BEFORE THE UNITED STATES
JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: AFLIBERCEPT PATENT LITIGATION	MDL No. 3103

BIOCON BIOLOGICS INC.'S AND MYLAN PHARMACEUTICALS INC.'S RESPONSE IN OPPOSITION TO REGENERON PHARMACEUTICALS, INC.'S MOTION TO TRANSFER TO THE NORTHERN DISTRICT OF WEST VIRGINIA

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Defendants Biocon Biologics Inc. ("Biocon") and Mylan Pharmaceuticals Inc. ("Mylan") (collectively, the "Biocon Defendants") respectfully submit this Opposition to Plaintiff Regeneron Pharmaceuticals, Inc.'s Motion to Transfer to the Northern District of West Virginia Pursuant to 28 U.S.C. § 1407.

Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron") seeks to centralize diverse patent litigation actions against six Defendants in the Northern District of West Virginia, but Regeneron does not meet the stringent requirements of 28 U.S.C. § 1407. While superficially the allegations against each Defendant involve patent infringement, in reality the specific facts Regeneron must show to meet its burdens of proof as to each and every element of the patent claims will vary widely, and are unique to each of the separate Defendants' products.

More specifically, the patents that will be the most complex and time consuming to address, from a discovery perspective, are those involving manufacturing methods and techniques. Each Defendant has an independent and proprietary method of development and manufacturing that is not in common with any other (or, at the very least, they are not common to the Biocon Defendants). There will be no fact witnesses in common. Each party will be required to have its own scientific non-infringement experts (as the Biocon Defendants would never agree to share any expert who accesses its proprietary information with a competitor on these issues).

Further, as to the Biocon Defendants, marked procedural disparities exist between its litigation, which was filed in 2022 and has already proceeded through extensive fact and expert discovery and an initial trial ("the Biocon Litigation"), and the five separate actions filed in recent months. Unlike the Biocon Litigation, each of the recently-filed subject actions have not substantively progressed; involve different patents and disparate allegations of patent infringement for which unique discovery is necessary; will likely involve new and/or different prior art and

invalidity theories compared to those litigated by the Biocon Defendants; and remain subject to motions to dismiss and/or without a scheduling order.

Thus, Regeneron has not established that the Section 1407 conditions of common factual questions, efficiencies or judicial economy, or the convenience of parties and witnesses, are satisfied. The Biocon Defendants oppose centralization on at least the grounds noted above and those discussed more fully below. The proposed centralization should be denied.

BACKGROUND

Regeneron sued the Biocon Defendants in August 2022, following lengthy exchanges between the parties pursuant to the Biologics Price Competition and Innovation Act ("BPCIA") based on Mylan's filing of a Biologics License Application ("BLA") with the U.S. Food and Drug Administration ("FDA") seeking licensure to market an aflibercept vial product in the United States.[1] *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, Case No. 22-cv-00061, Dkt. No. 1 (N.D.W. Va. Aug. 2, 2022) (the "Biocon Action").

Importantly, and contrary to Regeneron's suggestion, biosimilar litigation matters are vastly different from those brought pursuant to the Hatch-Waxman Act. Unlike Hatch-Waxman, the BPCIA does not limit the scope of patents that may be litigated. In the Hatch-Waxman cases that Regeneron cites, the scope of litigated patents is narrowly restricted by statute to Orange Book listings of the drug's active ingredient; its formulation; or its FDA-approved uses. 21 U.S.C. §§ 355(b)(1)(A)(viii)(1)-(2). Orange Book listings *cannot* include patents directed to methods of manufacturing the drug, test assays, impurity profiles, or packaging. *See, e.g.*, Kate S. Gaudry, *Exclusivity Strategies and Opportunities in View of the Biologics Price Competition and*

[1] Mylan's BLA was subsequently transferred to Biocon, pursuant to which Biocon was formally added as a party to the litigation.

Innovation Act, 66 FOOD & DRUG L.J. 587, 609 (2011) (explaining "not all patents are listed in the Orange Book, including patents claiming processes of manufacturing a drug, metabolites, packaging, and/or drug intermediates"). In the subject actions, Regeneron asserts a multitude of patents and claims that do not cover its own product, and which involve everything from the early stages of manufacturing up to and including specific packaging of the finished product, product intermediates, and off-label method-of-use patents.

Also, unlike Hatch-Waxman cases, the BPCIA did not establish a compulsory process for reference product sponsors, like Regeneron, to identify *all* patents that claim a biologic product or methods of using such products in advance of a biosimilar applicant seeking licensure by submission of a BLA. *Id.* ("Under the BPCIA, there is no public listing of potentially enforceable patents."). Instead, recognizing the complex, multi-step processes needed to manufacture biosimilar products, any pretrial disclosure of relevant patents by a reference product sponsor like Regeneron occurs during the "patent dance"—an orchestrated series of pretrial exchanges wherein a list of patents is provided for which "a claim of patent infringement could reasonably be asserted" *against a particular biosimilar product*. 42 U.S.C. §§ 262(l)(3)(A)-(C). Unsurprisingly then, when BPCIA litigation has proceeded against multiple defendants each seeking FDA licensure for a particular biosimilar product, each litigation involves different infringement allegations that are typically unique and specific to each independently-developed and manufactured product—both in the scope of issues and number of patents involved.[2] The subject actions here are no different.

[2] For example, in separate BPCIA litigation brought against four different biosimilar applicants related to bevacizumab (AVASTIN®), the number of asserted patents ranged from 10 patents to 25 patents, with only three patents in common among all four biosimilar applicants. (*See, e.g.*, *Genentech, Inc. v. Amgen Inc.*, Case No. 17-cv-01407, Dkt. No. 43 at ¶ 34 (D. Del. Dec. 13, 2017) (25 patents); *Genentech, Inc. v. Pfizer Inc.*, Case No. 19-cv-00638, Dkt. No. 1 at ¶ 32 (D. Del. Apr. 5, 2019) (22 patents); *Genentech, Inc. v. Samsung Bioepis Co., Ltd.*, Case No. 20-cv-00859, Dkt.

Shortly after commencing the Biocon Litigation in the Northern District of West Virginia, asserting infringement of 24 patents, the district court granted Regeneron an expedited schedule, wherein the parties undertook complex discovery concerning the details of the Biocon Defendants' BLA product, its manufacturing process, and proposed clinical uses of that product in order to proceed to an initial trial in June 2023—a mere eight months after entry of a scheduling order. (*See* Biocon Action, Dkt. No. 87). Along the way, the West Virginia Court construed claim terms of six patents then in dispute, including based on expert testimony concerning complex issues related to, among other things, allegations of infringement specific to the Biocon Defendants' proposed aflibercept vial product. (*Id.*, Dkt. No. 427). Regeneron took discovery of the Biocon Defendants' product and manufacturing process purportedly directed to the six patents Regeneron selected for an initial trial. The case was then narrowed to four patents, which proceeded through expert discovery, and eventually to a two-week trial in June 2023, involving selected claims from three of those patents: two patents directed to methods of dosing aflibercept and claims from a separate patent relating to aflibercept vial formulations. Before trial, and upon receipt of the district court's claim construction decision, Regeneron stipulated to invalidity or noninfringement for various claims. (*Id.*, Dkt. No. 433). The parties engaged in post-trial briefing, closing arguments, and Judge Kleeh issued his trial decision on December 27, 2023. (*Id.*, Dkt. No. 692). Notices of Appeal to the Federal Circuit were recently filed. (*Id.*, Dkt. Nos. 676-677).

Regeneron, having hand-picked three patents for trial in the initial phase of the Biocon Litigation, has left certain patents unadjudicated, many of which were already subject to discovery and claim construction, potentially unique to the Biocon Defendants' accused product. Pending

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No. 1 at ¶ 3 (D. Del. June 28, 2020) (14 patents); *Genentech, Inc. v. Centus Biotherapeutics Ltd.*, Case No. 20-cv-00361, Dkt. No. 1 at ¶ 9 (E.D. Tex. Nov. 12, 2020) (10 patents)).

before the West Virginia Court is the Biocon Defendants' expedited motion for entry of a scheduling order on the remaining patents, (Biocon Action, Dkt. No. 691), which seeks expedited proceedings on those remaining patents and a 2024 trial. With 18 months of litigation under their belt, the Biocon Defendants are substantially ahead of the other (later-filed) subject actions, have completed an initial trial, already completed *Markman* proceedings on most of the key patents, and have taken substantial discovery relevant to the remaining issues in the Biocon Litigation.

Beginning in November 2023, nearly 16 months after the Biocon Defendants' suit was filed, Regeneron initiated five separate litigations against a second group of aflibercept biosimilar applicants, with infringement allegations spanning anywhere from 32 patents to 52 patents against a particular biosimilar applicant. *See, e.g.*, *Regeneron Pharms., Inc. v. Celltrion, Inc.*, Case No. 23-cv-00089 (N.D.W. Va.) (the "Celltrion Action"); *Regeneron Pharms., Inc. v. Samsung Bioepis Co., Ltd.*, Case No. 23-cv-00094 (N.D. W. Va.) (the "First Samsung Action"); *Regeneron Pharms., Inc. v. Formycon AG*, Case No. 23-cv-00097 (N.D.W. Va.) (the "Formycon Action"); *Regeneron Pharms., Inc. v. Samsung Bioepis Co., Ltd.*, Case No. 23-cv-00106 (N.D.W. Va.) (the "Second Samsung Action"); *Regeneron Pharms., Inc. v. Amgen, Inc.*, Case No. 24-cv-00264 (C.D. Cal.) (the "Amgen Action"). Rather than proceeding to litigate the merits of Regeneron's allegations in those cases, however, the parties have been and continue to be engaged in disputes over service, (*see, e.g.*, Celltrion Action, Dkt. No. 52; First Samsung Action, Dkt. No. 50; Formycon Action, Dkt. No. 37), jurisdiction, (*see, e.g.*, Celltrion Action, Dkt. Nos. 68-69; First Samsung Action, Dkt. No. 47; Formycon Action, Dkt. Nos. 57-58; Second Samsung Action, Dkt. No. 14), and preliminary injunction proceedings, (*see, e.g.*, Celltrion Action, Dkt. No. 61; First Samsung Action, Dkt. No. 69; Formycon Action, Dkt. No. 45; Second Samsung Action Dkt. No. 40). The second group of West Virginia Defendants are subject to an injunction briefing and hearing

schedule that goes out to May 2024, with resolution of their various disputes possibly extending beyond May 2024, while Amgen will not even appear before the California Court to discuss PI proceedings until April 2024. (*Compare* Celltrion Action, Dkt. No. 61, *with* Amgen Action, Dkt. No. 51). Under the Biocon Defendants' submitted discovery schedule in West Virginia, the Biocon Defendants expect to be ready for trial before fact and expert discovery for the second-group Defendants meaningfully begins.

ARGUMENT

28 U.S.C. § 1407(a) permits centralization only where the movant demonstrates that (1) the "actions involv[e] one or more common questions of fact;" (2) centralization will further "the convenience of [the] parties and witnesses;" and (3) centralization "will promote the just and efficient conduct of [the] actions." "Centralization of any litigation—including patent cases—is not automatic, and will necessarily depend on the facts, parties, procedural history and other circumstances in a given litigation." *In re Select Retrieval, LLC, ('617) Patent Litig.*, 883 F. Supp. 2d 1353, 1354 (J.P.M.L. 2012) (quoting *In re Bear Creek Techs., Inc. ('722) Patent Litig.*, 858 F. Supp. 2d 1375, 1379 (J.P.M.L. 2012)) (internal quotation marks omitted). As here, "where only a minimal number of actions are involved, the proponents of centralization bear a heavier burden to demonstrate that centralization is appropriate." *In re JumpSport, Inc., ('845 & '207) Patent Litig.*, 338 F. Supp. 3d 1356, 1357 (J.P.M.L. 2018). Regeneron has not met its heavy burden; centralization should be denied.

A. Regeneron Has Not Demonstrated Sufficient Common Issues of Fact Justifying Centralization.

Regeneron's commonality arguments center on the purported overlap between the subject actions, relying vaguely on an assertion that 13 patents are common to all six suits. (*See* Brief in Support of Motion to Transfer to the Northern District of West Virginia Pursuant to 28 U.S.C. §

1407 ("Reg. Br.") at 2-3, 7). Regeneron, however, omits critical details, including that the Biocon Defendants have already invalidated 4 of the 13 patents, either in the Biocon Litigation or post-grant proceedings before the Patent Trial and Appeals Board, (*see* Biocon Action, Dkt. No. 692 (U.S. Patent Nos. 10,888,601 and 11,253,572); *Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, IPR2021-00881, 2022 WL 16842073 (P.T.A.B. Nov. 9, 2022) (U.S. Patent No. 9,254,338); *Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, IPR2022-01225, 2024 WL 111108 (P.T.A.B. Jan. 9, 2024) (U.S. Patent No. 10,130,681); *Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, IPR2022-01226, 2024 WL 110383 (P.T.A.B. Jan. 9, 2024) (U.S. Patent No. 10,888,601)), and that, on January 17, 2024, Regeneron filed a disclaimer with the U.S. Patent and Trademark Office disclaiming all claims of U.S. Patent No. 10,464,992. (Ex. 1, 1-17-24 Disclaimer). At best, then, Regeneron could suggest commonality for perhaps eight patents between the subject actions. That is a minor subset of the bulk of patents presently asserted in the actions (*i.e.*, over 50 patents are presently asserted against Samsung), which pertain to methods of manufacturing, analytical assays, formulations, and formulation packaging, each of which will involve discovery into processes and formulations that are unique *and confidential* to each party.

Further, centralization is not warranted based simply on rote identification of patents at issue in subject actions—Regeneron must show that common questions of fact *predominate* over individual questions of fact present in each of the subject actions. *See In re Westinghouse Elec. Corp. Emp't Discrimination Litig.*, 438 F. Supp. 937, 939 (J.P.M.L. 1977) (denying centralization under Section 1407 where "individual rather than common factual questions predominate[d]"). Regeneron's own summary chart belies its suggestion that sufficient commonality exists to justify centralization. As reflected in the below annotated table from Regeneron's brief in support of the

Motion (Reg. Br. at 2-3), vast differences exist between the subject actions, with anywhere from 11 to 39 uncommon patents at issue in a particular subject action:

Defendant(s)	Court & Case No.	Date filed	Number of patents asserted	Status
Mylan Pharmaceuticals Inc. and Biocon Biologics Ltd.	N.D. W. Va. (1:22-cv-00061)	8/2/22	24 (13 common to all complaints) **(11 uncommon patents)**	Trial held in June 2023 and post-trial order issued December 27, 2023. Request for injunctive relief not yet adjudicated.
Celltrion, Inc.	N.D. W. Va. (1:23-cv-00089)	11/8/23	38 (13 common to all complaints) **(25 uncommon patents)**	Schedule entered for preliminary injunction proceedings. Ex. 7. Responsive pleading not yet filed and request for injunctive relief not yet adjudicated.
Samsung Bioepis Co. Ltd.	N.D. W. Va. (1:23-cv-00094 & 1:23-cv-00106)	11/21/23; 12/27/23	37 in first complaint, 51 in second complaint (13 common to all complaints) **(39 uncommon patents)**	Schedule entered for preliminary injunction proceedings. Ex. 7. Responsive pleading not yet filed and request for injunctive relief not yet adjudicated.
Formycon AG	N.D. W. Va. (1:23-cv-00097)	11/29/23	39 (13 common to all complaints) **(26 uncommon patents)**	Schedule entered for preliminary injunction proceedings. Ex. 7. Responsive pleading not yet filed and request for injunctive relief not yet adjudicated.
Amgen Inc.	C.D. Cal. (2:24-cv-00264)	1/10/24	32 (13 common to all complaints) **(19 uncommon patents)**	No action beyond complaint filing.

For the Biocon Defendants, the 11 uncommon patents[3] involve dosing regimens, formulation, and cell culture media/manufacturing processes. The Biocon Defendants have already secured favorable unpatentability rulings at least one of these patents. *See Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, IPR2021-00880, 2022 WL 16841860 (P.T.A.B. Nov. 9, 2022) (U.S. Patent No. 9,669,069); *see also Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, IPR2023-00099, 2023 WL 2599926 (P.T.A.B. Mar. 1, 2023) (denying institution because Regeneron disclaimed U.S. Patent No. 10,857,205 subsequent to challenge). Further, Regeneron has already conceded non-infringement as to at least a handful of these patents based on the district court's claim construction of "CDM." *See* Biocon Action, Dkt. No. 433 (conceding non-infringement of contested claims of U.S. Patent No. 11,104,715, a family member initially asserted alongside, *e.g.*, U.S. Patent No. 11,053,280). To the extent Regeneron intends to relitigate issues specific to other manufacturing patents in a second wave, the Biocon Defendants and Regeneron have already taken substantial, relevant discovery.

Moreover, in view of the preliminary procedural posture of all subject actions other than the Biocon Litigation, Regeneron's patent-based commonality arguments are speculative, at best. The Panel has previously denied centralization where "the litigation has not progressed to a point that the parties have determined the specific nature of [the] alleged infringement or to what extent infringement allegations will be common to the defendants across [the subject] actions." *In re Select Retrieval*, 883 F. Supp. 2d at 1354. Each of the recently-filed subject actions involve distinct accused products, each with its own unique manufacturing, as evidenced by the diversity of patents asserted between the Defendants, (*see* Reg. Br. at 2-3), yet there has been no identification of

[3] U.S. Patent Nos. 7,070,959; 9,669,069; 10,406,226; 10,857,205; 10,927,342; 10,973,879; 11,053,280; 11,174,283; 11,186,625; 11,299,532; and 11,332,771.

which of the hundreds of distinct patent claims may apply to any particular accused product. In fact, Regeneron makes no attempt to even acknowledge the likely disparity among the subject actions on this basis. Again, one of the purported overlapping patents is illustrative: U.S. Patent No. 11,084,865 ("the '865 patent") is at issue in each of the subject actions, and was the subject of the June 2023 trial in the Biocon Litigation. Among the 64 claims of the '865 patent are distinct groups of claims that will, almost certainly, apply differently between the subject actions—certain claims directed to a vial formulation, others to a pre-filled syringe formulation, and others yet directed to distinct formulation components that likely apply differently to the various accused products, resulting in idiosyncrasies between the cases. *See In re Genetic Techs. Ltd. ('179) Patent Litig.*, 883 F. Supp. 2d 1337, 1338 (J.P.M.L. 2012) (denying centralization where "certain defendants have idiosyncratic potentially dispositive defenses that will implicate significant unique facts"); *see also In re Alexsam, Inc. ('608 & '787) Patent & Contract Litig.*, 437 F. Supp. 3d 1374, 1375 (J.P.M.L. 2020) (denying centralization where the "defendants make different 'accused products'" and "the same patent claims are not at issue in all actions"). The claims asserted will also influence the nature and scope of invalidity defenses and prior art associated therewith, and thus not even invalidity defenses will necessarily have commonality amongst the Defendants, depending on the nature and scope of claims asserted.

Regeneron's attempts to justify centralization by applying a blanket analogy between BPCIA litigation and generic pharmaceutical patent litigation filed under the Hatch-Waxman Act also must fail. As discussed above, BPCIA patent litigation is a different animal, particularly because the BPCIA permits inclusion of manufacturing process, intermediates, and packaging-type patents that are not justiciable under the Hatch-Waxman regime. *See, e.g.*, Michael P. Dougherty, *The New Follow-on-Biologics Law: A Section by Section Analysis of the Patent*

Litigation Provisions in the Biologics Price Competition and Innovation Act of 2009, 65 FOOD & DRUG L.J. 231, 234 (2010) ("The scope of the patents to be identified in [the BPCIA] process is broader than under the Hatch-Waxman Act, … [including] patents relevant to the product's manufacturing process."); *see also* Gaudry, *supra* at 609 (noting that "[u]nder the BPCIA, there is no public listing of potentially enforceable patents" to exclude claims directed to "processes of manufacturing a drug, metabolites, packaging, and/or drug intermediates"). The scope of manufacturing patents in the context of a biosimilar matter can be vast, and can include, for example, "upstream" cell culture methods and "downstream" protein purification methods, involving several different types of chromatography, cell culture media components, filtration methods, sterilization methods, analytical protein characterization methods, cell lines, recombinant expression vectors, and methods for engineering cell lines, among other processes. Each of these manufacturing steps will be specific and unique to each Defendant, and highly confidential. That each of the subject actions involves Defendants who have "submitted [a BLA] to FDA requesting approval to manufacture and market a biosimilar version of Eylea," (Reg. Br. at 7), by itself is not enough, particularly where patent protection for aflibercept—the active ingredient in Eylea—has expired, and an overwhelming number of asserted patents appear directed to discrete steps in the process for manufacturing a particular accused product. 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 among the subject actions, and Regeneron does nothing in its motion to address the lack of commonality that results where unique allegations of infringement—and therefore unique questions of invalidity—prevail. *See In re Blue Spike, LLC, Patent Litig.*, 278 F. Supp. 3d 1379, 1380 (J.P.M.L. 2017) (denying transfer because "Defendants' accused products vary

considerably" and "the degree of overlap among the 34 asserted patents varies widely among the cases"); *In re Uniloc USA, Inc., & Uniloc Luxembourg, S.A., HPE Portfolio Patent Litig.*, 304 F. Supp. 3d 1356, 1357 (J.P.M.L. 2018) (denying centralization where "[v]astly different technology is implicated by [the] patents" and the movant "failed to demonstrate 'that there is enough commonality to make centralization necessary or even advantageous'") (quoting *In re Charles R. Bobo Patent Litig.*, 829 F. Supp. 2d 1374, 1375 (J.P.M.L. 2011)).

At the very least, if the Panel is inclined to develop a more appropriate record on commonality, it should obligate Regeneron to first specify not only which patent, but which specific claims are supposedly common to all Defendants that it proposes to assert. Regeneron's failure to identify a single narrow patent and claim set common to all Defendants (as opposed to the hundreds asserted) simply validates the Biocon Defendants' position that these six cases lack common *factual* disputes that might benefit from centralization here.

B. Procedural Disparities Among the Subject Actions Fail to Promote Just and Efficient Conduct.

As discussed above, the Biocon Litigation is procedurally distinct from the rest of the subject actions, having progressed through fact and expert discovery, claim construction, and an initial trial, while the remaining actions are in their infancy. Such procedural disparities weigh heavily against centralization. *See In re Pilepro Antitrust & Patent Litig.*, 140 F. Supp. 3d 1350, 1351 (J.P.M.L. 2015) (denying centralization because subject actions "are in vastly different procedural postures," where one "has held a claims construction hearing, has ruled on a motion for partial summary judgment, and fact and expert discovery are closed" and another was "stayed pending mediation" with "no substantive rulings in the case to date"); *In re Dietgoal Innovations, LLC ('561) Patent Litig.*, 999 F. Supp. 2d 1380, 1381 (J.P.M.L. 2014) (denying centralization because it would "hinder the progress of the more advanced … actions … with a *Markman* hearing

already held, fact discovery concluding …, and jury selection scheduled to commence…"); *In re JumpSport, Inc.*, 338 F. Supp. 3d at 1357 (refusing centralization where "procedural disparit[ies] would complicate any centralized proceeding" and "result in delays to the completion of discovery and the anticipated trial date" for the advanced action); MULTIDISTRICT LIT. MAN. § 5:46 ("The Panel has declined to order transfer of a single advanced action for coordinated or consolidated pretrial proceedings with a group of relatively unadvanced actions for which transfer is ordered.").

The Biocon Litigation is at a significantly advanced stage compared to the other subject actions, and those actions will remain stationary for the foreseeable future, pending decisions on motions to dismiss for lack of personal jurisdiction and/or motions for preliminary injunction. Through significant resource investment, the Biocon Defendants have been at the forefront of the effort to get a lower cost anti-VEGF drug to market for treating angiogenic eye disorders, having filed their application with the FDA well before any other biosimilar applicants. As a result, as described above, the Biocon Litigation progressed through fact and expert discovery, claim construction, summary judgment proceedings securing noninfringement and invalidity concessions from Regeneron, and an initial trial in 2023. The Biocon Defendants also have requested the West Virginia Court set a subsequent trial in 2024 to resolve remaining issues in the Biocon Litigation concurrently with the Federal Circuit appeal of the decision from the June 2023 trial. The Biocon Defendants thus oppose any centralization that would unjustly delay or impede their efforts to complete pretrial activities in advance of a trial later in 2024. Under Panel precedent cited above, Defendants' requested trial in 2024 would unquestionably be not just complicated, but needlessly delayed if it is consolidated with all of the other Defendants for any pretrial purposes, since the second-group Defendants will not even start their regular proceedings until well after the Biocon Defendants are ready for trial.

CONCLUSION

For the reasons set forth above, the Biocon Defendants respectfully request that Regeneron's motion to transfer and centralization of the subject actions be denied.

Date: February 2, 2024

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Exhibit 1

to Biocon Biologics Inc.'s and Mylan Pharmaceuticals Inc.'s Response in Opposition to Regeneron Pharmaceuticals, Inc.'s Motion to Transfer to the Northern District of West Virginia

In re Aflibercept Patent Litigation
MDL No. 3103 (J.P.M.L.)

PTO/SB/43 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DISCLAIMER IN PATENT UNDER 37 CFR 1.321(a)

Name of Patentee	Docket Number (Optional)
Regeneron Pharmaceuticals, Inc.	
Patent Number	**Date Patent Issued**
10,464,992	November 5, 2019

Title of Invention
VEGF ANTAGONIST FORMULATIONS SUITABLE FOR INTRAVITREAL ADMINISTRATION

I hereby disclaim the following complete claims in the above identified patent: 1-18

Regeneron Pharmaceuticals, Inc. is disclaiming claims 1-18 in the '992 Patent for the sake of efficiency, as the patent is no longer needed.

The extent of my interest in said patent is (if assignee of record, state liber and page, or reel and frame, where assignment is recorded): Assignee of record (reel/frame: 047899/0360)

The fee for this disclaimer is set forth in 37 CFR 1.20(d).

- ☐ Patentee claims small entity status. See 37 CFR 1.27.
- ☐ Small entity status has already been established in this case, and is still proper.
- ☐ A check in the amount of the fee is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☒ The Director is hereby authorized to charge any fees which may be required or credit any overpayment to Deposit Account No. 50-2387 .

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Signed at TARRYTOWN, State of NEW YORK, this 17TH day of JANUARY 2024.

Frank R. Cottingham — Signature

50,437 — Registration Number, if applicable

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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 Biocon Biologics Inc.'s and Mylan Pharmaceuticals Inc.'s Response in Opposition to Regeneron Pharmaceuticals, Inc.'s Motion to Transfer to the Northern District of West Virginia and Proof of Service were served on February 2, 2024 to the following:

Clerks for the Pending Actions (Served via Federal Express):

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