BEFORE THE UNITED STATES JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

In re Aflibercept Patent Litigation	MDL No. 3103

REGENERON'S CONSOLIDATED REPLY BRIEF IN SUPPORT OF MOTION TO TRANSFER TO THE NORTHERN DISTRICT OF WEST VIRGINIA PURSUANT TO 28 U.S.C. § 1407

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In opposing Regeneron's Motion to Transfer, Defendants have coalesced around one alternative to multidistrict litigation: chaos. Amgen would like to stay in Los Angeles. Formycon would like to go to Seattle. Celltrion and Samsung Bioepis would settle for Delaware, but Samsung may prefer Massachusetts.[1] Mylan and Biocon are not leaving West Virginia. In other words, Defendants envision a world where Regeneron is forced to litigate the same patents and present practically identical evidence and arguments relating to the meaning of those patents, the validity of those patents, and the irreparable harm that will flow from infringement of those patents, in no fewer than four different jurisdictions, all in parallel. The MDL process was designed to avoid the very chaos, duplication (or quintuplication) and inefficiency that Defendants propose to create. Regeneron's Motion presents a paradigmatic case for transfer and centralization under 28 U.S.C. § 1407 to avoid wasteful expenditures of judicial and party resources and to reduce the possibility of conflicting rulings on identical issues.

Defendants' actual reason for opposing this Motion has nothing to do with judicial efficiency or factual differences between these cases, as the PI Defendants' proposal to transfer the cases through multidistrict litigation to Delaware unwittingly confirms. PI Defs. Br. at 8 ("[T]o the extent the Panel finds consolidation proper, it might choose Delaware instead . . . ."). They simply want to avoid the one Court with extensive experience adjudicating Regeneron's patent claims involving its Eylea® product: the Northern District of West Virginia. In that district, Chief Judge Kleeh has overseen the Mylan Action for more than a year and a half,

[1] *See* Samsung Bioepis Co., Ltd.'s, Celltrion, Inc.'s and Formycon AG's Opposition to Plaintiff's Motion to Transfer ("PI Defs. Br.") at 8 (noting Seattle and Delaware as possible venues); Ex. 8 (Excerpt of Jan. 5, 2024 Hr'g Tr.) at 28 (noting Massachusetts as possible venue). For consistency with the term used in Samsung, Celltrion, and Formycon's opposition brief, Regeneron jointly refers to these three Defendants as the "PI Defendants," though it is not entirely accurate because Amgen is also a defendant subject to preliminary injunction proceedings.

presided over a claim construction hearing and issued a claim construction order involving several patents asserted against all Defendants, heard argument and ruled on numerous summary judgment issues, and served as factfinder in a two-week bench trial and issued a 313-page post-trial decision upholding the validity of a patent asserted against all Defendants (U.S. Patent No. 11,084,865, "the '865 patent") and finding that patent infringed by Mylan and Biocon. That patent that Judge Kleeh adjudged valid and infringed is at the forefront of every single one of these cases—it is a principal basis on which Regeneron will seek, in the coming months, to enjoin Mylan and Biocon permanently, and Amgen, Samsung, Celltrion, and Formycon preliminarily, from commercializing their proposed biosimilar products. Defendants do not oppose transfer because their cases differ from Mylan and Biocon's case pending before Chief Judge Kleeh, but precisely because of their commonality.

Defendants tout the motions to dismiss filed in West Virginia by Samsung, Celltrion, and Formycon, as if those motions supersede the statutory considerations set forth in Section 1407. PI Defs. Br. at 7–8; Amgen Br. at 11. They do not. *See In re: Helicopter Crash Near Wendle Creek, B.C., on Aug. 8, 2002*, 542 F. Supp. 2d 1362, 1363 (J.P.M.L. 2008) ("In considering transfer under Section 1407, the Panel is not encumbered by considerations of in personam jurisdiction and venue."). To be clear, Regeneron's oppositions, to be filed on February 19, will demonstrate that Defendants' motions to dismiss for lack of personal jurisdiction are spurious, contrary to governing law, and emblematic of Defendants' desire to distance themselves from Chief Judge Kleeh's detailed post-trial opinion and urge a different judge (or several different judges) to issue an inconsistent ruling(s). Contrary to Defendants' allegation that Regeneron attempted to conceal these motions from the Panel, PI Defs. Br. at 4–5, Regeneron appended Chief Judge Kleeh's Order setting a briefing schedule to its Motion for Transfer, Regn. Ex. 7,

and noted explicitly in its Motion to Expedite that the scheduling order also addressed dispositive motions, Mot. to Expedite at 2.

Regeneron declined to devote space to these motions in its opening brief for the simple reason that they do not militate against transfer of the Amgen Action to West Virginia. When the motions to dismiss are properly denied, Defendants' arguments relying thereon will be moot.[2] In the unlikely event that one or more of those motions are granted and one or more of Defendants' cases are transferred elsewhere, all of the points in favor of centralization—including common questions of fact, efficient use of party and court resources, judicial consistency across rulings—would be amplified to prevent simultaneous injunction proceedings in as many as five different jurisdictions. Chief Judge Kleeh's court would still be the logical choice for centralization of these actions, given that he has already presided over a trial (along with numerous pretrial hearings) and issued several decisions on key patents, including patents at the forefront of the injunction proceedings.

Regarding those key patents, Defendants try to obscure the commonality of the actions by counting and re-counting patents that are not asserted in all six actions. PI Defs. Br. at 11; Amgen Br. at 5–6; Mylan Br. at 7–8. The Panel has squarely rejected this argument. *E.g., In re: Ozempic (Semaglutide) Pat. Litig.*, 621 F. Supp. 3d 1354, 1356 (J.P.M.L. 2022). Crucially, Defendants hardly confront the fact that 13 patents *are* common to all actions. That is more than enough similarity to support centralization. *See id.* ("In any event, the West Virginia action also involves ten patents that *are* asserted in the Delaware actions."). And Regeneron's irreparable harm case asserted against all six Defendants in injunction proceedings will be substantially the

[2] Briefing on the PI Defendants' motions to dismiss will be complete on February 26. Regn. Ex. 7. Regeneron will advise the Panel promptly of any decision Chief Judge Kleeh issues.

same, as each Defendant is seeking approval of a biosimilar version of the same reference product: Regeneron's Eylea®.

Further, pursuant to its efforts to pursue preliminary injunctive relief and the schedule entered by Chief Judge Kleeh, Regeneron has identified over the last month to each of Samsung, Celltrion, Formycon, and Amgen the patents it is asserting in its forthcoming preliminary injunction motions (collectively, the "PI Patents"). Seven patents may be asserted against one or more of the Defendants. Every single patent asserted against Samsung, Celltrion, or Formycon also is asserted against Amgen. Five of the seven total PI Patents are commonly asserted against two or more Defendants, and the '865 patent—recently held valid by Chief Judge Kleeh—is commonly asserted against all of them. Regeneron also is seeking a permanent injunction against Mylan and Biocon based on Chief Judge Kleeh's decision that their biosimilar product infringes the '865 patent, and Regeneron has proposed to the Court a schedule essentially matching that of the preliminary injunction proceedings against the other Defendants in West Virginia. Ex. 9. Put simply, absent MDL transfer, the court that adjudicates Regeneron's motion for preliminary injunction against Amgen alone will be assessing the scope, validity, and infringement of patents previously asserted in preliminary injunction proceedings in a different court against the PI Defendants, including the '865 patent tried to Chief Judge Kleeh last year. Regeneron's Motion to Transfer should be granted so that these proceedings can instead move forward efficiently and expeditiously in all six actions.

ARGUMENT

I. Centralization Will Maximize Efficiency, Convenience, and Justice.

As explained in Regeneron's Opening Brief in Support of its Motion, these six actions present the typical scenario where the Panel orders centralization. Regn. Br. at 5–6, n. 2 (citing cases). Defendants ask the Panel to disregard the purpose of Section 1407 and have Regeneron

litigate substantially similar, overlapping cases in as many as four or five different courts at once, merely because Chief Judge Kleeh has issued an opinion Defendants dislike.

Defendants' interest in obtaining conflicting rulings with the Northern District of West Virginia's post-trial decision, however, provides no cognizable basis to scatter these cases to disparate courts lacking any experience with the numerous common issues. *See, e.g.*, *Ozempic*, 621 F. Supp. 3d at 1355 (ordering centralization to "prevent inconsistent pretrial rulings (particularly with respect to claim construction and issues of patent validity)"). If transferred, all except the Mylan Action still would require preliminary injunction ("PI") motions to be decided within the 180-day window provided for in the Biologics Price Competition and Innovation Act ("BPCIA").[3] And unlike Chief Judge Kleeh in West Virginia, none of the transferee district court judges tasked with deciding the motions in that short timeframe would have any familiarity with the patents being asserted. In contrast, in the Northern District of West Virginia, a coordinated schedule already has been entered, and preliminary injunction proceedings against Samsung, Celltrion, and Formycon are underway. Regn. Ex. 7. Other than their own self-interest, there is no basis for Defendants' desire to have Regeneron litigate—and have courts decide—these accelerated, overlapping proceedings in parallel across the country.

Granting Regeneron's Motion to Transfer would avoid this chaotic outcome, fulfilling the aims of Section 1407 to promote "the convenience of parties and witnesses" and "the just and efficient conduct" of the actions. 28 U.S.C. § 1407. Following transfer of the Amgen Action to the Northern District of West Virginia, Chief Judge Kleeh can order an appropriate briefing schedule for preliminary injunction proceedings in view of Amgen's expected launch date for its

[3] In the Mylan Action, Regeneron would still be seeking a permanent injunction issued by Chief Judge Kleeh before expiry of Regeneron's regulatory exclusivity over Eylea® on May 18, 2024.

Eylea® biosimilar product. Assuming that hearing occurs after the consolidated preliminary injunction hearing scheduled for Samsung, Celltrion, and Formycon on May 2, 2024, the judiciary and litigants nevertheless will enjoy substantial efficiencies from transferring the Amgen Action to West Virginia, rather than having a different Court, just weeks later, address again the interpretation and validity of the same patents and the irreparable harm and public interest issues that comprise the preliminary injunction inquiry.

One patent that will be front and center in the injunction proceedings against all Defendants, including Amgen, is the '865 patent, previously adjudicated by Chief Judge Kleeh. Chief Judge Kleeh gained intimate familiarity with the '865 patent from the two-week bench trial last year against Mylan and Biocon, and the scope, validity, and infringement of that patent will be the subject of both the upcoming May 2024 preliminary injunction hearing involving Samsung, Celltrion, and Formycon[4] and the ensuing preliminary injunction proceedings against Amgen. The May 2024 hearing also will involve three additional patents that are asserted against both Samsung and Formycon, and likewise are preliminary-injunction patents asserted against Amgen as well. *See infra* Section II.A (discussing PI Patents' commonality in greater detail). Further, consistent with controlling law, the Court will have to address common issues of irreparable harm and public interest in all preliminary injunction proceedings. *See Metalcraft of Mayville, Inc. v. Toro Co.*, 848 F.3d 1358, 1363–64 (Fed. Cir. 2017); *infra* Section II.B. Centralizing all of the proceedings before Chief Judge Kleeh is the most efficient use of judicial

[4] As explained in Part III, Regeneron is confident that Samsung, Celltrion, and Formycon's motions to dismiss will be denied. In any event, a remote possibility that one or more of them could be transferred to a different jurisdiction prior to this hearing does not *diminish* the value of an MDL—it *enhances* it.

and party resources, and would prevent the risk of inconsistent rulings by additional judges considering these issues for the first time.

After injunction proceedings are complete, there will be additional discovery and litigation as the parties prepare for trial.[5] Again, 13 patents are common across the complaints filed against all six Defendants; 24 are commonly asserted against Amgen, Celltrion, Formycon, and Samsung.[6] This commonality is more than sufficient, as "[t]ransfer under Section 1407 does not require a complete identity, or even majority, of common factual issues as a prerequisite to transfer." *In re Ozempic (Semaglutide) Pat. Litig.*, 621 F. Supp. 3d 1354, 1356 (J.P.M.L. 2022) (quoting *In re Ameriquest Mortg. Co. Mortg. Lending Practices Litig.*, 408 F. Supp. 2d 1354, 1355 (J.P.M.L. 2005)). Centralizing pre-trial proceedings on non-PI patents in the Northern District of West Virginia will again be the most efficient course of action. This is true not just for the PI Defendants and Amgen, but also for Mylan and Biocon. Following permanent injunction proceedings to enforce Chief Judge Kleeh's post-trial opinion as to the '865 patent, a "second-phase" of the litigation against Mylan and Biocon will proceed as to patents not included in the June 2023 trial. Consistent with their argument to the Panel that their litigation should precede the other Defendants, Mylan Br. at 13, Mylan and Biocon filed an emergency motion before Chief Judge Kleeh on January 30, requesting an expedited schedule culminating in

[5] That Amgen may return to the Central District of California for trial at some point in the future, *see* Amgen Br. at 12 (discussing *Lexecon* rights), does not reduce the extensive efficiencies that will result from centralization of all pre-trial proceedings in the Northern District of West Virginia, as Section 1407 explicitly envisions. The Panel has long recognized the efficiency in having coordinated preliminary injunction proceedings in patent cases. *See, e.g., In re: BRCA1- & BRCA2-Based Hereditary Cancer Test Pat. Litig.*, 999 F. Supp. 2d 1377 (J.P.M.L. 2014).

[6] These 24 are U.S. Patent Nos. 9,222,106; 9,254,338; 9,816,110; 10,130,681; 10,415,055; 10,464,992; 10,669,594; 10,828,345; 10,888,601; 110,66,458; 11,084,865; 11,104,715; 11,253,572; 11,306,135; 11,472,861; 11,535,663; 11,542,317; 11,548,932; 11,555,176; 11,559,564; 11,707,506; 11,753,459; 11,769,597; 11,788,102.

a late 2024 trial; Judge Kleeh denied the request, noting the June 2027 expiry of the '865 patent Mylan and Biocon have been found to infringe. Mylan Action, No. 22-cv-00061-TSK-JPM, Dkt. 698 (Feb. 8, 2024 Order Denying Defendants' Expedited Motion for Entry of a Scheduling Order). As a result, pre-trial proceedings in the Mylan Action can easily be coordinated with pre-trial proceedings in the other five actions following PI and permanent injunction proceedings.[7] Mylan and Biocon's complaints about "procedural disparities" and "oppos[ition to] any centralization that would unjustly delay or impede their efforts to complete pretrial activities in advance of a trial later in 2024," Mylan Br. at 12–13, are now moot, given Chief Judge Kleeh's refusal to enter an expedited schedule for a second trial.

Beyond Chief Judge Kleeh's experience with relevant patents and evidence related to irreparable harm, there are a number of benefits of centralization in the Northern District of West Virginia that are unaffected by Amgen's PI hearing being held at a later date. Preservation of judicial resources is one. As of February 1, the Northern District of West Virginia had zero pending MDLs; the District of Delaware—the venue the PI Defendants propose for MDL transfer, if any, PI Defs. Br. at 8—had five. And the District of Delaware is the fourteenth-busiest courthouse in America by weighted filings per judgeship, while the Northern District of West Virginia is fifty-second. United States District Courts—National Judicial Caseload Profile (Dec. 31, 2023), https://www.uscourts.gov/file/78140/download.

Defendants' protests that West Virginia is inconvenient are insubstantial. Defendants discount the burden that would be imposed on Regeneron to travel to Los Angeles (and potentially Delaware and Seattle and Massachusetts), in addition to their multiple trips to West

[7] Chief Judge Kleeh specifically noted that Mylan and Biocon's infringement of a valid patent that expires in June 2027 negated the urgency professed in their Expedited Motion for a Scheduling Order. *Id.*

Virginia, calling it "Regeneron's self-serving interest in restricting the number and manner of its own witness depositions." Amgen Br. at 17; *see also* PI Defs. Br. at 14–15. But Section 1407 emphasizes "the convenience of parties and witnesses" for precisely this reason. *See also Ozempic*, 621 F. Supp. 3d. at 1356 ("Mylan also contends that centralization would interfere with its right to litigate the action in a proper forum. This argument is not well taken—under 28 U.S.C. § 1407, this Panel is authorized to select the appropriate venue for coordinated or consolidated pretrial proceedings of actions involving common factual questions.").

The PI Defendants further suggest that the Northern District of West Virginia "is relatively inaccessible to the parties" due to its distance from the Pittsburgh airport and because "[e]ach of the PI Defendants is a foreign corporation whose witnesses will be coming from abroad." PI Defs. Br. at 16. That the Northern District of West Virginia, like many other federal courts across the United States, is not home to a major airport hub should not preclude it from hosting multidistrict litigation, and has not in the past. *See In re: Monitronics Int'l, Inc., Tel. Consumer Prot. Act Litig.*, 988 F. Supp. 2d 1364, 1367 (J.P.M.L. 2013) (ordering centralization to N.D. W. Va.). West Virginia is as reasonable a place as any to host parties from South Korea (Celltrion and Samsung), from Germany (Formycon), from California (Amgen), from West Virginia (Mylan), and from New York (Regeneron). And of course, Regeneron filing the first action in West Virginia was not the result of any sort of "hometowning" or "gamesmanship"—the action had to be filed there because it is the home of Defendant Mylan Pharmaceuticals Inc. In any event, any burden on a Defendant to travel to West Virginia pales in comparison to their proposed alternative to centralization, in which Regeneron, over the next few months, would be forced to travel to Los Angeles and (if Defendants' motions are successful) at least Seattle and Delaware, in addition to West Virginia. Defendants also complain that the Northern District of

West Virginia lacks local patent rules, PI Defs. Br. at 15, but this posed no obstacle to a speedy trial before Chief Judge Kleeh in the Mylan Action.

Amgen also claims that centralization would be inconvenient because Defendants are competitors that "would require additional discovery protections." Amgen Br. at 13. There is no mention of what additional discovery protections it has in mind, and no explanation for why Amgen believes Chief Judge Kleeh would not be capable of enforcing such hypothetical protections. Those protections manifestly will be easier to coordinate and enforce if all parties are before the same court, rather than spread across as many as five courts. The PI Defendants in West Virginia—Celltrion, Formycon, and Samsung—already are "coordinating briefing efforts where (as here) possible," PI Defs. Br. at 16, indicating that Amgen's fears will not be realized. In any event, the Panel regularly orders centralization of Hatch-Waxman cases similarly involving patent infringement by direct competitors and implicating their commercially sensitive information. *See* Regn. Br. at 5–6, n. 2 (citing cases); *In re: Fenofibrate Pat. Litig.*, 910 F. Supp. 2d 708, 708, 713–15 (S.D.N.Y. 2012) (analyzing unique non-infringement defenses in MDL context).

Defendants' proposal of "informal coordination" is also not a feasible alternative to centralization. *See* Amgen Br. at 18; PI Defs. Br. at 16. Regeneron does not share Defendants' unfounded optimism that Regeneron and the Defendants—which, as Amgen notes, are direct competitors, each seeking to market an Eylea® biosimilar, Amgen Br. at 13—would be able to agree on discovery issues and achieve meaningful coordination without a single judge managing the proceedings. Notably, the PI Defendants and Amgen emphasize that they are willing to coordinate "with respect to discovery *following* preliminary injunction proceedings," Amgen Br. at 19 (emphasis added); PI Defs Br. at 16, leaving unsaid that they will *not* be willing to

consolidate discovery in advance of the PI hearing, when litigation is moving most swiftly and multiple depositions (and other duplication) would be most prejudicial to Regeneron.

II. Common Questions of Fact Across the Six Actions Warrant Centralization.

Defendants try to distinguish robust precedent supporting centralization in patent infringement suits like these by raising irrelevant differences between the BPCIA and the Hatch-Waxman Act, Amgen Br. at 5; PI Defs. Br. at 12–13; Mylan Br. at 10; irrelevant differences between Defendants' products, Amgen Br. at 7; PI Defs. Br. at 9; Mylan Br. at 9–10; and speculative differences between defenses that Defendants might raise as to common PI patents, Amgen Br. at 8–9; PI Defs. Br. at 9; Mylan Br. at 10. None of these arguments detracts from the compelling case for centralization, and certainly none justifies having as many as five different courts across the country determine whether Regeneron will be irreparably harmed by the marketing of biosimilar copies of its drug Eylea.

As an initial matter, the interests favoring centralization in this BPCIA context do not meaningfully differ from those in the Hatch-Waxman context. *See AbbVie Inc. v. Alvotech hf.*, 582 F. Supp. 3d 584, 588 (N.D. Ill. 2022) ("The BPCIA's aBLA procedure closely resembles one that was already available under the Hatch-Waxman Act for small molecule drugs."). Like the Hatch-Waxman Act, the BPCIA prioritizes speedy relief. *Id.* ("The BPCIA creates a procedure by which the parties can litigate the most contested and consequential patents immediately."). The BPCIA's 180-day window that Defendants emphasize, Amgen Br. at 16; PI Defs. Br. at 12, cuts in *favor* of centralization, because efficient coordination of all related proceedings before a judge familiar with the issues would be even more necessary to meet the "need for swift progress in litigation," *In re Kerydin (Tavaborole) Topical Sol. 5% Pat. Litig.*, 366 F. Supp. 3d 1370, 1371 (J.P.M.L. 2019). Any suggestion that the BPCIA discourages consolidating cases against multiple alleged patent infringers is wrong; the opposite is true.

Congress defined carefully which patent actions properly may be consolidated, 35 U.S.C. § 299, and the two types of cases that are appropriately consolidated are Hatch-Waxman and BPCIA cases (*i.e.*, those cases involving allegations of infringement under 35 U.S.C. § 271(e)(2)).

Defendants' generalized musings about differences between the two statutes and the types of patents they cover have no import. Regeneron has informed the PI Defendants and Amgen which patents it will assert against them in PI proceedings. As demonstrated by the below chart, there are seven in total.

Patent No.	Mylan/Biocon	Celltrion	Formycon	Samsung	Amgen
11,084,865	✔	✔	✔	✔	✔
11,793,926		✔			✔
11,160,918					✔
11,104,715	✔		✔	✔	✔
11,472,861			✔	✔	✔
11,535,663			✔	✔	✔
11,548,932					✔

Five of the patents asserted against Amgen are asserted against at least one of the Defendants in West Virginia; all patents asserted against at least one of the West Virginia Defendants also is asserted against Amgen. The '865 patent, which is the subject of injunction proceedings across all six actions, is a formulation patent that Chief Judge Kleeh knows well. The other patents to be asserted in the PI proceedings relate to manufacturing processes (U.S. Patent Nos. 11,104,715; 11,472,861; 11,535,663; and 11,548,932) and drug packaging (U.S. Patent Nos. 11,793,926 and 11,160,918). The universe of arguments to be made related to these patents is limited, and there will be a great deal of commonality across the actions.

A. The Actions Share Common Issues of Fact as to Patent Infringement and Validity.

As discussed above, Regeneron will assert seven patents in total in PI proceedings across the actions. One patent (the '865 patent) is common to all PI proceedings; three patents are common to all of Amgen, Samsung, and Formycon's PI proceedings; and one additional patent is common to Amgen and Celltrion's PI proceedings. Common issues of claim construction and validity inevitably arise when common patents are asserted; Defendants quibble only with how many of those issues will be common.

Defendants' oppositions asserted that there are differences between their potential non-infringement and invalidity arguments they could make as to PI Patents (as well as post-PI patents), *see, e.g.*, PI Defs. Br. at 9–11; Amgen Br. at 6–9; Mylan Br. at 9–11. Defendants' assertion of non-commonality before this Panel diverged from Regeneron's understanding that the Defendants have not exchanged information that would allow them to make informed statements about the similarities or differences between their non-infringement and invalidity arguments. Accordingly, Regeneron sought clarification from the PI Defendants and Amgen as to whether they "reviewed the defenses asserted by other Defendants or otherwise conferred regarding their content." Ex. 10 at 2 (Email to Amgen); Ex. 11 at 2 (Email to Celltrion); Ex. 12 at 1–2 (Email to Formycon); Ex. 13 at 3 (Email to Samsung). Each of the Defendants either refused to clarify or confirmed that they had not shared their arguments with the other defendants. Ex. 10 at 1 ("Our MDL opposition brief does not suggest that we have shared Amgen confidential information with the other defendants."); Ex. 11 at 1; Ex. 12 at 1; Ex. 13 at 2.

Based on these communications from Defendants, Defendants' arguments regarding the non-commonality of their defenses are rank speculation. The language in Defendants' oppositions confirms as much, s*ee, e.g.* PI Defs. Br. at 9 ("[T]here will *likely* be little to no

overlap as to most of the patents . . . .") (emphasis added); *id.* at 13 ("[T]here are *likely* to be little to no common questions of fact as to each PI Defendant's confidential manufacturing process . . . .") (emphasis added); Amgen Br. at 9 ("[T]he case against Amgen is *likely* to involve different claim construction issues from the other defendants . . . .") (emphasis added); Mylan Br. at 10 ("Among the 64 claims of the '865 patent are distinct groups of claims that will, *almost* certainly, apply differently between the subject actions.") (emphasis added); Mylan Br. at 11 ("Due to *expected* variations in the distinct manufacturing processes and characteristics of the accused products themselves, Regeneron is *expected* to assert claims of the various accused patents differently . . . .") (emphasis added). Defendants' less equivocal statements lack any factual basis, improperly suggest a level of knowledge that Defendants have since indicated they do not have, and should not be credited. *See, e.g.*, PI Defs. Br. at 9 ("myriad unique questions of law and fact" and "idiosyncratic noninfringement defenses"); Mylan Br. at 10 ("idiosyncrasies between the cases").

Regeneron is the only party in possession of sufficient information to explain the extent of the overlap between Defendants' non-infringement and invalidity arguments. Under the BPCIA's pre-suit provisions, applicants seeking approval of a biosimilar product (*e.g.*, Defendants) are required to provide the owner of the reference product (*e.g.*, Regeneron) with "a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the [Defendant] that such patent is invalid, unenforceable, or will not be infringed" by its proposed biosimilar product." 42 U.S.C. § 262(*l*)(3)(B)(ii). Regeneron sought permission from the PI Defendants and Amgen to furnish those contentions to the Panel under seal. *See* Ex. 10 at 2 (Email to Amgen); Ex. 11 at 2 (Email to Celltrion); Ex. 12 at 1–2 (Email to Formycon); Ex. 13 at 3 (Email to Samsung). Each of Amgen, Celltrion, Formycon, and Samsung responded

that they refused Regeneron's proposal to share such information with the Panel, threatened Regeneron with unspecified injunctive relief in the event that Regeneron provided excerpts of their non-infringement and invalidity contentions to the Panel under seal, and in one case (Samsung) threatened to seek a temporary restraining order this morning to prevent Regeneron from doing so. *See* Ex. 10 at 1; Ex. 11 at 1; Ex. 12 at 1; Ex. 13 at 1–2. For clarity, Regeneron considers these threats improper—the operative statute is not designed to prevent the sealed submission of pre-suit contentions to adjudicative bodies like this Panel, and the notion that Defendants may prevent this Panel from accessing that information, after asserting non-commonality in their Oppositions, is as unwarranted as it is unfair.[8] Nevertheless, out of an abundance of caution, and to avoid further disputes, Regeneron is not appending Defendants' contentions or otherwise conveying information about those contentions in response to Defendants' speculative assertions about the uniqueness of their arguments. In the event that the Panel orders Regeneron to furnish the information demonstrating whether the Defendants' contentions overlap, Regeneron will do so, promptly.

Further, Defendants' suggestion that process/manufacturing patents are somehow too complicated or sensitive to be included in an MDL lacks any support. *See* Amgen Br. at 13–14; PI Defs. Br. at 9–10, 13; Mylan Br. at 11. The Northern District of West Virginia is as capable as any court of enforcing protective orders and handling confidential information about Defendants' manufacturing processes. Indeed, U.S. Patent No. 11,104,715 is a manufacturing patent to be asserted against multiple Defendants in preliminary injunction proceedings, and was the subject of discovery and claim construction already in the Mylan Action.

[8] When Regeneron asked the PI Defendants to identify the arguments they would advance in opposing Regeneron's motion for preliminary injunction, they refused to do so. *See, e.g.*, Ex. 14 (Email from Celltrion); Ex. 15 (Email from Formycon).

B. The Actions Share Many Common Issues of Fact Beyond Likelihood of Success on the Merits.

The foregoing issues of patent infringement and validity go to the "likelihood of success" factor in the preliminary injunction analysis. Chief Judge Kleeh will need to decide three other factors as part of preliminary injunction proceedings: the prospect of irreparable harm to Regeneron, the balance of the hardships, and whether injunctive relief is in the public interest. *Metalcraft of Mayville*, 848 F.3d at 1363–64. These same factors are involved in determining Regeneron's entitlement to a permanent injunction in the Mylan Action. *See Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1148 (Fed. Cir. 2011). Amgen and the PI Defendants argue that these factors will implicate each Defendant's unique and commercially sensitive information. Amgen Br. at 16–17; PI Defs. Br. at 14. But in truth, the Venn diagram of the facts underlying these analyses in the six actions is practically a circle.

Regeneron will show that it will suffer irreparable harm arising from competition between Regeneron and any Defendant's biosimilar product. This showing will involve nearly identical facts across all six actions. The central fact unpinning the irreparable harm analysis in every action is that a Defendant is seeking to commercialize a biosimilar version of Regeneron's Eylea® product, thereby competing directly with Regeneron. *See Douglas Dynamics, LLC v. Buyers Prods. Co.,* 717 F.3d 1336, 1345 (Fed. Cir. 2013) ("Where two companies are in competition against one another, the patentee suffers the harm—often irreparable—of being forced to compete against products that incorporate and infringe its own patented inventions."). No Defendant disputes that its proposed biosimilar product will, if commercialized, compete with Regeneron's Eylea®, and Regeneron's evidence about the effect of unlawful, infringing competition on Regeneron will not vary significantly across Defendants. The possibility that some of each Defendant's "business information," Amgen Br. at 16, or "marketing and pricing

strategy," PI Defs. Br. at 14, will be relevant to Regeneron's argument does not detract from the overwhelmingly common factual analysis.

The "balance of the equities" factor will require Chief Judge Kleeh to balance the harm that Regeneron may suffer without an injunction against the harm that Defendants may incur if an injunction is granted. *See Hybritech Inc. v. Abbotts Labs.*, 849 F.2d 1446, 1457 (Fed. Cir. 1988). The harm to Regeneron will be the same across the actions, as discussed above. And the "harm" of an injunction to each Defendant is obvious, and identical: because none of the Defendants have launched their products yet, an injunction would only delay commercialization of each Defendant's biosimilar product. *See Par Pharms., Inc. v. TWI Pharms., Inc*., 2014 WL 3956024, at *4-5 (D. Md. Aug. 12, 2014) (finding that the balance of harms "weighs in favor of granting a stay" because the infringer had not yet entered the market, thus it did not "face the same kind of structural harm if the status quo [was] maintained that [the patentee] would suffer if it [was] not"); *see also Robert Bosch*, 659 F.3d at 1156 ("[R]equiring [a patentee] to compete against its own patented invention, with the resultant harms . . ., places a substantial hardship on [the patentee].").

To determine whether an injunction is in the public interest, Chief Judge Kleeh will consider the injunction's "impact on the public interest." *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1374, 1383–84 (Fed. Cir. 2006) (internal quotation omitted). Yet again, the public interests are identical across these six cases and are not Defendant-specific. Most notably, a key public interest in all of the actions is protecting intellectual property rights and encouraging investment in drug research and development from innovative companies like Regeneron. *See Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1348 (Fed. Cir. 2006); *Apple Inc. v. Samsung Elecs. Co.*, 809 F.3d 633, 647 (Fed. Cir. 2015) ("[T]he public interest nearly always

weighs in favor of protecting property rights in the absence of countervailing factors, especially when the patentee practices his invention."). That is true whether the accused infringer is Amgen, Celltrion, Formycon, Samsung, Mylan, or Biocon. Common issues of fact are nearly the *only* issues of fact in terms of these three PI factors.

III. Personal Jurisdiction Motions Do Not Diminish the Need for Centralization.

Defendants' final argument relates to the motions to dismiss for lack of personal jurisdiction filed by Samsung, Formycon, and Celltrion in four of the pending cases in the Northern District of West Virginia. The motions do not diminish the merits of Regeneron's Motion to Transfer the Amgen Action, and accusations that Regeneron is "seek[ing] to circumvent the PI Defendants' challenge to personal jurisdiction," PI Defs. Br. at 4, are baseless.

First, these motions to dismiss are without merit. Federal Circuit case law plainly governs and supports personal jurisdiction in any United States jurisdiction where a defendant seeks approval to market an infringing product, including West Virginia. *Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755, 762–63 (Fed. Cir. 2019). Chief Judge Kleeh has already issued a schedule for adjudicating the motions to dismiss without slowing down preliminary injunction proceedings (in his court or any other). *See* Regn. Ex. 7. Indeed, Chief Judge Kleeh's ability to coordinate the multiple actions already in front of him illustrates that this case is well-suited to centralization. Defendants' meritless motions to dismiss are no reason to deny transfer of the action against Amgen, a different Defendant, to West Virginia.

Second, even if Chief Judge Kleeh were to grant the motions to dismiss, the merits of Regeneron's Motion to Transfer would be stronger, not weaker. Scattering the actions across several jurisdictions enhances the need for transfer and centralization. The common questions of fact discussed above remain applicable to any transferred defendants, and thus the efficiencies, convenience, and desire to avoid inconsistent rulings created by centralization would be

amplified if more than just Amgen were outside of the Northern District of West Virginia. And "the power of the Panel and the courts to effectuate a transfer under [Section] 1407 is not vitiated by the transferor court's lack of personal jurisdiction over a defendant." *In re Libr. Editions of Children's Books*, 299 F. Supp. 1139, 1142 (J.P.M.L. 1969). Chief Judge Kleeh would not lose any of his prior knowledge of the key issues in the case, and centralization before him in the Northern District of West Virginia would remain the most logical choice, including for all the reasons explained above.

Third, Regeneron's Motion to Transfer was not made with any "improper purpose" to "circumvent" Chief Judge Kleeh's ruling on the motions to dismiss. PI Defs. Br. at 1. Defendants themselves recognize that "personal jurisdiction is not generally a pertinent factor in the Section 1407 analysis." *Id.* at 5; *see also In re: Helicopter Crash*, 542 F. Supp. 2d at 1363; *In re FMC Corp. Pat. Litig.*, 422 F. Supp. 1163, 1165 (J.P.M.L. 1976). The straightforward purpose of the Motion was to transfer the Amgen Action to West Virginia. The meritless motions to dismiss filed by Defendants other than Amgen were not particularly relevant and not ripe for discussion (two of them had not even been filed yet). Further, Regeneron did not conceal anything from the Panel. It filed as an exhibit Chief Judge Kleeh's "Order Setting Briefing Schedule *on Motions to Dismiss* and Setting Schedule for Preliminary Injunction Proceedings," Regn. Ex. 7 (emphasis added), and even noted explicitly that the schedule pertained to preliminary injunction proceedings and dispositive motions to make the posture abundantly clear, *see* Mot. to Expedite at 2.

Defendants also try to portray Regeneron's Motion to Expedite as some sort of smoking gun showing that Regeneron was trying to "circumvent" the motions to dismiss. PI Defs. Br. at 6–7. Not at all true, nor fair. The goal of the Motion to Expedite—as stated repeatedly therein,

see Mot. to Expedite at 2, 4—was to facilitate a preliminary injunction schedule for the Amgen Action that matched the schedule already entered by Chief Judge Kleeh as to Samsung, Celltrion, and Formycon. It was not related to the motions to dismiss, and it mentioned dispositive motion briefing to take place in those actions. *Id.* at 2 ("Chief Judge Kleeh entered a schedule for those proceedings (as well as for dispositive motion briefing) in West Virginia."). While Amgen may now be on a different schedule for preliminary injunction proceedings, centralization in the Northern District of West Virginia is nonetheless warranted, as explained above.

The PI Defendants conclude their discussion of the motions to dismiss by proposing that the Panel "choose Delaware instead" of West Virginia for centralization of these actions. PI Defs. Br. at 8. This proposal concedes the entire dispute—these defendants recognize that an MDL makes sense, they just do not want the MDL to be convened in West Virginia. But Chief Judge Kleeh already has substantially more experience with the common issues of law and fact than any judge in Delaware, and there can be no credible dispute that the District of Delaware's docket is more congested than the Northern District of West Virginia's. The proper place to convene the MDL is before the judge who has already invested over a year of time and hundreds of pages of rulings on these matters.

CONCLUSION

For the foregoing reasons and those in its opening brief, Regeneron respectfully requests that the Panel transfer *Regeneron Pharmaceuticals, Inc. v. Amgen Inc.*, C.A. No. 2:24-cv-00264, currently pending in the United States District Court for the Central District of California, to Chief Judge Kleeh in the United States District Court for the Northern District of West Virginia, for coordinated pretrial proceedings.

Dated: February 9, 2024

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EXHIBIT 8

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF WEST VIRGINIA

Regeneron Pharmaceuticals, Inc.
Plaintiff,
VS. CIVIL ACTION NO. 1:23-cv-89
Celltrion, Inc.
Defendant.

- - -

Regeneron Pharmaceuticals, Inc.
Plaintiff,
VS. CIVIL ACTION NOS. 1:23-cv-94
Samsung Bioepis Co., Ltd. 1:23-cv-106
Defendant.

- - -

Regeneron Pharmaceuticals, Inc.
Plaintiff,
VS. CIVIL ACTION NO. 1:23-cv-97
Formycon AG,
Defendant.

- - -

Proceedings had in the status conference of the above-styled action on January 5, 2024, before Honorable Thomas S. Kleeh, District Judge, at Clarksburg, West Virginia.

- - -

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Proceedings recorded utilizing realtime translation.
Transcript produced by computer-aided transcription.

If I could just briefly address some of the points that were just made by Regeneron's counsel. First of all, on the timeline, there were many communications between Samsung and Regeneron that aren't on the timeline.

THE COURT: One of the many, many benefits of me escaping that side of the room and coming up here is I no longer concern myself with daily emails among counsel, largely. I appreciate all the good and hard work everyone does, but yeah, understood.

MR. TRAUPMAN: Fair enough, and I won't say anything more on that point, Your Honor.

THE COURT: Understood.

MR. TRAUPMAN: And to be clear, we do have a problem with the schedule. We laid that out in our papers yesterday. And the fundamental problem we have is, as we stated, this whole notion that there needs to be extensive discovery before a preliminary injunction motion is filed. From our view, Regeneron already has -- I forget how many -- 160,000-plus pages of documents from us. And if you read the statute, it talks about engaging and cooperating in discovery after the preliminary injunction motion has been filed.

So Samsung Bioepis's view of the way things should proceed is we should get through the jurisdictional issues. Again, I'll note that under the default local rule schedule, at least with respect to Samsung's motion to dismiss, it can and,

in our view, should be fully dismissed by January 25th. What we said in our briefing is thereafter, if the Court determines it has jurisdiction, then the parties can meet and confer on a schedule, but Regeneron's proposal that we have problems with for some of the reasons I just mentioned, but Regeneron's proposal envisions them filing their preliminary injunction motion sometime in late February.

If the Court will have fully briefed to the jurisdictional issues by January 25th, the Court has some time to decide the personal jurisdiction issues, and we can still conceivably, depending on how things play out, have Regeneron file their preliminary injunction motion in late February, again, without any of the pretrial discovery, because we don't think that's necessary on a merits-based level, but of course we also think it's inappropriate because of the jurisdictional issues we raised. So we do have a problem with this schedule, and I don't think how Regeneron characterized our position was accurate.

But I also just want to point out two points in -- one point from the case law, which is, ordering this discovery is discretionary, and we certainly think that the appropriate discretion here is to not move forward, particularly with a timely filed -- and again, it's only been a week since the second complaint was filed. We are really trying to get these issues resolved promptly. Again, the schedule can get fully

briefed by February 25th.

But we heard about the alleged burden on Regeneron. Again, this is a problem entirely of Regeneron's own making. We told them these issues. We articulated the legal theories on November 21st, the day before they filed the first complaint, and yet they're here in West Virginia, when they could have been somewhere else and we could have been moving things along.

So for them to come, at least with respect to Samsung Bioepis, and claim burden, rings hollow, in our opinion, Your Honor. This is a situation -- and they could fix the situation tomorrow or Monday, I guess, because it's Friday, if they so chose.

THE COURT: I don't think they're shutting PACER down over the weekend.

MR. TRAUPMAN: Probably not.

So the point is, maybe they could get something on file by 5:00 p.m. today, I don't know, but this is, again, from our view, a situation entirely of their own making.

And so, again, we have structured our case such that the personal jurisdiction briefing can be fully done by January 25th. That would still give the parties enough time with this 180-day clock, even if the Court finds not personal jurisdiction is improper here, so that's what we think should happen.

And then this other notion of, well, if the merits-based discovery progresses, it's going to be useful anywhere else, that's good in theory, but I think it does raise some practical questions. And I'm not saying any of this is going to happen, but these are things to think about. If the Court issues a discovery ruling in the -- while things are pending and it turns out it doesn't have personal jurisdiction, are the parties still bound? Is that discovery ruling still binding on the parties in the next court where the Court has made a judicial determination on an issue in a case in which it didn't have jurisdiction?

The protective order, if there's a violation of the protective order, there's protective order issues I think that's come up in the *Mylan* case, and then the Court finds that it doesn't have jurisdiction, I mean, is that still valid?

THE COURT: That's a wonderful civil procedure exam y'all have created. Counsel, I'm certainly mindful of all of those issues, and I think they're appropriately raised here on behalf of the District Judges' union.

One concern I have is if this Court determines it does not have jurisdiction and then how it would be perceived in the District Court of Massachusetts or wherever else, if this Court determines it does not have jurisdiction, it lands when that District Judge sees this has been filed and starts muttering profanity under his or her breath at me because let's

say I take 44 or 69 days or whatever the over/under might be pending on these, all that time metes against the clock that ultimately some District Court is going to have to deal with, because that 180-day number is not going anywhere. So that's part of the concern.

But I'm certainly mindful of the jurisdictional quagmire created if we do have parallel tracks dealing with the jurisdictional challenges and the merits. Again, it's a master's-level class here.

MR. TRAUPMAN: That's why this -- in our view, the simple solution is Regeneron just pursue this action in a jurisdiction where it's appropriate. But unless Your Honor has any other questions, that's everything.

THE COURT: I don't. I don't. I'm sorry. Okay.

Celltrion. Counsel, anything else?

MR. GOTTLIEB: Yes, Your Honor, briefly. Apologies. It's a bit of a maze to get up here with everyone.

THE COURT: It is, but again, it's lovely carpet now.

MR. GOTTLIEB: It's beautiful carpet, much improved, Your Honor.

THE COURT: It may or may not be the basis -- I know all of our out-of-state lawyers are very, very concerned about the state of Mountaineer basketball, as we all are here. This carpet might also be one of the unidentified bases for certain recusal orders that were entered at the end of 2023.

MR. GOTTLIEB: Recusal orders that the bar of West Virginia enjoyed greatly.

THE COURT: My 16-year-old son is still not speaking to me.

MR. GOTTLIEB: Your Honor, to go quickly, one, there's all this talk of 69 days or whatever it is, but it's clear -- two things are clear. And to the extent the Court intends to rely on the factual allegations in that presentation, Celltrion would request an opportunity to submit a bench memorandum that provides our side of the coin, Your Honor.

But moving past that, Celltrion had made very clear to Regeneron, when it could have sued Celltrion months ago, if you're going to sue us, sue us in a certain location and we won't have any problems and we'll get it going. Celltrion, Your Honor, even proposed a trial schedule in which let's do this cooperatively and let's lay this out. When Regeneron did file here, Your Honor, again, Celltrion asked, give us the 4(d) waiver or give -- serve us properly and we'll get going. They didn't do that. Here we are.

And more to that, Your Honor, we actually do have a proposed schedule, and with apologies to Regeneron, we've got a lot more moving parts here, and we haven't even been formally served but, Your Honor, we do have issues with the proposed schedule, but this closely aligns to what Regeneron had

EXHIBIT 9

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

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC., and BIOCON BIOLOGICS INC.,

Defendants.

Case No. 1:22-cv-00061-TSK

REGENERON'S PROPOSED PERMANENT INJUNCTION SCHEDULE

Event	Deadline
Regeneron delivers targeted requests for production to Defendants (limited to issues relevant to injunction proceedigns)	January 19, 2024 [Completed]
Regeneron produces documents relevant to permanent injunction proceedings	Within two business days of entry of this order.
Defendants produces documents responsive to Regeneron's requests	February 15, 2024
Regeneron to file motion for permanent injunction and supportive memorandum	The later of February 22, 2024 or seven days after Defendants produce documents responsive to Regeneron's requests.
Depositions of any Regeneron declarants complete	March 13, 2024
Defendants file opposition to motion for permanent injunction	March 21, 2024
Deposition of Defendants' declarants complete	April 10, 2024
Regeneron files reply in support of permanent injunction	April 18, 2024

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

EXHIBIT 10

Griffin, Renee

From: Brett A. Postal <bpostal@rothwellfigg.com>
Sent: Thursday, February 8, 2024 10:23 AM
To: Kayali, Kathryn; Gutman, Siegmund Y.; John R. Labbe; kflower@marshallip.com; tburns@marshallip.com; E. Anthony Figg; Joseph A. Hynds; Jennifer Nock; wendy@amgen.com; eagovino@amgen.com; ppelleti@amgen.com
Cc: Eylea; Eylea Biosimilars
Subject: RE: MDL No. 3103: In re Aflibercept Patent Litigation

Kat:

We do not understand the basis for your request and disagree with the characterizations in your email. Our MDL opposition brief does not suggest that we have shared Amgen confidential information with the other defendants. Rather, our brief states that Amgen's action will involve defenses unique to Amgen because certain defenses are based on Amgen's confidential manufacturing processes, such as its defenses under 35 U.S.C. § 273. Opp. at 8. As also explained in our brief, Amgen is a direct competitor of the other defendants and "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." Opp. at 13.

As you know, Amgen's contentions pursuant to 28 U.S.C. § 262(l)(3)(B) include highly confidential information and are designated as confidential pursuant to 28 U.S.C. § 262(l). By statute, such information cannot be provided to third parties such as the Celltrion, Samsung, Formycon, and Mylan defendants. 28 U.S.C. § 262(l)(C). Moreover, "[c]onfidential information shall be used for the sole and exclusive purpose of determining with respect to each patent assigned to or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted if the subsection (l) applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k)." 28 U.S.C. § 262(l)(D). Regeneron's proposed use of such information would be in clear violation of these statutory restrictions.

Amgen does not agree to Regeneron's service of unredacted copies of excerpts from Amgen's 28 U.S.C. § 262(l)(3)(B) contentions. Moreover, Amgen will not agree to any use by Regeneron of Amgen's confidential information designated as such pursuant to 28 U.S.C. § 262(l), including any such use in Regeneron's reply in support of its JPML motion, which would be a clear violation of the BPCIA provisions.

Best regards,
Brett

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Cc: Eylea <Eylea@wc.com>; Eylea Biosimilars <Eylea.Biosimilars@weil.com>
Subject: [EXTERNAL] MDL No. 3103: In re Aflibercept Patent Litigation

Counsel,

In your MDL opposition brief, you stated that your defenses differ from the defenses raised by other Defendants (Formycon, Celltrion, Samsung Bioepis, Mylan and/or Biocon). We therefore assume you reviewed the defenses asserted by other Defendants or otherwise conferred regarding their content. Please confirm that you therefore agree to Regeneron's service of unredacted copies of excerpts of Amgen's contentions pursuant to 28 U.S.C. § 262(*l*)(3)(B) (or information contained therein) on outside counsel for each of the other Defendants, which will be included as part of Regeneron's JPML reply. Any such material will be filed under seal or redacted and not visible to the public. To the extent your position differs as to Amgen's infringement contentions and Amgen's invalidity contentions, please so specify. In the absence of agreement, we will need to serve outside counsel only with redacted copies of Regeneron's reply.

In the alternative, if your client does not consider its contentions to be confidential, please let us know so that we may dispense with the sealing process.

Best,

Kat

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Cc: Eylea; Eylea Biosimilars
Subject: RE: MDL No. 3103: In re Aflibercept Patent Litigation

Counsel,

You are not authorized to use Celltrion's 3(B) contentions in support of Regeneron's reply brief in support of its MDL transfer, and any attempt to do so is a clear violation of the BPCIA. Per the parties' September 13, 2023 Confidentiality Agreement, Celltrion's 3(B) contentions were provided "for the sole and exclusive purpose of permitting Regeneron to determine whether a claim of patent infringement could reasonably be asserted with respect to one or more patents," not for Regeneron to improperly use them to buttress jurisdictional arguments. The BPCIA itself is consistent with this limitation. Section 262(*l*)(1)(D) of the statute clearly limits the use of Celltrion's 3(B) contentions "for the sole and exclusive purpose of determining, with respect to each patent assigned to or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k)." As such, you do not have permission to attach, quote, or reference Celltrion's 3(B) contentions in support of your reply brief, or to circulate the contentions to third parties. Please immediately confirm that you will not take any such action in violation of the parties' Confidentiality Agreement, or the BPCIA. To the extent Regeneron continues to misuse the 3(B) contentions, Celltrion reserves all rights to seek appropriate relief, e.g., under Section 262(*l*)(1)(H).

Best,
Mike

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Subject: MDL No. 3103: In re Aflibercept Patent Litigation

Counsel,

In your MDL opposition brief, you stated that your defenses differ from the defenses raised by other Defendants (Amgen, Formycon, Samsung Bioepis, Mylan and/or Biocon). We therefore assume you reviewed the defenses asserted by other Defendants or otherwise conferred regarding their content. Please confirm that you therefore agree to Regeneron's service of unredacted copies of excerpts of Celltrion's contentions pursuant to 28 U.S.C. § 262(*l*)(3)(B) (or information contained therein) on outside counsel for each of the other Defendants, which will be included as part of Regeneron's JPML reply. Any such material will be filed under seal or redacted and not visible to the public. To the extent your position differs as to Celltrion's infringement contentions and Celltrion's invalidity contentions, please so specify. In the absence of agreement, we will need to serve outside counsel only with redacted copies of Regeneron's reply.

In the alternative, if your client does not consider its contentions to be confidential, please let us know so that we may dispense with the sealing process.

Best,

Kat

Kathryn S. Kayali
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EXHIBIT 12

Griffin, Renee

From: Fogel, Louis E. <LFogel@ enner.com>
Sent: Thursday, February 8, 2024 12:14 PM
To: Kayali, Kathryn; bspann@tcspllc.com; dgriffith@tcspllc.com; an Horn, Shaun M.; Mascherin, Terri L.
Cc: Eylea; Eylea Biosimilars; DL FYB203Internal
Subject: RE: MDL No. 3103: In re Aflibercept Patent Litigation

Counsel,

We reject your request to serve unredacted copies of excerpts of Formycon's Detailed Statement pursuant to 42 U.S.C. § 262( )(3)(B) or information contained therein on outside counsel for other defendants. As you acknowledge, Formycon designated its § 262( )(3)(B) contentions as confidential information pursuant to the parties' August 23, 2023 Section 262( ) Confidentiality Agreement and § 262( )(1). Pursuant to the Confidentiality Agreement, only Regeneron's Authorized Evaluators may view Formycon's confidential information. And pursuant to § 262( )(1)(D), such confidential information "shall be used for the sole and exclusive purpose of determining, with respect to each patent assigned to or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k)." Regeneron's JPML reply clearly falls outside the scope of that sole and exclusive purpose for using Formycon's confidential information. And nothing about the statement in our JPML opposition suggests a waiver of Formycon's rights with respect to its confidential information.

As such, any disclosure or use of Formycon's confidential information in connection with Regeneron's JPML reply would constitute a violation of the parties' Confidentiality Agreement and § 262( )(1), for which Formycon would be entitled to seek immediate injunctive relief. Formycon reserves all rights with respect to the confidentiality of its § 262( )(3)(B) contentions.

Best regards,
Louis

Kayali, Kathryn <KKayali@wc.com>
Wednesday, February 7, 2024 4:15 AM
bspann@tcspllc.com; dgriffith@tcspllc.com; Fogel, Louis E. <LFogel@jenner.com>; an Horn, Shaun M. <SanHorn@jenner.com>; Mascherin, Terri L. <TMascherin@jenner.com>
Eylea <Eylea@wc.com>; Eylea Biosimilars <Eylea.Biosimilars@weil.com>
MDL No. 3103: In re Aflibercept Patent Litigation

Counsel,

In your MDL opposition brief, you stated that your defenses differ from the defenses raised by other Defendants (Amgen, Celltrion, Samsung Bioepis, Mylan and/or Biocon). We therefore assume you reviewed the defenses asserted by other Defendants or otherwise conferred regarding their content. Please confirm that you therefore agree to Regeneron's service of unredacted copies of excerpts of Formycon's contentions pursuant to 28 U.S.C. § 262( )(3)(B) (or information contained therein) on outside counsel for each of the other Defendants, which

will be included as part of Regeneron's JPML reply. Any such material will be filed under seal or redacted and not visible to the public. To the extent your position differs as to Formycon's infringement contentions and Formycon's invalidity contentions, please so specify. In the absence of agreement, we will need to serve outside counsel only with redacted copies of Regeneron's reply.

In the alternative, if your client does not consider its contentions to be confidential, please let us know so that we may dispense with the sealing process.

Best,

Kat

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EXHIBIT 13

Griffin, Renee

From: Kayali, Kathryn
Sent: Thursday, February 8, 2024 :4 PM
To: ach Summers; Laura Fairneny; clt@simmermanlaw.com; fes@simmermanlaw.com; trey@simmermanlaw.com; Matthew Robson; Matthew Traupman; Ray Nimrod; skl@schraderlaw.com
Cc: Eylea; Eylea Biosimilars; E Samsung Bioepis
Subject: RE: MDL No. 3103: In re Aflibercept Patent Litigation

Counsel:

Needless to say, we disagree entirely with your posture and rhetoric below. Requesting permission to disclose information is not a "threat" nor does it in any way violate the BPCIA to the contrary, such requests are explicitly contemplated by statute. While we thoroughly dispute that, for example, an assertion that a public document anticipates or renders obvious a public patent could possibly be confidential, we will abide by your refusal to permit the JPML to view materials relevant to its decision. Accordingly, we will not disclose the contents of Samsung Bioepis's contentions in our MDL filings or otherwise attach excerpts of those contentions as exhibits. We will inform the JPML that we requested permission to do so and permission was denied. We trust this resolves your concerns.

Best,

Kat

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kkayali@wc.com | www.wc.com

From: ach Summers <zachsummers@quinnemanuel.com>
Sent: Thursday, February 8, 2024 5:11 PM
To: Laura Fairneny <laurafairneny@quinnemanuel.com>; Kayali, Kathryn <KKayali@wc.com>; clt@simmermanlaw.com; fes@simmermanlaw.com; trey@simmermanlaw.com; Matthew Robson <matthewrobson@quinnemanuel.com>; Matthew Traupman <matthewtraupman@quinnemanuel.com>; Ray Nimrod <raynimrod@quinnemanuel.com>; skl@schraderlaw.com
Cc: Eylea <Eylea@wc.com>; Eylea Biosimilars <Eylea.Biosimilars@weil.com>; E - Samsung Bioepis <qe-samsungbioepis@quinnemanuel.com>
Subject: RE: MDL No. 3103: In re Aflibercept Patent Litigation

Counsel:

We have not received any response from you. Please confirm Regeneron and its counsel have immediately ceased their use of SB's confidential information for the MDL or any other purpose not permitted by the statute. In particular, please confirm before 8 pm ET today that Regeneron withdraws its threat to use or reference the contents of SB's 3B contentions in its MDL papers. If Regeneron does not do so, SB intends to seek a TRO from the Court tomorrow morning, pursuant to 42 U.S.C. § 262(l)(1)(H). That provision specifies that injunctive relief is appropriate and necessary for any violation or threatened violation of the confidentiality provisions of the BPCIA, which still govern that material here. *See* 42 U.S.C. § 262(l)(1)(H) ("[t]he disclosure of any confidential information in violation of this paragraph shall be

deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to be an appropriate and necessary remedy for any violation or threatened violation of this paragraph").

Best,
ach

From: Laura Fairneny <laurafairneny@quinnemanuel.com>
Sent: Wednesday, February 7, 2024 9:48 AM
To: Kayali, Kathryn <KKayali@wc.com>; clt@simmermanlaw.com; fes@simmermanlaw.com; trey@simmermanlaw.com; Matthew Robson <matthewrobson@quinnemanuel.com>; Matthew Traupman <matthewtraupman@quinnemanuel.com>; Ray Nimrod <raynimrod@quinnemanuel.com>; ach Summers <zachsummers@quinnemanuel.com>; skl@schraderlaw.com
Cc: Eylea <Eylea@wc.com>; Eylea Biosimilars <Eylea.Biosimilars@weil.com>; E - Samsung Bioepis <ge-samsungbioepis@quinnemanuel.com>
Subject: RE: MDL No. 3103: In re Aflibercept Patent Litigation

Counsel,

Your email is deeply troubling. As your email notes, SB designated its 3B contentions as confidential pursuant to 42 U.S.C. § 262(*l*)(1). Section 262(*l*)(1)(D) provides explicit limitations on the use of SB's confidential information: "Confidential information shall be used for the ***sole and exclusive purpose of determining***, with respect to each patent assigned to or exclusively licensed by the reference product sponsor, ***whether a claim of patent infringement could reasonably be asserted*** if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k)." (emphases added). Plainly, Regeneron's briefing in support of its motion to transfer and centralize its lawsuits against third parties Biocon, Mylan, Celltrion, Formycon and Amgen falls outside the scope of permissible uses of SB's confidential information. Yet, your email demonstrates that Regeneron already has used SB's confidential information for the impermissible purpose of preparing its reply brief. SB demands that Regeneron and its counsel immediately cease their use of SB's confidential information for purposes not permitted by the statute. Any reference to the contents of SB's 3B contentions in Regeneron's brief before the JPML would constitute a breach of the statutory use limitations, and in particular your stated intention of attaching or quoting all or part of SB's 3B contentions in connection with Regeneron's upcoming reply brief would constitute an egregious violation of statute for which SB will seek immediate relief.

Your email is the latest in a long and ongoing deliberate set of acts by Regeneron and its outside counsel of misusing confidential information produced by aflibercept biosimilar applicants. SB expects Regeneron to immediately take steps to ensure its full compliance with the relevant confidentiality provisions, and SB reserves its right to seek appropriate relief from Regeneron's repeated and ongoing misuse of confidential information.

Regards,
Laura

From: Kayali, Kathryn <KKayali@wc.com>
Sent: Tuesday, February 6, 2024 11:49 PM
To: clt@simmermanlaw.com; fes@simmermanlaw.com; trey@simmermanlaw.com; Laura Fairneny <laurafairneny@quinnemanuel.com>; Matthew Robson <matthewrobson@quinnemanuel.com>; Matthew Traupman <matthewtraupman@quinnemanuel.com>; Ray Nimrod <raynimrod@quinnemanuel.com>; ach Summers <zachsummers@quinnemanuel.com>; skl@schraderlaw.com
Cc: Eylea <Eylea@wc.com>; Eylea Biosimilars <Eylea.Biosimilars@weil.com>
Subject: MDL No. 3103: In re Aflibercept Patent Litigation

T NAL MAIL from kkayali wc.com

Counsel,

In your MDL opposition brief, you stated that your defenses differ from the defenses raised by other Defendants (Amgen, Formycon, Celltrion, Mylan and/or Biocon). We therefore assume you reviewed the defenses asserted by other Defendants or otherwise conferred regarding their content. Please confirm that you therefore agree to Regeneron's service of unredacted copies of excerpts of Samsung Bioepis's contentions pursuant to 28 U.S.C. § 262( )(3)(B) (or information contained therein) on outside counsel for each of the other Defendants, which will be included as part of Regeneron's JPML reply. Any such material will be filed under seal or redacted and not visible to the public. To the extent your position differs as to Samsung Bioepis's infringement contentions and Samsung Bioepis's invalidity contentions, please so specify. In the absence of agreement, we will need to serve outside counsel only with redacted copies of Regeneron's reply.

In the alternative, if your client does not consider its contentions to be confidential, please let us know so that we may dispense with the sealing process.

Best,

Kat

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EXHIBIT 14

Griffin, Renee

From: Aviv alcenstein <a alcenstein@geminilaw.com>
Sent: Friday, February 2, 2024 4:0 PM
To: Patel, Priyata; DG Aflibercept; FG aflibercept@willkie.com
Cc: Eylea Biosimilars; Eylea; REGENER N PATENT
Subject: RE: Regeneron v. elltrion: [redacted]

Dear Priya,

[redacted]

Moreover, Regeneron affirmatively chose to submit a schedule, which the Court accepted, that did not require Celltrion to provide any invalidity contentions in advance of Regeneron's PI motion. At the January 5 conference, Mr. Berl told the Court that Regeneron "proposed a schedule that [it] thought was fair." Tr. at 20:24-21:1. Regeneron cannot now claim prejudice from a schedule that it proposed.

Regards,

Aviv alcenstein
e

GEMINI

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New York, NY 10010
o 1 917 226 7720
azalcenstein@geminilaw.com | geminilaw.com

From: Patel, Priyata <Priyata.Patel@weil.com>
Sent: Wednesday, January 31, 2024 7:28 AM

To: DG-Aflibercept <DG-Aflibercept@NETORG8512690.onmicrosoft.com>; WFG-aflibercept@willkie.com
Cc: Eylea Biosimilars <Eylea.Biosimilars@weil.com>; Eylea <Eylea@wc.com>; REGENERON PATENT <REGENERONPATENT@lists.kellogghansen.com>
Subject: Regeneron v. Celltrion: [redacted]

Counsel,

[redacted]

By February 6, 2024, we request that Celltrion supplement its invalidity contentions to identify the particular art, arguments, and reference claims that it actually intends to rely on in the PI proceedings, for the eight PI patents. Celltrion's failure to timely put forward its positions, as required, is causing ongoing and material prejudice, and Regeneron reserves all rights.

Thanks,

Weil

Priyata Y. Patel
Pronouns: She/her/hers

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priyata.patel@weil.com
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EXHIBIT 15

Griffin, Renee

From: Fogel, Louis E. <LFogel@ enner.com>
Sent: Tuesday, February , 2024 :1 PM
To: Mahaffy, Shaun; an Horn, Shaun M.; Tuchman, Haley B.; Kang, Michael B.
Cc: Eylea; Eylea Biosimilars; DL FYB203Internal
Subject: RE: Regeneron v. Formycon: [redacted]

Counsel,

[redacted]

Formycon's Detailed Statement does *n t* relate to Regeneron's motion for preliminary injunction it neither sets forth the invalidity contentions Formycon intends to assert in the PI proceedings nor limits the invalidity contentions Formycon may assert in the proceedings. *enente n en n* , 2020 WL 636439, at 4 5 (D. Del. Feb. 11, 2020). The preliminary injunction schedule entered in this case does not include a date for Formycon to identify its non-infringement or invalidity contentions. Tellingly, Regeneron proposed this schedule and made the strategic decision not to include this event. Mr. Berl then repeatedly told the court during the Scheduling Conference that Regeneron's proposed schedule was "fair." What is unfair is Regeneron's belated request that Formycon provide non-infringement and invalidity contentions it intends to rely on prior to Regeneron filing its preliminary injunction motion. Regeneron had the opportunity to include this in its proposed schedule, but chose not to do so.

For at least these reasons, Formycon reserves the right to assert any and all non-infringement and invalidity grounds in opposition to Regeneron's motion for preliminary injunction, including those not presented in Formycon's Detailed Statement.

Best regards,
Louis

From: Mahaffy, Shaun <SMahaffy@wc.com>
Sent: Wednesday, January 31, 2024 1:30 AM
To: Fogel, Louis E. <LFogel@jenner.com>; an Horn, Shaun M. <S anHorn@jenner.com>; Tuchman, Haley B. <HTuchman@jenner.com>; Kang, Michael B. <MKang@jenner.com>
Cc: Eylea <Eylea@wc.com>; Eylea Biosimilars <Eylea.Biosimilars@weil.com>
Subject: Regeneron v. Formycon: [redacted]

Counsel,

[redacted]

[redacted]

By February 6, 2024, we request that Formycon supplement its invalidity contentions with the particular art combinations and arguments that it actually intends to rely on in the PI proceedings, for the eight PI patents. Formycon's failure to timely put forward its positions, as required, is causing ongoing and material prejudice, and Regeneron reserves all rights.

Thanks,

Shaun

Sha n P. Maha y

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BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

In re Aflibercept Patent Litigation	MDL No. 3103

SCHEDULE OF ACTIONS

Case Captions	Court	Civil Action No.	Judge
Plaintiff: Regeneron Pharmaceuticals, Inc. **Defendants:** Mylan Pharmaceuticals Inc. Biocon Biologics Inc. **Counter Claimants:** Mylan Pharmaceuticals Inc. Biocon Biologics Inc. **Counterclaim Defendant:** Regeneron Pharmaceuticals, Inc. **Intervenors:** Amgen USA, Inc. Celltrion, Inc.	N.D. W. Va.	1:22-cv-00061	Kleeh, C.J.
Plaintiffs: Regeneron Pharmaceuticals, Inc. **Defendants:** Celltrion, Inc.	N.D. W. Va.	1:23-cv-00089	Kleeh, C.J.
Plaintiffs: Regeneron Pharmaceuticals, Inc. **Defendants:** Samsung Bioepis Co. Ltd.	N.D. W. Va.	1:23-cv-00094	Kleeh, C.J.

Plaintiffs: Regeneron Pharmaceuticals, Inc. **Defendants:** Samsung Bioepis Co. Ltd.	N.D. W. Va.	1:23-cv-00106	Kleeh, C.J.
Plaintiffs: Regeneron Pharmaceuticals, Inc. **Defendants:** Formycon AG	N.D. W. Va.	1:23-cv-00097	Kleeh, C.J.
Plaintiffs: Regeneron Pharmaceuticals, Inc. **Defendants:** Amgen Inc.	C.D. Cal.	2:24-cv-00264	Holcomb, J.

Dated: February 9, 2024

OF COUNSEL:

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*/s/ David I. Berl*_____

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Attorneys for Plaintiff Regeneron Pharmaceuticals, Inc.

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 Consolidated Reply Brief, Exhibits, Schedule of Actions, and Proof of Service were served by Email on February 9, 2024 to the following:

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

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

Counsel for Defendants/Counter Claimants Mylan Pharmaceuticals Inc. and Biocon Biologics Inc.

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

Counsel for Defendant Celltrion, Inc.

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Regeneron Pharmaceuticals, Inc. v. Samsung Bioepis Co. Ltd.,
N.D. W. Va., C.A. No. 1:23-cv-00094-TSK
N.D. W. Va., C.A. No. 1:23-cv-00106-TSK

Counsel for Defendant Samsung Bioepis Co. Ltd.

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***Regeneron Pharmaceuticals, Inc. v. Formycon AG*,**
N.D. W. Va., C.A. No. 1:23-cv-00097-TSK

Counsel for Defendant Formycon AG

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M. David Griffith, Jr.
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Dated: February 9, 2024

OF COUNSEL:

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Anish R. Desai
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