BEFORE THE UNITED STATES JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

In re: Aflibercept Patent Litigation	MDL No. 3103

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

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,

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