| 48 | 11,478,588 | PFS/needle shield | Grygus | No | No | No | No | No | Yes | No |
| 49 | 11,160,918 | Packaging/sterilization | Cook | No | No | Yes | No | No | Yes | No |
| 50 | 10,182,969 | Injection device | Arnott | No | No | No | No | No | Yes | No |
| 51 | 11,103,552 | High concentration aflibercept formulations | Graham | No | No | No | No | No | Yes | No |
| 52 | 11,707,506 | Method of treatment | Yancopoulos | No | Yes | Yes | Yes | Yes | Yes | No |
| 53 | 11,732,024 | Formulation | Furfine | No | Yes | No | Yes | Yes | Yes | No |
| 54 | 11,753,459 | Oxo-aflibercept | Wang | No | Yes | Yes | Yes | Yes | Yes | No |
| 55 | 11,769,597 | Method of treatment (SNP) | Perlee | No | Yes | Yes | Yes | Yes | Yes | No |
| 56 | 11,788,102 | Expression/EESYR | Shen | No | Yes | Yes | Yes | Yes | Yes | No |
| 57 | 11,793,926 | PFS packaging | Cook | No | Yes | Yes | No | No | Yes | Yes |
| 58 | 11,525,833 | Method of identifying peptide or protein via chromatogrpahy | Yan | No | Yes | No | No | No | No | No |
| 59 | 7,771,997 | Expression/EESYR | Chen | No | No | No | Yes | No | No | No |
| 60 | 9,932,605 | Expression/EESYR | Chen | No | No | No | Yes | No | No | No |
| 61 | 11,268,109 | CHO integration sites | Shen | No | No | No | Yes | No | No | No |
| 62 | 11,549,154 | PAC plasmid | Monpoeho | No | No | No | Yes | No | No | No |
| 63 | 11,680,930 | Chromatography data analysis | Mao | No | No | Yes | Yes | No | No | No |

* U.S. Patent Nos. 10,888,601; 11,084,865; and 11,253,572 were addressed in the Mylan decision. *See Regeneron Pharms., Inc. v. Mylan Pharms. Inc., et al.*, C.A. No. 22-061-TSK-JPM, ECF No. 692 (N.D.W. Va. Jan. 31, 2024). The asserted claims of U.S. Patent Nos. 10,888,601 and 11,53,572 were found invalid as obvious. *Id.*

**BEFORE THE UNITED STATES JUDICIAL PANEL**
**ON MULTIDISTRICT LITIGATION**

| In re Aflibercept Patent Litigation | MDL No. 3103 |
|---|---|

**PROOF OF SERVICE**

In compliance with Rule 4.1(a) of the Rules of Procedure for the United States Judicial Panel on Multidistrict Litigation, I hereby certify that copies of the foregoing Opposition to Plaintiffs' Motion to Transfer was served on all parties in the following cases electronically via CM/ECF, or as indicated below, on this 2nd day of February 2024.

**Served via Federal Express**
Clerk of Court
Northern District of West Virginia
United States Courthouse
500 West Pike Street, Room 301
Clarksburg, WV 26301

**Served via Federal Express**
Clerk of Court
Central District of California
Roybal Courthouse
225 East Temple Street, Suite 180
Los Angeles, CA 90012-4701

***Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*,**
**N.D.W. Va., C.A. No. 1:22-cv-00061-TSK-JPM**

***Regeneron Pharmaceuticals, Inc. v. Celltrion, Inc.*,**
**N.D.W. Va., C.A. No. 1:23-cv-00089-TSK**

***Regeneron Pharmaceuticals, Inc. v. Samsung Bioepis Co., Ltd.*,**
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***Regeneron Pharmaceuticals, Inc. v. Amgen Inc.,***
**C.D. Cal., C.A. No. 2:24-cv-00264-JWH**

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