BEFORE THE UNITED STATES JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

In re Aflibercept Patent Litigation	MDL No. 3103

AMGEN'S OPPOSITION TO PLAINTIFF'S MOTION FOR TRANSFER TO THE NORTHERN DISTRICT OF WEST VIRGINIA PURSUANT TO 28 U.S.C. § 1407

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Pursuant to Panel Rule 6.1(c), Defendant Amgen Inc. ("Amgen") respectfully submits this opposition to Regeneron's Motion for Transfer of Action to the Northern District of West Virginia Pursuant to 28 U.S.C. § 1407 for Coordinated Pretrial Proceedings (the "Motion").

I. INTRODUCTION

Regeneron's request that this Panel centralize an action against Amgen in the Central District of California with five other actions in the Northern District of West Virginia should be rejected because the common issues are few and the differences are many. When examined carefully, the specific circumstances of the actions show that Regeneron cannot demonstrate that there are enough efficiencies to be gained through centralization, which is fatal when compared to the risk of prejudice to Amgen and the other defendants.

Glossing over the facts, Regeneron overreaches in arguing that this Panel's Hatch-Waxman Act precedent controls whether this action, which arises under the Biologics Price and Competition Act ("BPCIA"), should be centralized. There are key differences between the two statutory schemes, including the subject matter they govern. These differences produce important legal and factual distinctions relevant to whether centralization is appropriate. The BPCIA governs "biosimilars," which are biologic medicines—large, complex molecules produced using living organisms permitting only similarity, not identity, with the reference product—and include medicines such as antibodies and vaccines. The Hatch-Waxman Act governs "generics," which are less complex chemically synthesized drugs (small molecules) that are, as a result, structurally identical to a reference product. Although biosimilars are highly similar to an approved reference product, biosimilars, unlike generics, generally exhibit high molecular complexity and sensitivity to changes in manufacturing processes.

In recognition of these differences and the importance of processes used to manufacture biologics, the BPCIA requires a biosimilar applicant to provide manufacturing information to the

reference product sponsor and provides a framework for litigating patent infringement claims relating to manufacturing processes. In contrast, the Hatch-Waxman Act limits the type of patents that reference sponsors can list in an FDA database known as the "Orange Book"—a listing that forms the basis for the subsequent patent litigation. Manufacturing process patents are expressly prohibited from being listed in the Orange Book. This means Hatch-Waxman cases usually involve a much smaller set of overlapping, statutorily limited patents, and infringement is often conceded by generic manufacturers. BPCIA litigation, on the other hand, generally involves litigation of a much larger individualized and fact-specific list of patents for each biosimilar applicant.

That is the case here, as Regeneron has asserted 32 patents against Amgen but only 13 that are common among all defendants. Importantly, Regeneron fails to mention that the common patents are primarily directed either to pharmaceutical formulations of aflibercept or protein manufacturing processes. Each defendant, including Amgen, independently developed its own aflibercept formulation, and its own processes for producing aflibercept. Thus, they will differ from each other in material respects. Regeneron ignores these differences and proclaims that the actions involve "nearly identical" products. But these differences will be at the heart of the disputes and produce unique infringement, validity, and claim construction issues for each defendant. Moreover, the number of common patents pales when compared to the large number of non-overlapping patents that Regeneron has asserted. Thus, "the potential for [this litigation, if centralized,] to become mired in the unique factual and legal issues raised in each action . . . is significant." *In re Constellation Techs. LLC Pat. Litig.*, 38 F. Supp. 3d 1392, 1393 (J.P.M.L. 2014).

Centralization is also directly at odds with the "just and efficient" conduct of these actions. Despite claiming that Amgen will "not be prejudiced in any way" from having its case transferred to West Virginia, Regeneron's opening submission declines to mention that three of the other

defendants have sought to dismiss or transfer their actions from West Virginia for improper personal jurisdiction. If these motions are granted, the net effect of centralization would be unjust: Amgen would be forced to defend suit in a jurisdiction where it could not have been properly sued, with only one other party (Mylan) that has already had a trial decision on the merits.

Furthermore, Amgen has not waived its *Lexecon* right to have its case transferred back to California after pretrial proceedings. This further diminishes the likelihood that any meaningful efficiencies would be achieved through centralization.

Regeneron's motion is largely predicated on an argument that centralization is necessary to achieve efficiencies associated with preliminary injunction proceedings. In fact, far from promoting efficiency, the procedural status of the actions shows that centralization will unnecessarily complicate case management of the West Virginia actions. The West Virginia Court has already set a schedule for preliminary injunction proceedings against three other defendants. That schedule is expedited, because each of those defendants has already provided its 180-day notice of commercial marketing. The schedule is tailored to allow the parties sufficient time for discovery and briefing in advance of a hearing set for May 2, 2024, and presumably a decision by the court before expiration of Regeneron's regulatory exclusivity on May 18, 2024. Dkt. 1-7 at 3. In sharp contrast to this compressed schedule, the parties in the Amgen action are not even set to discuss a preliminary injunction briefing schedule with the court until April 5, 2024. Ex. 1 at 3. Centralizing and forcing Amgen to litigate on the same schedule as the other litigants in West Virginia, as Regeneron demands, is unrealistic, unnecessary, disruptive, and unfair to Amgen.

Finally, centralization in West Virginia will not serve the convenience of the parties or witnesses. There is nothing convenient about West Virginia for Amgen or Regeneron. Most of Amgen's documents and witnesses are in California, not West Virginia. Most of Regeneron's

documents and witnesses are likely in New York, not West Virginia. Amgen will not be on the same schedule for injunction proceedings. Informal coordination amongst the parties would be a more efficient and preferable alternative. Should the need arise, given the limited number of cases and overlapping counsel, the parties and courts can rely on informal coordination to avoid unnecessarily burdening witnesses or counsel with appearing in duplicative pre-trial proceedings.

There will be significant differences between the Amgen action and the other actions. Centralization is not only unnecessary, as Regeneron has failed to meet its burden of showing sufficient efficiencies, but also threatens to disrupt and unnecessarily complicate the ongoing actions in West Virginia and prejudice Amgen. This Panel should deny Regeneron's motion.

II. ARGUMENT

Transfer may be ordered only when (1) the actions sought to be centralized and transferred share common issues of fact, (2) transfer would promote the just and efficient conduct of the actions, and (3) transfer would serve the convenience of the parties and witnesses. 28 U.S.C. § 1407; *In re Eli Lilly & Co. Oraflex Prods. Liab. Litig.*, 578 F. Supp. 422, 423 (J.P.M.L. 1984) (denying centralization because the Panel was "not persuaded that these common questions of fact will, in the future course of this litigation, predominate over individual questions of fact present in each action"). Because "only a minimal number of actions are involved," Regeneron bears "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).

Amgen's case is about a unique biosimilar product, with its own formulation, made using confidential processes developed independently by Amgen scientists and engineers. Any "efficiencies" to be gained are unlikely to be achieved in view of the technology and procedural differences between the cases, and because Amgen has not waived its *Lexecon* rights. By contrast, the risk and prejudice to Amgen and the other defendants is significant. The relatively small

number of asserted patents that are common to all defendants means that a centralized proceeding would be a complicated conglomerate of issues and disputes. And because all the other defendants in the pre-trial stage have moved to dismiss or transfer their actions from West Virginia, there is a distinct possibility that Amgen would be required to conduct pre-trial proceedings in a court where it could not have been sued and where there are no other defendants in the pre-trial stage.

A. Differences predominate the primary issues to be tried among the cases.

Regeneron begins by arguing this Panel's prior decisions in Hatch-Waxman cases should control whether centralization is appropriate for these BPCIA matters. Dkt. 1-1 at 1-2, 5-6. The Panel, however, has never addressed centralization of BPCIA cases. As discussed above, BCPIA cases arise under a materially different statutory scheme than the Hatch-Waxman cases cited by Regeneron.[1] Contrary to the central theme of Regeneron's brief, "[c]entralization 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 Retrieval, LLC, ('617) Pat. Litig.*, 883 F. Supp. 2d 1353, 1354 (J.P.M.L. 2012) (citation omitted); *In re Uponor, Inc., F1960 Plumbing Fittings Prod. Liab. Litig.*, 895 F. Supp. 2d 1346, 1348 (J.P.M.L. 2012) ("Centralization is not a cure-all for every group of complicated cases.").

When viewed in their totality, the specific facts and circumstances here demonstrate that any efficiencies to be gained through centralization are speculative, and there is significant risk of both unnecessary complication and disruption of the matters against the other defendants, and prejudice to Amgen. Material differences predominate the underlying liability issues among the cases. Regeneron seeks to brush aside these differences by drawing attention to the number of commonly asserted patents in all actions (allegedly thirteen). But the mere presence of common

[1] For example, the BPCIA, unlike the Hatch Waxman Act, contemplates litigation of process patents, (*infra* Section II.B.4), and early preliminary injunction proceedings, (*infra* Section II.C).

patents alone is not sufficient to warrant consolidation under § 1407. *See In re JumpSport*, 338 F. Supp. 3d at 1357 (declining to centralize cases although each involved infringement allegations on the same two patents). And when compared with the large number of patents that do not overlap among all defendants (at least 45), it becomes clear that centralization risks overcomplicating these matters while achieving little in the way of efficiency. Indeed, all the other defendants in the pre-trial stage potentially impacted by Regeneron's motion oppose centralization and recognize the disruptive impact of Regeneron's request, unlike the vast majority of Hatch Waxman cases cited by Regeneron where most parties did not even oppose centralization.

1. There are factual differences because Amgen's biosimilar product is unique and made using proprietary processes.

In attempting to paint Amgen and other defendants with the same broad brush, Regeneron does not even try to address the specific nature of the common patents. Here is why. Of the thirteen common patents, four come from a single patent family with claims that have already been held invalid by either the U.S. Patent & Trademark Office's ("USPTO") Patent Trial and Appeal Board ("PTAB") or the West Virginia court.[2] Regeneron also disclaimed a fifth patent that had been challenged before the PTAB, stating that "the patent is no longer needed." *See* Ex. 6. These five patents are thus irrelevant to the centralization question.

The eight remaining patents concern either specific formulations of aflibercept, or processes related to protein manufacturing. Regeneron fails to allege, let alone establish, how common factual issues will predominate a case involving these patents. Indeed, Amgen independently developed its own aflibercept formulation and process for making aflibercept. In

[2] Ex. 2 (USPTO holding all challenged claims of U.S. Patent No. 9,254,338 unpatentable); Ex. 3 (USPTO holding claims of U.S. Patent No. 10,130,681 unpatentable); Ex. 4 (USPTO holding claims of U.S. Patent No. 10,888,601 unpatentable); Ex. 5 (N.D.W. Va. Court holding claims of U.S. Patent Nos. 10,888,601 and 11,253,572 invalid as obvious).

doing so, Amgen applied its decades of experience and innovation in formulating and manufacturing of biologic medicines to the development of its biosimilar.

The action against Amgen will thus involve unique issues relating to non-infringement, such as: (a) whether Amgen's unique biosimilar product has certain components required by Regeneron's formulation patents; (b) whether Amgen's confidential manufacturing processes use certain steps required by Regeneron's process patents; and (c) whether the delivery device containing Amgen's biosimilar product has certain features. Although Regeneron has failed to present information regarding the specific issues to be litigated in the other actions, each of the other defendants also has likely developed its own formulations and processes that raise different infringement questions. That Regeneron has asserted over two dozen patents against other defendants, that are not asserted against Amgen, strongly suggests as much.[3] This is yet another difference from the Hatch-Waxman cases cited by Regeneron, where typically only a small number of patents are at issue and infringement is often conceded, leaving a common issue of validity to be litigated by the parties. This counsels against centralization. *E.g.*, *In re Uniloc USA, Inc., & Uniloc Luxembourg, S.A., HPE Portfolio Pat. Litig.*, 304 F. Supp. 3d 1356, 1357 (J.P.M.L. 2018) (denying centralization where "the products at issue also vary significantly"); *In re Blue Spike, LLC, Pat. Litig.*, 278 F. Supp. 3d 1379, 1380 (J.P.M.L. 2017) (denying centralization where "Defendants' accused products vary considerably").

[3] Patents asserted against other biosimilars but not Amgen include: two formulation patents, including U.S. Patent Nos. 11,732,024 and 11,103,552; fourteen process patents, including: U.S. Patent Nos. 7,771,997; 9,562,238; 9,932,605; 10,927,342; 11,312,936; 11,549,154; 11,332,771; 11,268,109; 11,053,280; 11,174,283; 11,299,532; 11,186,625; 11,485,770; and 11,525,833; and ten device-related patents, including: U.S. Patent Nos. 10,182,969; 11,577,025; 11,478,588; 11,439,758; 11,433,186; D906,102; D934,069; D961,376; D961,377; and D858,754.

Furthermore, Amgen's action will involve additional defenses unique to Amgen's confidential manufacturing processes. Pursuant to 35 U.S.C. § 273, Amgen has advanced a defense against 12 Regeneron patents, including two of the common patents, based on Amgen's prior use of its manufacturing processes more than one year before Regeneron's patent applications were filed. *See, e.g.*, Ex. 7, Answer at ¶ 421; Ex. 7, Counterclaims at ¶¶ 112, 287, 332, 368, 405, 417, 453, 465, 501, 513, 546, and 579.[4] This defense involves discovery and evidence relating to Amgen's manufacturing process and is a personal defense specific to Amgen. *E.g.*, *In re Genetic Techs. Ltd. ('179) Pat. Litig.*, 883 F. Supp. 2d 1337, 1338 (J.P.M.L. 2012) (no centralization where "certain defendants have idiosyncratic potentially dispositive defenses that will implicate significant unique facts").

Finally, any potential efficiencies with respect to issues of patent invalidity are speculative. Because Regeneron has asserted so many patents against each defendant (no fewer than 24 against each defendant; 32 against Amgen), Regeneron will be required to narrow its case, including for trial, to a more limited number of patents. There are no assurances that Regeneron will seek only to adjudicate common patents or issues at trial; indeed, this would be unlikely given the varying infringement questions among defendants. There is thus no basis to conclude that centralization will meaningfully alleviate discovery burdens for the parties nor guarantee a streamlined resolution of the issues relating to claim construction, infringement and invalidity. *E.g., In re Alexsam, Inc. ('608 & '787) Pat. & Contract Litig.*, 437 F. Supp. 3d 1374, 1375 (J.P.M.L. 2020) (denying centralization where "the same patent claims are not at issue in all actions"); *In re Droplets, Inc.,*

[4] Regeneron fails to acknowledge this unique and fact-dependent defense in its opening submission, even though Amgen informed Regeneron about this defense in November 2023.

Pat. Litig., 908 F. Supp. 2d 1377, 1378 (J.P.M.L. 2012) (fact that "the claim terms in dispute are not identical from action to action" weighs against centralization).

2. There are unlikely to be common claim construction issues because Amgen has a different product and process.

Regeneron also exaggerates the risk of inconsistent claim construction rulings if the actions are not centralized. *First,* in the action against Mylan that has already proceeded through trial, the District Court Judge issued an order construing claim terms of only four patents—two of which he later found invalid, and thus, should not be at issue against Amgen. *See* Ex. 8 at 1; Ex. 5. As to the other two patents, Judge Kleeh addressed claim construction issues that are related to non-infringement defenses that Mylan sought to advance concerning its formulation and manufacturing process, and which are not applicable to Amgen. *See In re Droplets, Inc., Pat. Litig.*, 908 F. Supp. 2d at 1378 (fact that "the claim terms in dispute are not identical from action to action" weighs against centralization).

Second, the case against Amgen is likely to involve different claim construction issues from the other defendants for the reasons described above. These differences will "hinder [Amgen's and the other defendants'] ability to adopt common positions regarding the interpretation of common claims of the various patents, which thereby diminishes potential efficiencies created by centralization." *In re ArrivalStar S.A. Fleet Mgmt. Sys. Pat. Litig.*, 802 F. Supp. 2d 1378, 1379 (J.P.M.L. 2011) (denying centralization despite the actions involving "similar allegations of infringement or invalidity of one or more of sixteen patents in a common family of [] patents"). That different claim construction issues will likely arise weighs against centralization.

3. Centralization unnecessarily complicates the actions because there are many non-overlapping issues for each defendant.

In seeking to centralize these different actions, Regeneron asks this Panel to construct a truly massive litigation. By Amgen's calculations, the end result of centralization would be a single

case for pre-trial proceedings involving four different defendants, and 57 different patents with a total of 70 named inventors as potential fact witnesses.[5]

Because only a small portion of these patents overlap, the overwhelming majority of any centralized proceeding would involve issues unique to one or more of the defendants. Furthermore, the non-overlapping patents involve a wide variety of technologies, including those directed to methods of treatment, processes for making aflibercept, methods of making host cells for recombinant proteins, cell culture media, sterilization processes, drug delivery devices, packaging components, and packaging design. Regeneron fails to address how such a complicated proceeding could be managed in a streamlined and effective matter. Rather, reasoned decision-making dictates that it cannot. *E.g.*, *In re Uniloc USA, Inc.*, 304 F. Supp. 3d at 1357 (denying centralization of actions involving seven patents because "only two of the seven patents are related, which makes it unlikely that the cases will involve a significant number of common claim terms," "[t]he patents were invented by eighteen separate inventors," "the products at issue also vary significantly" and "all patents are not asserted against all defendants"); *In re Blue Spike, LLC, Pat. Litig.*, 278 F. Supp. 3d at 1380 (denying centralization where "the degree of overlap among the 34 asserted patents varies widely among the cases."); *In re Constellation Techs. LLC Pat. Litig.*, 38 F. Supp. 3d at 1393 (denying centralization where "only one patent . . . is at issue in all actions" and all twenty-nine patents raised in the actions "involve a wide range of technologies and do not descend from a common patent 'family' (*i.e.*, the patents have many different inventors)").

B. Centralization is at odds with the "just and efficient" conduct of the actions.

The "basic purpose underlying the enactment of 28 U.S.C. § 1407 was to secure, in multidistrict civil litigation as in all other civil litigation, the 'just, speedy and inexpensive

[5] Amgen assumes Mylan would not be involved in these pre-trial proceedings, because Mylan's case may be on a different schedule. Ex. 9.

determination of every action.'" *In re Nat'l Student Mktg. Litig.*, 368 F. Supp. 1311, 1316 (J.P.M.L. 1972) (quoting Fed. R. Civ. P. 1). Centralization would serve neither purpose here.

1. The defendants in four cases have moved to dismiss or transfer their actions from West Virginia.

Regeneron's opening submission fails to mention, let alone address, the fact that defendants Celltrion, Formycon, and Samsung have each moved to dismiss Regeneron's complaints based on lack of personal jurisdiction. Celltrion and Formycon further alternatively seek transfer to another jurisdiction under 28 U.S.C. § 1404. Briefing on those motions to dismiss will not be completed until February 26, 2024. *See* Dkt. 1-10 at 3-4.

There is thus a substantial possibility that nearly all the purported efficiencies argued by Regeneron would be eliminated. There is likewise a significant risk to Amgen that it would be transferred to a jurisdiction with only one other party (Mylan), which has already had a trial decision on the merits that the parties are preparing to appeal. Although there are still outstanding patents asserted against Mylan that remain to be litigated, that case will be on a different schedule relative to Amgen's case. *See* Ex. 9. Mylan has argued that any attempt to consolidate Mylan's actions with the other actions would be prejudicial and disruptive to Mylan. *See id.* at 6-8 ("[T]he Court should place the Biocon Defendants on track to reach a final trial with minimal and expedited discovery, without subjecting them to the ongoing procedural entanglements confronting the other aflibercept applicants.").[6] This would leave Amgen to litigate alone in a jurisdiction where it could not have been properly sued, an outcome that would be unjust.[7] The uncertain future of these West

[6] Biocon Biologics Ltd. ("Biocon") is a co-defendant in the Mylan litigation. Biocon and Mylan are collectively referred to in this brief as "Mylan."

[7] The reason there are other cases in West Virginia to begin with, is that the first defendant to be sued (Mylan) resides and had to be sued there according to venue and jurisdictional requirements.

Virginia actions and potential prejudice to Amgen further confirms that centralization is neither necessary nor appropriate.

2. Amgen has not waived its *Lexecon* rights.

Section 1407 "obligates the Panel to remand any pending case to its originating court when, at the latest, those pretrial proceedings end." *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 27 (1998). Amgen has not waived its *Lexecon* rights, so its case will be transferred back to the Central District of California for trial. The Honorable Judge Holcomb presently presides over the Amgen case. Judge Holcomb is a member of the Patent Program in the Central District of California, and has significant experience handling patent matters, including complex matters such as this one. Judge Holcomb will need to become familiar with the parties, patents, claim construction rulings, and facts at issue in advance of trial, whether or not the Amgen case is transferred for pre-trial purposes. *E.g.*, *In re Gerber Probiotic Prods. Mktg. & Sales Practices Litig.*, 899 F. Supp. 2d 1378, 1380 (J.P.M.L. 2012) (recognizing disadvantages of "multiple trials after the Panel remands actions to the [] transferor court[]" and need for "transferor courts to spend time to re-familiarize themselves with [] actions" upon remand).

3. There are limited efficiencies to be gained from the prior Mylan action.

Contrary to Regeneron's assertions, any efficiencies to be gained by centralization in West Virginia are limited. Although the court in West Virginia held a trial on three Regeneron patents, the court declared the claims at issue for two of those patents invalid. *See* Ex. 5. Because those and related patents have already been held invalid, they should not be counted to serve as a basis for efficiencies relating to any preliminary injunction or pre-trial proceedings against Amgen.

The Amgen action thus will involve at most one patent that was tried in the Mylan action: U.S. Patent No. 11,084,865 ("the '865 Patent"), which is directed to pharmaceutical formulations of aflibercept. Amgen's independently developed biosimilar product will involve non-

infringement issues that were not at issue in the Mylan case. *See supra* Section II.A.1. There is no basis to conclude that proceeding before the West Virginia court would be more efficient.

As to any other patents that Regeneron asserts against Amgen, Regeneron has not demonstrated that the West Virginia Court is in any better position to handle the underlying issues pertaining to those patents than the court in the Central District of California. Indeed, Judge Holcomb is particularly well equipped to handle the Amgen matter, given his technical background and participation in the Central District of California's Patent Program.

4. Management of a centralized case is complicated because the defendants are also competitors.

The defendants, including Amgen, are all direct competitors and each considers the details of its product and manufacturing processes and the research and development that created them to be highly confidential, and potentially trade secrets. If centralized, the defendants would require additional discovery protections, which would "complicate case management due to the need to protect trade secret and confidential information." *In re Proton–Pump Inhibitor Prods. Liab. Litig.*, 273 F. Supp. 3d 1360, 1362 (J.P.M.L. 2017); *In re Spray Polyurethane Foam Insulation Prods. Liab. Litig.*, 949 F. Supp. 2d 1364, 1364 (J.P.M.L. 2013) (denying centralization as "placing direct competitor manufacturer defendants into the same litigation would require protecting trade secret and confidential information from disclosure to all parties and complicate case management"). Mylan has raised this exact concern before the West Virginia court. Ex. 9 at 9 ("[N]on-infringement defenses across multiple patent families are likely to be disparate and unique to each defendant, not to mention highly confidential, which will further complicate any possible consolidation of the Biocon Defendants with those of the other, later-filed biosimilar applicants.").

Twenty of the 32 patents asserted against Amgen are related to confidential manufacturing processes. The inclusion of so many process patents implicating highly confidential information

is one of many distinctions between this BPCIA case and the Hatch-Waxman cases cited by Regeneron. Unlike the Hatch-Waxman Act, which precludes the listing of process patents in the Orange Book, the BPCIA requires a biosimilar applicant to provide to the reference product sponsor "such other information that describes the process or processes used to manufacture the biological product," which information is then used to prepare a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted against that specific biosimilar applicant. *Compare* 21 C.F.R. § 314.53(b)(1) *with* 42 U.S.C. §§ 262(l)(2)(A), (3)(A). Thus, this confidentiality issue is heightened in this BPCIA case as compared to the Hatch-Waxman cases cited by Regeneron.

The prior history of these cases illustrates the dangers and difficulties associated with confidentiality issues. In the action against Amgen, Regeneron improperly disclosed Amgen's confidential information on the public record. *See* Ex. 10 at 2. In the Mylan action, the defendant has alleged that Regeneron breached the protective order and has filed a motion seeking sanctions. Ex. 11. And despite being entered on December 27, a redacted post-trial decision in the Mylan action was not made publicly available until January 31 because the parties were unable to agree on what information is confidential. Centralization in West Virginia would greatly complicate efforts by the Court and the parties to manage the confidentiality of each defendant's information.

C. There are no efficiencies to be gained by transferring Amgen to West Virginia for preliminary injunction proceedings.

Regeneron is wrong again in arguing that centralization is necessary so that it can pursue preliminary injunctive relief against each defendant in a single consolidated proceeding, under the "identical schedule" set forth by the West Virginia court. Dkt. 1-1 at 5; *see id*. at 8-9. The West Virginia preliminary injunction proceedings are on a compressed and expedited schedule to permit a hearing on the merits on May 2, 2024. Dkt. 1-7 at 2. That schedule requires document production

to be completed today (February 2), with Regeneron to file its motion-in-chief on February 22, followed by defendants' oppositions on March 21, and Regeneron's reply on April 18. *Id.* at 3.

Regeneron's unrealistic efforts to force Amgen onto the expedited West Virginia preliminary injunction schedule have already been rejected twice. First, by this Panel in denying Regeneron's request for expedited relief on its motion. Second, by the District Court in the Central District of California in rejecting Regeneron's request for *ex parte* relief to enter its requested preliminary injunction schedule. Instead, the District Court ordered that the Amgen action proceed on a different schedule "[i]n view of the fact that this case was filed after the West[] Virginia cases[.]" Ex. 1 at 2. The Amgen action will necessarily trail the West Virginia cases by some time, as the Court set a hearing date of April 5, 2024 to discuss a briefing schedule for injunctive relief. *Id.* at 3.

Given the advanced stage of the preliminary injunction proceedings against the other defendants, it would be disruptive to the other defendants and unfair to Amgen to shoehorn Amgen into those proceedings, as Regeneron proposes. *See e.g.*, *In re JumpSport, Inc.*, 338 F. Supp. 3d at 1357 (denying centralization where procedural differences "would complicate any centralized proceeding and likely would result in delays to the completion of discovery and the anticipated trial date"). This would also severely prejudice Amgen and its ability to develop its defenses and arguments in response to any preliminary injunctive relief sought by Regeneron.

The only reasonable conclusion is that two sets of separate preliminary injunction proceedings are required whether the Amgen action is transferred to West Virginia or not. The presence of two different time-sensitive preliminary injunction proceedings also distinguishes this case from the Hatch-Waxman cases cited by Regeneron. The Hatch-Waxman Act provides a 30-month stay of generic approval upon the timely filing of a patent infringement lawsuit, thus

avoiding early preliminary injunction proceedings. *See* 21 U.S.C. § 355(j)(5)(B)(iii). In contrast, the BPCIA contemplates preliminary injunctions during a 180-day period following a biosimilar applicant's notice of commercial marketing. *See* 42 U.S.C. § 262(l)(8)(A). Regeneron rushed to transfer the Amgen case during preliminary injunction proceedings in West Virginia, but transfer would disrupt and delay those proceedings rather than create any efficiency.

Moreover, Regeneron overlooks the substantial differences that may be at issue in Amgen's preliminary injunction proceeding relative to the other defendants' proceedings. "A party can obtain a preliminary injunction by showing that (1) it is 'likely to succeed on the merits,' (2) it is 'likely to suffer irreparable harm in the absence of preliminary relief,' (3) 'the balance of equities tips in its favor,' and (4) 'an injunction is in the public interest.'" *Disney Enters., Inc. v. VidAngel, Inc.*, 869 F.3d 848, 856 (9th Cir. 2017) (internal brackets omitted) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). *First*, as of today, Regeneron has not identified which patents (or claims) it intends to assert in seeking a preliminary injunction against Amgen, and thus has necessarily failed to show that there is any overlap of issues with the preliminary injunction proceedings in West Virginia. *Second*, as discussed above in Section II.A.1, there are substantial differences between Amgen's biosimilar product and manufacturing processes and the other biosimilar defendants. As a result, an analysis of Regeneron's likelihood to succeed on the merits will be substantially different for each defendant and may implicate different claim construction issues and different defenses. *Third*, Amgen also is differently situated from the other defendants with respect to the remaining preliminary injunction factors. For example, discovery on the issue of balance of hardships and irreparable harm will likely implicate Amgen's confidential and competitively sensitive business information. Thus, any efficiencies to be gained through

centralization are diminished as it relates to preliminary injunctive relief, particularly since it is a factually intensive inquiry.

D. Centralization in West Virginia will not serve the convenience of the parties and witnesses.

Regeneron proclaims that centralization would "best serve the convenience of the parties and witnesses." Dkt. 1-1 at 9. But the only party served by centralization is Regeneron. The Court in the Amgen action has already rejected Regeneron's attempt to manufacture a "common schedule" for preliminary injunction proceedings, thereby mooting Regeneron's principal arguments. As for witness convenience, the only specific efficiencies alleged by Regeneron concern the burden that would befall its own witnesses (i.e., the inventors) if required to appear at multiple depositions. But this Panel should be wary of placing undue weight on Regeneron's self-serving interest in restricting the number and manner of its own witness depositions, especially because informal coordination can be used to minimize inconvenience. *See* Section II.D.2 below.

Even if there are potential benefits to Regeneron, left unaddressed in Regeneron's brief is what will happen to Amgen and its witnesses if the case is centralized. There is nothing convenient about West Virginia for Amgen.[8] Amgen does not have any witnesses located in West Virginia (nor does Regeneron). Rather, Amgen's witnesses are primarily located in California, which is where the Amgen action is already pending. Both parties have retained national counsel who reside outside of West Virginia and would therefore be subject to travel for any in-person hearings.

[8] Regeneron argues that "Amgen will not be prejudiced in any way . . . given that it has already intervened in the Mylan Action to obtain access to various records and appeared in that court." Dkt. 1-1 at 10. That is simply not credible. That Amgen hired local counsel in West Virginia to file a limited motion to intervene to obtain access to judicial records in no way diminishes the prejudice and inconvenience that Amgen would suffer if it were forced to litigate a complex 32-patent infringement action in West Virginia along with other direct competitors.

1. The small number of actions weighs against centralization.

There are only six actions pending in two districts, and all five West Virginia actions are currently pending before the same judge. The Amgen action is the only proceeding outside of West Virginia. As a small number of cases are at issue, Regeneron "bears a heavier burden to demonstrate that centralization is appropriate." *See In re SLB Enter. Rico Litig.*, 412 F. Supp. 3d 1350, 1352 (J.P.M.L. 2019). This Panel routinely denies centralization in such situations. *See In re Droplets, Inc., Pat. Litig.*, 908 F. Supp. 2d at 1378 (denying centralization of actions "pending in just three districts"); *In re JumpSport*, 338 F. Supp. 3d at 1357; *In re Nelnet Servicing, LLC, Customer Data Sec. Breach Litig.*, 648 F. Supp. 3d 1377, 1377-78 (J.P.M.L. 2022) (denying centralization where "only one of the twenty-two actions . . . is pending outside the District of Nebraska" since "[e]ffectively, then, there are two actions at issue here") (internal quotation marks omitted).

2. Informal coordination is preferable to transfer under § 1407.

The overlapping counsel and locations of the witnesses makes informal coordination preferable to centralization. Regeneron, the sole plaintiff in all six actions, is represented by the same counsel for all actions. This facilitates coordination. *See In re Droplets, Inc., Pat. Litig.*, 908 F. Supp. 2d at 1378 (denying centralization because "informal coordination among the three involved courts seems practicable—just as it does among the parties, given that [patent owner] is represented in all actions by the same law firm"); *In re Zeroclick, LLC*, 437 F. Supp. 3d 1362, 1362 (J.P.M.L. 2020) ("These circumstances – the small number of actions, minimal number of districts, and presence of common counsel – suggest that alternatives to centralization are practicable, and that formal centralization under Section 1407 is not necessary.").

Although Regeneron argues that centralization would reduce the burden placed on fact witnesses by having to appear at multiple depositions and court proceedings, informal coordination

amongst the parties can minimize that burden. Indeed, Amgen has tried to engage Regeneron on multiple occasions to discuss a schedule, minimize duplication of discovery, and informally coordinate with the West Virginia actions. *See* Ex. 12. But Regeneron has refused to provide Amgen with basic information required to facilitate coordination with the West Virginia actions. Among other things, Regeneron has rebuffed Amgen's requests for: (i) the list of patents at issue in the preliminary injunction proceedings in West Virginia; (ii) the list of patents that will be at issue in Regeneron's preliminary injunction proceeding against Amgen[9]; (iii) the schedule for further proceedings in the Mylan case; and (iv) information about any potential case schedule for post-injunction proceedings in the other West Virginia actions. *Id*. at 1-3. And although Regeneron has had Amgen's initial document production of over 145,000 pages since September 2023, Regeneron has refused to provide Amgen with any documents, including even those already produced in the other actions. *Id.* at 1.

Amgen is not alone in maintaining that informal coordination is a practicable alternative to formal centralization. Amgen has conferred with all three of the other defendants in pre-trial proceedings, namely Celltrion, Samsung, and Formycon. All four defendants are prepared and willing to informally coordinate wherever it is feasible, including in particular, with respect to discovery following preliminary injunction proceedings.

Rather than engaging in a discussion about informal coordination, Regeneron jumps to the conclusion that Amgen's requests for coordination "across cases pending in multiple jurisdictions with different governing protective orders—appears unworkable." *Id*. at 3; *see also id*. ("To the

[9] In view of the extensive information Regeneron has received about Amgen's product and processes, it surely knows what patents it will assert in a preliminary injunction motion. Should Regeneron disclose the patents it will assert by its reply to this Panel, Amgen may seek an opportunity to respond further by addressing the extent, if any, to which patents Regeneron finally identifies involve common issues of fact and law.

extent that Amgen seeks to enhance efficiency by coordinating pre-trial discovery proceedings with those cases pending in West Virginia, it should accede to Regeneron's request for multi-district litigation transfer."). Yet, Regeneron never explains why coordination among the relatively small number of cases and counsel will be unworkable. The parties have various tools at their disposal to, should the need arise, minimize the potential for duplicative discovery. It cannot be that informal coordination is not feasible because the moving party says so; indeed, this Panel has "often stated that centralization under Section 1407 should be the last solution after considered review of all other options." *In re Gerber Probiotic Prod. Mktg. & Sales Practices Litig.*, 899 F. Supp. 2d at 1379 (internal quotation marks and citations omitted).

III. CONCLUSION

For the foregoing reasons, Amgen respectfully requests that the Panel deny Regeneron's Motion for Transfer of Action to the Northern District of West Virginia Pursuant to 28 U.S.C. § 1407 for Coordinated Pretrial Proceedings.

Dated: February 2, 2024 */s/ Siegmund Y. Gutman*

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